DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 410, 414, 424, 484, 488, and 489

[CMS–1780–F]

RIN 0938–AV03

Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements

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

ACTION: Final rule.

SUMMARY: This final rule sets forth routine updates to the Medicare home health payment rates for calendar year (CY) 2024 in accordance with existing statutory and regulatory requirements. This rule—discusses comments received regarding access to home health aide services; implements home health payment-related changes; rebases and revises the home health market basket and revises the labor-related share; codifies statutory requirements for disposable negative pressure wound therapy (dNPWT); and implements the new items and services payment for the home intravenous immune globulin (IVIG) benefit. In addition, it—finalizes changes to the Home Health Quality Reporting Program (HH QRP) requirements and the expanded Home Health Value-Based Purchasing (HHVBP) Model; implements the new Part B benefit for lymphedema compression treatment items, codifies the Medicare definition of brace, and makes other codification changes based on recent legislation; adds an informal dispute resolution (IDR) and special focus program (SFP) for hospice programs; codifies DMEPOS refill policy; and finalizes proposed revisions for Medicare provider and supplier enrollment requirements.

DATES: These regulations are effective on January 1, 2024.

FOR FURTHER INFORMATION CONTACT:

Brian Slater, (410) 786–5229, for home health and home IVIG payment inquiries.

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

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

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

For more information about the expanded Home Health Value-Based Purchasing Model, please visit the Expanded HHVBP Model web page at *https://innovation.cms.gov/innovation-models/expanded-home-health-value-based-purchasing-model.*

For more information about the hospice informal dispute resolution and special focus program, send your inquiry to *QSOG_hospice@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary and Issuance of the Proposed 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 payment rates for home health agencies (HHAs) for CY 2024. In this final rule we discuss comments received on our request for information (RFI) related to access to home health aide services. This rule finalizes a permanent prospective adjustment to the CY 2024 home health payment rate to account for the differences between assumed and actual behavior changes on estimated aggregate expenditures. It also finalizes the proposal to recalibrate the PDGM case-

mix weights and update the 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 that start in CY 2024. This rule finalizes the proposal to rebase and revise the home health market basket and finalizes the proposal to revise the labor-related share. Additionally, this rule finalizes the proposal to codify statutory requirements for dNPWT and updates the CY 2024 fixed-dollar loss ratio (FDL) for outlier payments (so that outlier payments as a percentage of estimated total payments are not to exceed 2.5 percent, as required by section 1895(b)(5)(A) of the Act).

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 the addition of two quality measures to the HH QRP, the removal of two Outcome and Assessment Information Set (OASIS)-based data elements the codification of the previously finalized 90 percent OASIS data completion threshold policy in the Code of Federal Regulations (CFR) and the public reporting of four measures. We also note that the proposed rule included a request for information on future HH QRP measure concepts and an update on health equity in the HH QRP.

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

In accordance with the statutory authority at section 1115A of the Act, we are finalizing proposed updated policies, including the codification of previously finalized measure removal factors, changes to the applicable measure set, updating the Model baseline year, and an amendment to the appeals process with conforming regulation text changes for the expanded HHVBP Model. We are also including an update on health equity and a reminder about public reporting.

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

As required under Division FF, section 4134 of the Consolidated Appropriations Act, 2023 (CAA, 2023), this final rule will implement coverage and payment for items and services related to the administration of IVIG in the home of a patient with a diagnosed primary immune deficiency disease (PIDD).

e. Hospice Informal Dispute Resolution and Special Focus Program

As required under Division CC, section 407 of the Consolidated Appropriations Act of 2021 (CAA, 2021), as codified in section 1822(b) of the Act, this final rule will implement a special focus program (SFP) for poor performing hospices that includes the SFP algorithm (including data sources) to identify indicators of hospice poor performance, the criteria for selection and completion of the SFP, hospice termination from Medicare, and public reporting of the SFP. We are also finalizing our proposed regulatory changes to implement an informal dispute resolution (IDR) process to provide hospice programs an informal opportunity to resolve disputes related to condition-level survey findings for those hospice programs that are seeking recertification for continued participation in Medicare.

f. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Products and CAA 2023 Related Changes

Section 3712 of the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act (Pub. L. 116–136, March 27, 2020) *https://www.govinfo.gov/link/plaw/116/public/136* requires that Medicare payment rates for durable medical equipment (DME) in areas other than rural and noncontiguous areas during the coronavirus disease 2019 (COVID–19) public health emergency (PHE) be equal to 75 percent of the adjusted payment amounts (based on the DME competitive bidding program information), and 25 percent of the unadjusted fee schedule amounts. The regulations at § 414.210(g)(9)(v) codified these payment rates for the duration of the PHE. Section 4139 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328, December 29, 2022) requires payment based on these rates through the end of the COVID–19 PHE or December 31, 2023, whichever is later. We are finalizing the proposed changes to the regulations to codify these payment rates through the end of the COVID–19 PHE or unless otherwise specified by law.

The scope of the benefit and payment for lymphedema compression treatment items in section 4133 of the CAA, 2023 adds section 1861(s)(2)(JJ) to the Act, adding the Medicare Part B benefit for lymphedema compression treatment items effective January 1, 2024. This rule addresses the scope of the new benefit by defining what constitutes a standard or custom fitted gradient compression garment and determining what other compression items may exist that are used for the treatment of lymphedema and will fall under the new benefit.

This rule also implements section 1834(z) of the Act in establishing payment amounts for items covered under the new benefit and frequency limitations for lymphedema compression treatment items. CMS expects to conduct outreach for individuals with Medicare and issue provider education regarding this benefit.

The definition of brace in section 1861(s)(9) of the Act provides coverage under Part B for leg, arm, back, and neck braces. This rule codifies the existing definition of a brace found in the Medicare Benefit Policy Manual (CMS Pub. 100–02) and clarifies that this definition encompasses newer, technology-powered devices.

g. Documentation Requirements for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Products Supplied as Refills to the Original Order

Section 1893(b)(1) of the Act, authorizes ''[r]eview of activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this title . . . including medical and utilization review . . .''. The requirement for documentation to support DMEPOS refills originally arose in response to concerns related to auto-shipments and delivery of DMEPOS products that may no longer be needed or not needed at the same level of frequency/volume. This rule will codify our long-standing refill policy, with some changes. We proposed to require documentation indicating that the beneficiary has confirmed their need for the refill within the 30-day period prior to the end of the current supply. We also proposed to codify our requirement that delivery of DMEPOS items (that is, date of service) be no sooner than 10 calendar days before the expected end of the current supply. We sought comments for potential future rulemaking on ways to balance beneficiary burden with the potential program integrity risk of not verifying the beneficiary's need for recurring supplies for certain individuals with permanent conditions and will consider the commenter submissions.

h. Provider and Supplier Enrollment Requirements

The purpose of our provider enrollment provisions is to strengthen

and clarify certain aspects of the provider enrollment process. This includes, but is not limited to: (1) subjecting a greater number of providers and suppliers, such as hospices, to the highest level of screening, which includes fingerprinting all 5 percent or greater owners of these providers and suppliers; (2) applying the change in majority ownership (CIMO) provisions in 42 CFR 424.550(b) to hospices; and (3) reducing the period of Medicare non-billing for which a provider or supplier can be deactivated under § 424.540(a)(1) from 12 months to 6 months. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers and/or that owners of these entities are carefully screened. We believe that fulfilling these objectives will assist in protecting the Trust Funds and Medicare beneficiaries.

2. Summary of the Provisions of This Final Rule

a. Home Health Prospective Payment System (HH PPS)

In section II.B.2. of this final rule, we discuss comments related to access to home health aide services. In section II.C.1. of this rule, we are finalizing a permanent prospective adjustment of −2.890 percent to the CY 2024 home health payment rate.

In section II.C.2. of this rule, we are finalizing the proposal to recalibrate the PDGM case-mix weights, LUPA thresholds, functional levels, and comorbidity adjustment subgroups for CY 2024.

In section II.C.3. of this rule, we are finalizing the proposals to rebase and revise the home health market basket to reflect a 2021 base year and revise the labor-related share.

In section II.C.4. of this rule, we are finalizing our proposals to update the home health wage index, the CY 2024 national, standardized 30-day period payment rates, and the CY 2024 national per-visit payment amounts by the home health payment update percentage. The final home health payment update percentage for CY 2024 is 3.0 percent. Additionally, this rule finalizes the CY 2024 FDL ratio to ensure that aggregate outlier payments do not exceed 2.5 percent of the estimated total aggregate payments, as required by section 1895(b)(5)(A) of the Act.

In section II.C.5 of this rule, we finalize our proposal to codify statutory payment changes for negative pressure wound therapy using a disposable device (dNPWT).

b. Home Health Quality Reporting Program (HH QRP)

In section III. of this final rule, we will finalize the adoption of the measure ''COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date'' (Patient/Resident COVID–19 Vaccine) to the HH QRP beginning with the CY 2025 HH QRP. CMS also finalizes the adoption of the ''Functional Discharge Score'' (DC Function) measure to the HH QRP beginning with the CY 2025 HH QRP. With the addition of the Discharge Function measure, we are finalizing the removal of the ''Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function'' (Application of Functional Assessment/Care Plan) measure from the HH QRP beginning with the CY 2025 HH QRP. CMS additionally is finalizing the removal of two OASIS items no longer necessary for collection, the M0110—Episode Timing and M2200- Therapy Need items. We are also finalizing technical changes to § 484.245(b) to codify our requirement that HHAs must meet or exceed a data submission threshold set at 90 percent of all required OASIS and submit the data through the CMS designated data submission systems. Lastly, we summarize input on CMS's request for information on future HH QRP measure concepts and CMS updates on HH QRP health equity initiatives.

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

In section IV. of this final rule, we are finalizing codification of the HHVBP measure removal factors at § 484.380. We will remove five and add three quality measures to the applicable measure set. Along with the proposed revisions to the current measure set, we proposed to revise the weights of the individual measures within the OASIS-based measure category and within the claims-based measure category starting in the CY 2025 performance year. We are finalizing to update the Model baseline year from CY 2022 to CY 2023 starting in the CY 2025 performance year to enable CMS to measure competing HHAs performance on benchmarks and achievement thresholds that are more current for all applicable measures. Additionally, we are finalizing to amend the appeals process such that reconsideration decisions may be reviewed by the Administrator. We are also making conforming regulation text changes at § 484.375(b)(5). We included an update to the RFI, *Future Approaches to Health Equity in the Expanded HHVBP Model,* that was published in the CY 2023 HH PPS rule. We are also including a reminder that we will begin public reporting HHVBP performance data on or after December 1, 2024.

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

As required under Division FF, section 4134 of the Consolidated Appropriations Act, 2023 (CAA, 2023), section V. of this rule finalizes proposed regulations to implement coverage and payment of items and services related to administration of IVIG in a patient's home for a patient with PIDD.

e. Hospice Informal Dispute Resolution and Special Focus Program

In section VI. of this final rule, we are finalizing our proposal for a new hospice informal dispute resolution (IDR) process at § 488.1130 to align with the process that is available for home health agencies (HHAs). We proposed that the hospice IDR would address disputes related to condition-level survey findings following a hospice program's receipt of the official survey statement of deficiencies. The proposed IDR would provide hospice programs an informal opportunity to resolve disputes in the survey findings for those hospice programs that are seeking recertification from the State Survey Agency (SA) or reaccreditation from an accrediting organization (AO) for continued participation in Medicare. Additionally, the proposed IDR may be initiated for those hospice programs that are currently under SA monitoring (either through a complaint investigation or validation survey) and those in the finalized SFP. In section VI. of this rule, we are finalizing our proposal to add the hospice Special Focus Program (SFP) at § 488.1135. In the final rule, we are finalizing the SFP algorithm (including data sources) to identify indicators of hospice poor performance, the criteria for selection and completion of the SFP, hospice termination from Medicare, and public reporting of the SFP. In response to previous comments in the CY 2022 HH PPS rule urging CMS to seek technical expert panel (TEP) recommendations to better inform the development of the SFP, a TEP was convened to gain input from key stakeholders on various aspects of the proposed SFP. The finalized hospice SFP becomes effective beginning the effective date of this final rule with implementation during CY 2024. We will periodically review the effectiveness of the finalized methodology and algorithm.

f. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Products and CAA 2023 Related Changes

In section VII.A.3. of this rule, we are finalizing without modification the conforming changes to § 414.210(g)(9), consistent with section 4139(a) and 4139(b) of the CAA, 2023. First, section 4139 of the CAA, 2023 does not change the current policy under § 414.210(g)(9)(iii) of paying for DMEPOS items and services furnished in rural and non-contiguous non-competitive bidding areas (CBAs) based on a 50/50 blend of adjusted and unadjusted fee schedule amounts through the duration of the PHE for COVID–19.

As a result, we are finalizing revisions under § 414.210(g)(9)(iii), to state that for items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) or December 31, 2023, whichever is later, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

We are finalizing revisions to § 414.210(g)(9)(v) to state that for items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020 through December 31, 2023 or through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under this section and 25 percent of the unadjusted fee schedule amount.

We are finalizing our proposal to remove outdated text from § 414.210(g)(9)(v) that states ''for items and services furnished in areas other than rural or noncontiguous areas with dates of service from the expiration date of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), through December 31, 2020, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.''

We are finalizing our proposal to revise § 414.210(g)(9)(vi) to state that for items and services furnished in all areas with dates of service on or after January 1, 2024, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, the fee schedule amount for the area is equal to the adjusted payment amount established under paragraph (g) of this section.

We are finalizing the proposal to make conforming changes to § 414.210(g)(2) for the rural and non-contiguous areas in order to specify the December 31, 2023 date specified in section 4139 of the CAA, 2023.

In section VII.B.8. of this rule, we discuss the amendment of 42 CFR 410.36(a) to add paragraph (4) and the following new category of medical supplies, appliances, and devices covered under Medicare Part B, Lymphedema compression items including: standard and custom fitted gradient compression garments, gradient compression wraps with adjustable straps, compression bandaging systems, and other items determined to be lymphedema compression treatment items under the process established under § 414.1670. Other covered items will include accessories such as zippers, liners, and padding or fillers that are necessary for the effective use of a gradient compression garment or wrap with adjustable straps.

We are finalizing our proposal to modify and add to the existing HCPCS Level II codes for lymphedema compression treatment items.

We are finalizing our proposal to add § 414.1670 under new subpart Q and use the same process described in § 414.240 to obtain public consultation on preliminary benefit category determinations and payment determinations for new lymphedema compression treatment items.

We are finalizing our proposal to add a new subpart Q under the regulations at 42 CFR part 414 titled, ''Payment for Lymphedema Compression Treatment Items'' to implement the provisions of section 1834(z) of the Act to establish payment amounts for lymphedema compression treatment items.

We are finalizing our proposal to add § 414.1600 to explain the purpose and definitions found in subpart Q.

We are finalizing our proposal to add § 414.1660 to address continuity of pricing when HCPCS codes for lymphedema compression treatment items are divided or combined.

We are finalizing our proposal to add § 414.1680 with details regarding frequency limitations for lymphedema compression treatment items. Medicare will cover and pay for three daytime garments or wraps every six months and two nighttime garments or wraps every 2 years.

We are finalizing our proposal to revise the regulations for competitive bidding under at 42 CFR part 414, subpart F to include lymphedema compression treatment items under the competitive bidding program as mandated by section 1847(a)(2)(D) of the Act. We are adding lymphedema compression treatment items to the definition of item at § 414.402. We are revising § 414.408 to indicate that payment for these items will be calculated on a lump sum purchase basis and payment under the program will be made in accordance with any frequency limitations established under subpart Q in accordance with section 1834(z)(2) of the Act. We are also adding lymphedema compression treatment items to § 414.412 to address limiting bids submitted under the program using the payment established under subpart Q.

We are finalizing our proposal to add § 414.1690 indicating that the payment amounts established under § 414.1650(b) may be adjusted using information on the payment determined for lymphedema compression treatment items as part of implementation of the competitive bidding programs under subpart F using the methodologies set forth at § 414.210(g).

In section VII.C.3. of this rule, we are finalizing our proposal to amend the regulations at 42 CFR 410.2 to add the definition of brace and to add clarification at § 410.36(a)(3)(i) for the purpose of determining the Medicare Part B benefit and scope for leg, arm, back, and neck braces and making benefit category determinations regarding specific items in accordance with the review process for benefit category and payment determinations under § 414.240.

g. Documentation Requirements for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Products Supplied as Refills to the Original Order

We are finalizing our proposed refill documentation requirements. We will be updating the refill documentation requirements such that a beneficiary affirmation will need to be documented by the supplier. We will require documentation indicating that the beneficiary confirmed the need for the refill within the 30-day period prior to the end of the current supply. We will codify our requirement that delivery of DMEPOS items (that is, date of service) be no sooner than 10 calendar days before the expected end of the current supply. There is no associated paperwork burden as the burden is already accounted for and approved by

the Office of Management and Budget under OMB control number 0938–0969 (CMS–10417).

h. Provider and Supplier Enrollment Requirements

We proposed several changes to our Medicare provider and supplier enrollment requirements. These included but were not limited to: (1) provisions related to hospice enrollment and ownership; and (2) deactivation of providers and suppliers.

3. Summary of Costs, Transfers, and Benefits

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TABLE A1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2024 HH PPS Payment Rate Update		The overall economic impact related to the changes in payments under the HH PPS for CY 2024 is estimated to be $140 million (0.8 percent). The $140 million increase in estimated payments for CY 2024 reflects the effects of the CY 2024 home health payment update percentage of 3.0 percent ($525 million increase), an estimated 2.6 percent decrease* that reflects the effects of the permanent behavioral assumption adjustment ($455 million) and an estimated 0.4 percent increase that reflects the effects of an updated FDL ($70 million increase).	To ensure that home health payments are consistent with statutory payment authority for CY 2024.
HH QRP		The total economic impact of these proposals including the addition of the COVID-19 QM, removal of the Application of Functional Assessment/Care Plan, and the removal of the M0110 – Episode Timing and M2220- Therapy Needs OASIS items proposed for implementation in CY 2025 is an estimated reduction in cost of $5,123,430.	The reduction of unnecessary data collection burden and the introduction of more impactful quality measures.
Expanded HHVBP Model		The overall economic impact of the expanded HHVBP Model for CYs 2024 through 2027 is an estimated $3.376 billion in total savings to FFS Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the expanded Model.	
Home IVIG Items and Services		The overall economic impact for CY 2024 is an estimated increase of $8.7 million in total costs to Medicare FFS.	To implement a new payment under the home intravenous immune globulin benefit in accordance with section 4134 of the CAA of 2023, in order to ensure beneficiaries have comprehensive access to home IVIG.

Provision Description	Costs and Cost Savings	Transfers	Benefits
Hospice Informal Dispute Resolution and Special Focus Program	The IDR is an administrative process conducted by CMS, the SA, or the AOs to be added as part of their existing survey activities and is separate from the SFP. The Congress has already allocated $10 million annually to CMS to implement the CAA 2021 hospice provisions, which includes the SFP. Additionally, CMS obligates monies to the SAs to carry out survey and certification responsibilities under their agreement with CMS. SAs and AOs may already have existing IDR processes in place for the HHA IDR requirements. The hospice IDR requirements will align with the IDR requirements for HHAs. Therefore, no additional burden will be incurred by CMS, SAs, the AOs.		
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Products and CAA 2023 -Related Changes		For the conforming change to sections in CAA of 2023 provision, the overall economic impact for CY 2023 and CY 2024 is an estimated $100 million in total cost to FFS Medicare (with approximately $9 million in Medicaid dual cost-sharing: $5.1 federal and $3.9 state). For the lymphedema provision, the overall economic impact for CYs 2023 to 2028 is an estimated $150 million in total cost to FFS Medicare (with approximately $9 million in Medicaid dual cost-sharing: $5.1 federal and $3.9 state).	
Documentation Requirements for DMEPOS Products Supplied as Refills to the Original Order	The fiscal impact of these requirements cannot be estimated as claims often deny for multiple reasons, which may include non-compliance with our refill requirements; creating an inability for us to accurately demonstrate a causal relationship. In addition, to demonstrate impacts we will have to be able to predict behaviors and anticipated non-compliance in future claim submissions, which are unknown variables to us.		The codification of refill requirements is intended to help ensure the appropriateness of recurring DMEPOS payments, to protect both beneficiaries and the Trust Fund.
Provider Enrollment Provisions	As explained in the collection of information and regulatory impact sections of this final rule, we expect a combined annual cost to affected providers and suppliers of $1,081,782.		To strengthen CMS' ability to detect and deter fraud, waste, and abuse in the Medicare program.

*The estimated 2.6 percent decrease related to the behavioral assumption adjustment includes all payments, while the -2.890 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.

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B. Issuance of the Proposed Rule

The proposed rule titled ''Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements'' appeared in the **Federal Register** on July, 10, 2023 (88 FR 43654) hereinafter referred to as the CY 2024 HH PPS proposed rule or July 2023 proposed rule).

The proposed rule set forth proposed payment and policy changes to the Medicare Home Health prospective payment system for CY 2024, 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, enacted August 5, 1997) 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. We issued a final rule which appeared in the November 9, 2006 **Federal Register** (71 FR 65935), to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

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

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

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

Division FF, section 4136 of the Consolidated Appropriations Act, 2023 (CAA, 2023) 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) using a disposable device 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 is to be equal to the supply price used to determine the relative value for the service under the Medicare Physician Fee Schedule (PFS) (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 minus the productivity adjustment as described in section 1886(b)(3)(B)(xi)(II) 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 NPWT using a disposable device (though this rule is finalizing changes to this provision pursuant to section 4136 of the CAA, 2023), but such drug and services 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 NPWT using a disposable device.

To better align payment with patient care needs and to better ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized case-mix methodology refinements through the Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. The PDGM did not change eligibility or coverage criteria for Medicare home health services, and as long as the individual meets the criteria for home health services as described at 42 CFR 409.42, the individual can receive Medicare home health services, including therapy services. For more information about the role of therapy services under the PDGM, we refer readers to the Medicare Learning Network (MLN) Matters article SE20005 available at *https://www.cms.gov/regulations-and-guidanceguidance transmittals2020-transmittals/se20005*. To adjust for case-mix for 30-day periods of care beginning on and after January 1, 2020, the HH PPS uses a 432-category case-mix classification system to assign patients to a home health resource group (HHRG) using patient characteristics and other clinical information from Medicare claims and the Outcome and Assessment Information Set (OASIS) assessment instrument. These 432 HHRGs represent the different payment groups based on five main case-mix categories under the PDGM, as shown in Figure B1. Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care. For periods of care with visits less than the low-utilization payment adjustment (LUPA) threshold for the HHRG, Medicare pays national per-visit rates based on the discipline(s) providing the services. Medicare also adjusts the national standardized 30-day period payment rate for certain intervening events that are subject to a partial payment adjustment. For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

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

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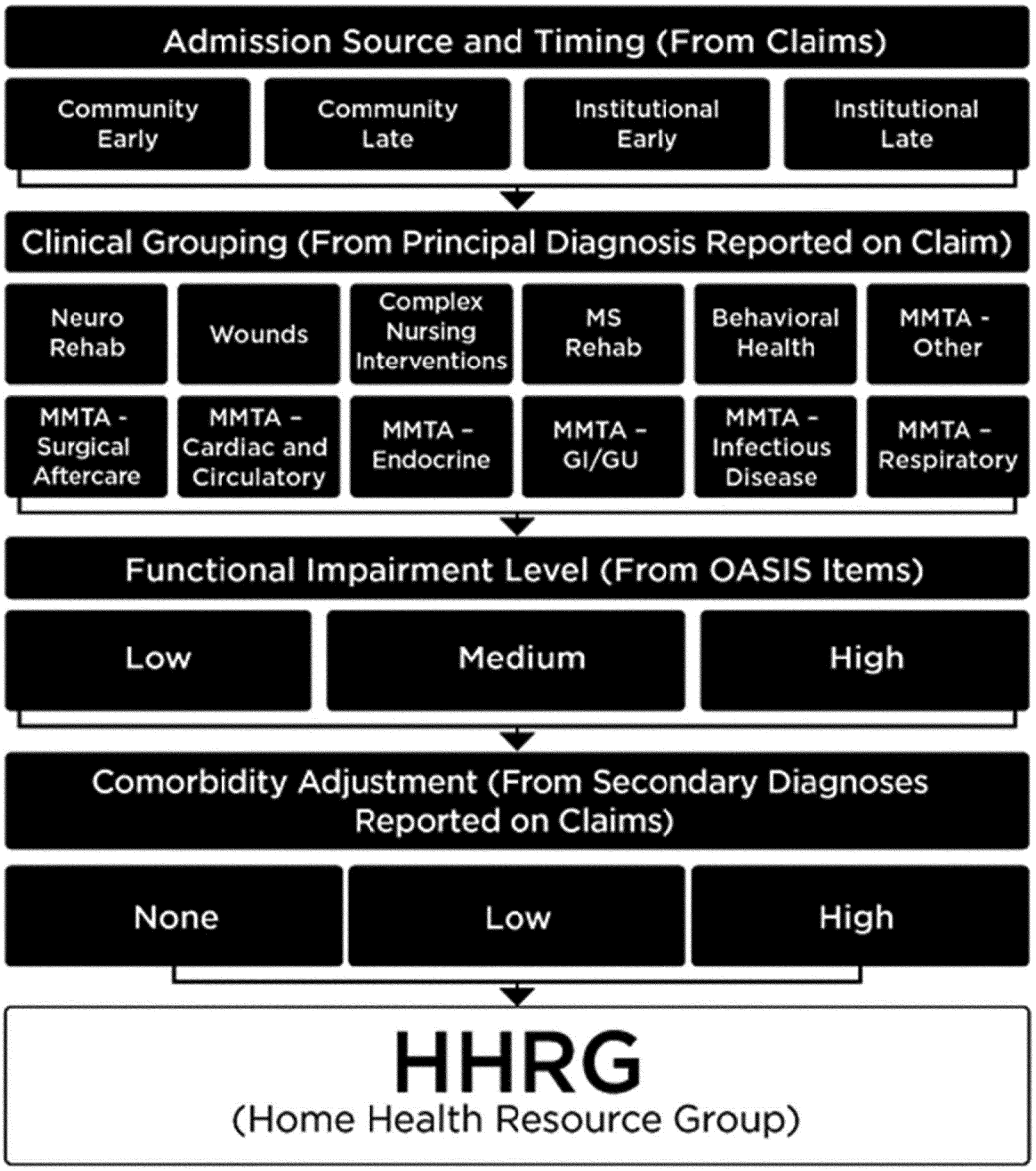
FIGURE B1: CASE-MIX VARIABLES IN THE PDGM



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B. Monitoring the Effects of the Implementation of PDGM

1. Routine PDGM Monitoring

In the CY 2024 HH PPS proposed rule (88 FR 43663), CMS provided data analysis on Medicare home health benefit utilization, including but not limited to, overall total 30-day periods of care and average periods of care per HHA user; distribution of the type of visits in a 30-day period of care; the percentage of periods that receive the LUPA; estimated costs; the percentage of 30-day periods of care by clinical group, comorbidity adjustment, admission source, timing, and functional impairment level; and the proportion of 30-day periods of care with and without any therapy visits, nursing visits, and/or aide/social worker visits. We received one comment on the analysis presented in the proposed rule.

Comment: The commenter stated that while the utilization patterns before and after PDGM implementation show a continuous downward trend, there is lack of data analysis and explanation by CMS indicating whether the appropriate level of home health care is being provided to beneficiaries. They also suggested that CMS should expand the data collected to include geographic, racial, ethnic, socioeconomic, sexual orientation and gender identifiers which could highlight whether disparities in home health usage vary in diverse populations.

Response: We thank the commenter for their feedback on the home health utilization data presented in the CY 2024 HH PPS proposed rule. The intent of the monitoring section is to show the trends in the data presented. We discuss our analysis of these data in the discussion of our RFI related to home health aides and in the discussion of the PDGM behavioral assumption adjustments. We will continue to monitor and analyze home health trends and vulnerabilities within the home health payment system and will consider the additional monitoring suggested by the commenter for future rulemaking.

2. Request for Information (RFI) for Access to Home Health Aide Services

As we continue to focus on promoting access and value within the home health benefit, in the CY 2024 HH PPS proposed rule (88 FR 43654), we solicited comments from the public, including home health providers as well as patients and advocates, regarding certain trends in the data that coincide with home health coverage misinformation obtained anecdotally from beneficiaries; that is, information related to the provision of home health aide services as needed when a patient is under the home health benefit. We queried interested parties on the potential basis for continued decline in utilization of home health aide services despite persistent need, particularly among higher acuity beneficiaries. Also, in an effort to better understand the decline in utilization and improve the provision of the home health aide services under the home health benefit, we solicited comments specifically on how home health agencies' recruitment and retention challenges, wage disparities, aide care impact and wage alignment, Medicare-Medicaid coordination, physician plans of care, and expected beneficiary outcomes might be interconnected.

In response to our request for information on access to home health aide services, we received a total of 85 comments, where commenters highlighted a multitude of challenges and offered several recommendations to improve the provision of home health aide services under Medicare. These comments and our responses are summarized in this section of the rule.

Comment: Commenters broadly stated that the decline in the utilization of home health aide services is not indicative of a reduced need for such services. Commenters also stated that despite Medicare laws allowing for substantial home health aide hours, the actual provision is dwindling, especially affecting those with chronic or long-term conditions, who often require a combination of skilled and aide services for optimal health and safety at home. A commenter further stated that both CMS' and home health agencies' policies and practices have resulted in barriers that devalue and disincentivize the provision of these essential services. Specifically, the commenter stated that Medicare's current payment model, PDGM, discourages HHAs from employing aides and providing necessary aide services. The commenter stated that this is especially true for patients with high functional impairments and multiple comorbidities. The commenter stated ''the PDGM base calculation amount favors post-institutional care and the initial 30 days of services through higher case-mix adjustment for admission source and timing and there is a low percentage of additional reimbursement for beneficiaries with high functional impairments and multiple comorbidities, relative to beneficiaries with low functional impairments and no co-morbidities.'' The commenter stated that because these are ostensibly the beneficiaries that would need the most aide services (and HHAs have surmised that the more aide visits they provide the lower their overall reimbursement will potentially be in the future), this has led HHAs tell patients that ''Medicare does not pay for aides.''

In addition to comments stating that the PDGM discourages the provision of aide services, commenters also stated that HHAs' engage in selective practices and strategic preference for serving lower acuity patients to maximize profits, which they assert has a disproportionately negative effect on higher acuity patients (that is, those with multiple comorbidities or high functional impairment) and often leaves them underserved or completely neglected. Commenters suggested that CMS has not fulfilled its oversight of HHAs conducting such discriminatory practices and has failed to enforce the nondiscrimination conditions of participation for Medicare-certified HHAs. They stated that CMS should investigate the practices of HHAs that tend to exclude or underserve beneficiaries with chronic, disabling conditions and take enforcement action to ensure that patients with long-term disabilities do not face discrimination in the provision of aide services.

Commenters identified multiple barriers that they stated affected HHAs in recruiting and retaining home health aides, including low compensation, competition for labor in different job markets, inadequate/limited training opportunities, and demanding work conditions. Commenters' suggestions to overcome these barriers included improved compensation, including aide services more directly in care plans, providing advanced training, and establishing centralized systems for employee development.

Commenters stated that they had noticed wage disparities between home health aides and similar positions in other care settings, such as inpatient hospitals and nursing homes, attributing the disparities to various factors like the nature of work, working conditions, and level of institutional support available. They stated that reevaluating compensation structures is necessary for parity. A commenter stated that CMS's episodic reimbursement for home health does not support robust staffing, particularly in rural areas. Commenters stated this creates a situation where HHAs cannot justify separate visits by a home health aide when nurses or occupational therapists can perform these functions within their scope of practice during a skilled or therapy visit.

Commenters urged both HHAs and CMS to overhaul the current reimbursement compensation to better incentivize fulfillment of home health aide services in order to ensure aides receive fair wages commensurate with the critical nature of their role and their impact on patient care. A commenter suggested the need for CMS to establish new payment mechanisms specifically designed to ensure HHAs are compensated fairly for delivering all necessary services, specifically home health aide services.

Commenters stated that the effectiveness of coordination between Medicare and Medicaid varies by state and is generally limited (especially for dually eligible beneficiaries) and that gaps in coordination are a systemic issue arising from differences in eligibility, coverage, and administrative factors. Commenters also stated that although dually eligible beneficiaries might receive somewhat better access to aide services through Medicaid, better care coordination is vital for boosting utilization rates and addressing disparities in access to services.

Further, commenters stated that they believed a dual issue affected physicians' care plans for home health aide services. They stated there is limited availability of aides to provide the aide services included on care plans due to difficulties in finding qualified staff and inadequate reimbursements from CMS, as well as the fact that physicians themselves are increasingly less likely to include home health aide services in care plans. Commenters stated that this physician hesitance is fueled by HHAs reporting that aide services are either very limited or not available at all. Commenters stated that, as a result, practitioners have substantially reduced or altogether eliminated requests for aide services. Additionally, commenters stated that HHAs often refuse to initiate aide services unless family/caregivers commit to learning how to perform the aide functions themselves (even if those caregivers are not willing and/or able to continue the care and even if the patient objects to having a family member

provide aide care). A few commenters stated that HHAs also have a practice of either refusing to staff aides adequately or understaffing them deliberately.

Commenters also stated that there were consequences to beneficiaries' lack of adequate access to home health aide services, including outcomes such as unnecessary hospitalizations, nursing facility admissions, potentiated health complications, family/caregiver burnout, and even forced institutionalizations that lead to a significant loss of independence and quality of life.

Response: CMS appreciates the comments and suggestions received regarding home health aide service utilization (especially among higher acuity Medicare beneficiaries), the status of Medicare and Medicaid home health aide coordination, physician care plans, HHA recruitment and retention challenges, as well as wage disparities in other care settings, in influencing both the availability and quality of home health aide services for Medicare beneficiaries. We thank commenters for their feedback suggesting various changes for the equitable and adequate provision of home health aide services, as well as for payment reform, recruitment, and retention strategies, improved inter-program coordination between Medicare and Medicaid, and an overall shift in how the value of home health aide services is recognized, how home health aides are compensated, and how home health aide services are effectively integrated into plans of care. We do note that the current HH PPS, which generally bundles payment for all goods and services furnished in a 30-day period, including home health aide services, is set forth by statute. As such, suggestions related to the payment structure of the HH PPS, including regarding how aides are paid, are more appropriately addressed to Congress for consideration.

We would like to thank commenters for their responses regarding payment rates for home health aide services. In response to the comments detailing concern that HHAs may be influencing practitioners to curtail or omit aide services, or are refusing to initiate such services as ordered, we would like to direct readers' attention to the home health Conditions of Participation (CoPs) at 42 CFR 484.60. As a reminder, per the regulations, each patient is required to receive home health services as delineated in an individualized plan of care. Such 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 unduly influence a practitioner based on the HHA's own service constraints.

Overall, the feedback provided by respondents will help guide our policy formulation processes. One of CMS' objectives is to continually enhance home health policies to optimize both access and quality of care for Medicare beneficiaries. Likewise, in keeping with the President's Executive Order (E.O.) on Increasing Access to High-Quality Care and Supporting Caregivers,[1] we find the comments and suggestions received relevant to identifying ''gaps in knowledge about the home- and community-based workforce serving people with disabilities and older adults.'' As such, all comments and suggestions will be considered alongside the goals of this E.O., including identifying opportunities to expand analyses, supplementing data, or launching new efforts to provide important data on the home- and community-based workforce, such as home health aides, as appropriate. This information may assist in policy development, addressing barriers, and fostering coordination under the home health benefit for future regulatory updates.

C. Provisions for CY 2024 Payment Under the HH PPS

1. CY 2024 Final Behavior Assumption Adjustments Under the HH PPS

(a) Background

As discussed in section II.A.1. of this rule, starting in CY 2020, the Secretary was statutorily required by Section 1895(b)(2)(B) of the Act, to change the unit of payment under the HH PPS from a 60-day episode of care to a 30-day period of care. CMS was also required to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and the case-mix adjustment factors that eliminated the use of therapy thresholds. In the CY 2019 HH PPS final rule with comment period (83 FR 56455), we finalized three behavior change assumptions as to documentation, coding, and the LUPA thresholds, 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 the effects of these behavior 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 in CYs 2021 and 2022 relating to the behavior assumptions that were finalized in the CY 2019 HH PPS final rule with comment period, or to the negative 4.36 percent behavior change assumption adjustment, that was finalized in the CY 2020 HH PPS final rule with comment period.

In the CY 2023 HH PPS final rule (87 FR 66796), we concluded that the three assumed behavior changes had in fact occurred. Additionally, this monitoring showed that other behavioral changes, such as changes in the provision of therapy and functional impairment levels, also resulted from implementing the PDGM. We also restated, as we originally noted in the CY 2020 HH PPS final rule with comment period (84 FR 60513), that we interpret actual behavior changes to encompass both behavior changes that were previously outlined and assumed by CMS, as well as other behavior changes that were 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 other behavior changes occurred, including that 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 2024 HH PPS proposed rule (88 FR 43663 through 43671), we stated that our analysis continues to show that the actual 30-day periods are similar to the simulated 30-day periods, overall. The number of therapy visits (total and average) continue to decline, indicating that HHAs changed their behavior to reduce therapy visits. The analysis continues to support the presence of the original three assumed behavior changes (for example, in the volume of visits for LUPAs), as well as other individual behavior changes (for example, therapy visits). To capture all such behavior changes, we use the entirety of all behaviors to calculate estimated aggregate expenditures. The law instructs CMS 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, as required by section 1895(b)(3)(A)(iv)

[1] Exec. Order No. 14,095, 3 CFR 24669–24676. (April 18, 2023).

and 1895(b)(3)(D) of the Act. We accordingly use the aggregate data.

Section 4142(a) of the CAA, 2023, requires 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 LDS and descriptive files and the description of actual behavior changes that affected CY 2023 payment rate development. Additionally, on March 29, 2023, CMS conducted a webinar entitled Medicare Home Health Prospective Payment System (HH PPS) Calendar Year (CY) 2023 Behavior Change Recap, 60-Day Episode Construction Overview, and Payment Rate Development. The webinar was open to the public and discussed the actual behavior changes that occurred upon implementation of the PDGM, our approach used to construct simulated 60-day episodes using 30-day periods, payment rate development for CY 2023, and information on the supplemental data files containing information on the simulated 60-day episodes and actual 30-day periods used in calculating the permanent adjustment to the payment rate. Materials from the webinar, including the presentation and the CY 2023 descriptive statistics from the supplemental LDS files, containing information on the number of simulated 60-day episodes and actual 30-day periods in CY 2021 that were used to construct the permanent adjustment to the payment rate, as well as information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments, can be found on the Home Health Patient-Driven Groupings Model web page at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/homehealthpps/hh-pdgm*. In the CY 2024 HH PPS proposed rule, we continued to describe actual behavior changes (88 FR 43663 through 43672) identified through our analysis of CYs 2020–2022 claims data. We posted a descriptive statistics file with the release of the CY 2024 HH PPS proposed rule. Additionally, the LDS file available for purchase contained the simulated 60-day episodes and actual 30-day periods. Furthermore, to promote data transparency, we will continue to describe the behavior changes analyzed through CY 2026 claims and we will continue to post the descriptive statistics file and the LDS file with the simulated 60-day episodes and actual 30-day periods in annual rulemaking.

(b) Method To Annually Determine the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Expenditures

In the CY 2022 HH PPS proposed rule (86 FR 35889 through 35892) we solicited comments on our methodology to annually determine the impact of differences between assumed and actual behavior changes on estimated aggregate expenditures. We received feedback from this comment solicitation, as well as commenter's feedback when this methodology was proposed in the CY 2023 HH PPS proposed rule. We finalized this methodology in the CY 2023 HH PPS final rule (87 FR 66804) stating that this methodology aligns with the statutory requirements as required by 1895(b)(3)(D) of the Act. Under that methodology, for CYs 2020 through 2026, we will evaluate whether the 30-day budget neutral payment rate and resulting aggregate expenditures are equal under the PDGM to what they would have been under the 153-group case-mix system and 60-day unit of payment. An overview of the methodology is listed in this section, followed by detailed instructions on each step.

- Create simulated 60-day episodes from actual 30-day periods.
- Price out the simulated 60-day episodes and determine aggregate expenditures.
- Price out only the actual 30-day periods which were used to create the simulated 60-day episodes and determine aggregate expenditures.
- Compare aggregate expenditures between the simulated 60-day episodes and actual 30-day periods.
- Determine what the 30-day payment rate should have been to equal the simulated 60-day episodes aggregate expenditures using the 153-group case-mix system and 60-day unit of payment.

(1) Create Simulated 60-Day Episodes From 30-Day Periods

The first step in our methodology is to determine which PDGM 30-day periods of care could be grouped together to form simulated 60-day episodes of care. To facilitate grouping, we made some exclusions and assumptions as described later in this section prior to pricing out the simulated 60-day episodes of care. We note in the early months of CY 2020, there were 60-day episodes which started in 2019 and ended in 2020 and therefore, some of these exclusions and assumptions may be specific to the first year of the PDGM. We identify, through footnotes, if an exclusion or assumption is specific to CY 2020 only.

(a) Exclusions

- Claims where the claim occurrence code 50 date (OASIS assessment date) occurred on or after October 31 of that year. This exclusion was applied to ensure the simulated 60-day episodes contained both 30-day periods from the same year and would not overlap into the following year (for example, 2021, 2022, 2023). This is done because any 30-day periods with an OASIS assessment date in November or December might be part of a simulated 60-day episode that would continue into the following year and where payment would have been made based on the ''through'' date. For CYs 2021 through 2026, we also excluded claims with an OASIS assessment date before January 1 of that year.[2] Again, this is to ensure a simulated 60-day episode (simulated from two 30-day periods) does not overlap years.
- Beneficiaries and all of their claims if they have overlapping claims from the same provider (as identified by CCN).[3]
- Beneficiaries and all of their claims if three or more claims from the same provider are linked to the same occurrence code 50 date.[4]

(b) Assumptions

- If two 30-day periods of care from the same provider reference the same OASIS assessment date (using occurrence code 50), then we assume those two 30-day periods of care would have been billed as a 60-day episode of care under the 153-group system.
- If two 30 day-periods of care reference different OASIS assessment dates and each of those assessment dates is referenced by a single 30-day period of care, and those two 30-day periods of care occur together close in time (that is, the ''from'' date of the later 30-day period of care is between 0 to 14 days after the ''through'' date of the

[2] There are no 30-day PDGM claims which started in CY 2019 and ended in CY 2020, and therefore this exclusion would not apply to the CY 2020 dataset.

[3] Claims are dropped from the same provider that extend into the following calendar year to ensure episode timing is accurate for simulated 60-day episodes. All of a beneficiary's claims are dropped, rather than only a subset, so as not to create a conflict in assigning episode timing.

[4] This is done because if three or more claims link to the same OASIS it would not be clear which claims should be joined to simulate a 60-day episode.

earlier 30-day period of care), then we assume those two 30-day periods of care also would have been billed as a 60-day episode of care under the 153-group system.

- For all other 30-day periods of care, we assume that they would not be combined with another 30-day period of care and would have been billed as a single 30-day period.

(2) Price Out the Simulated 60-Day Episodes and Determine Aggregate Expenditures

After application of the exclusions and assumptions described previously, we have the simulated 60-day episodes dataset for each year. We assign each simulated 60-day episode of care as a normal episode, PEP, LUPA, or outlier based on the payment parameters established in the CY 2020 HH PPS final rule with comment period (84 FR 60478) for 60-day episodes of care. Next, using the October 2019 3M Home Health Grouper (v8219)[5] we assign a HIPPS code to each simulated 60-day episode of care using the 153-group methodology. Finally, we price the simulated 60-day episodes of care using the payment parameters described in the CY 2020 final rule with comment period (84 FR 60537) for 60-day episodes of care.

For CYs 2021 through 2026, we adjust the simulated 60-day base payment rate to align with current payments for the analysis year (that is, wage index budget neutrality factor and home health payment update). For example, to calculate the CY 2021 simulated 60-day episode base payment rate, we started with the final CY 2020 60-day base payment rate ($3,220.79) and multiplied by the final CY 2021 wage index budget neutrality factor (0.9999) and the CY 2021 home health payment update (1.020) to get an adjusted 60-day base payment rate ($3,284.88) for CY 2021. We used that adjusted 60-day base payment rate ($3,284.88) to price out the CY 2021 simulated 60-day claims. Once each claim is priced under the pre-PDGM HH PPS, that is each claim is adjusted from the base payment rate by case-mix, wage index, etc., we calculate the estimated aggregate expenditures for all simulated 60-day episodes in CY 2021. This method is then replicated to price out the simulated 60-day episodes for each year of claims data through CY 2026.

[5] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/CaseMix GrouperSoftware.*

(3) Price Out the 30-Day Periods and Determine Aggregate Expenditures

Next, we calculated the PDGM aggregate expenditures for the specific year (for example, CY 2020) using those specific 30-day periods that were used to create the simulated 60-day episodes. Therefore, both the actual PDGM expenditures and the simulated pre-PDGM aggregate expenditures are based on the exact same claims for the permanent adjustment calculation.

(4) Compare Aggregate Expenditures Between the Simulated 60-Day Episodes and Actual 30-Day Periods

We determine if the total aggregate expenditures under the PDGM were higher or lower than under the 153-case mix group system in each year beginning with CY 2020 through CY 2026. If expenditures were higher under the PDGM (that is, we paid more than we would have if the 153-group payment system was in place), then the actual base payment rate we implemented was too high. If the expenditures were lower under the PDGM (that is, we paid less than we would have if the 153-group payment system was in place), then the actual base payment rate we implemented was too low.

(5) Determine What the 30-Day Payment Rate Should Have Been

Using an iterative process, we determine what the 30-day base payment rate should have been, in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes. This is our recalculated (''repriced'') base payment rate.

(c) Calculating Permanent and Temporary Payment Adjustments

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

To offset retrospectively for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes in any given year, we calculate a temporary prospective adjustment by calculating the dollar amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment rate for the same year. In other words, when determining the temporary retrospective dollar amount, we use the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. In accordance with section 1895(b)(3)(D)(iii) of the Act, the temporary adjustment is to be applied on a prospective basis and shall apply only with respect to the year for which such temporary increase or decrease is made. Therefore, after we determine the dollar amount to be reconciled in any given year, we calculate a temporary adjustment factor to be applied to the base payment rate for that year. The temporary adjustment factor is based on an estimated number of 30-day periods in the next year using historical data trends, and as applicable, we control for a permanent adjustment factor, case-mix weight recalibration neutrality factor, wage index budget neutrality factor, and the home health payment update. The temporary adjustment factor is applied last. While we did not propose any changes to the methodology finalized in the CY 2023 HH PPS final rule (87 FR 66804), we did receive comments on the CY 2024 HH PPS proposed rule which are summarized in this section.

Comment: Many commenters opposed the behavioral adjustment methodology finalized in the CY 2023 HH PPS final rule based on legal and technical concerns that mostly repeated objections raised in the last rulemaking cycle. The legal arguments mostly restated we are violating the Medicare statute. These commenters repeated technical concerns including the use of therapy visits, accepted diagnosis codes, timing assignment, and missing OASIS items. Commenters stated ''home health agencies have predictably provided fewer therapy sessions,'' and the methodology's reliance on this change in therapy utilization is not appropriate to use in determining behavior changes since the law required the elimination of the therapy thresholds. Commenters again stated the methodology is unreasonable because ''claims billed under one case-mix system, with different incentives, coding and billing rules, and unit of payment'' cannot be compared. They requested that CMS reverse the permanent payment adjustment taken in CY 2023, withdraw the proposal of a permanent payment

adjustment for CY 2024, and develop and propose a new methodology after input from a technical expert panel. Similarly, a few commenters stated again that the methodology performs an unauthorized rebasing of the 30-day payment rate. Lastly, several commenters stated beneficiaries using home health are becoming more complex and have higher acuity needs, for which reimbursement does not match. We received a new comment on the methodology requesting CMS to consider how to further integrate the acuity of patients into the behavioral assumption methodology and how to better account for acuity overall in the PDGM.

Response: We appreciate the comments and recommendations we received regarding the behavior adjustment methodology. We did not propose any changes to the behavior adjustment methodology in this year's proposed rule and will not be finalizing any changes. As noted, most of these comments were similar to comments we received on the CY 2023 HH PPS proposed rule, so we refer readers to our responses to these concerns in the CY 2023 HH PPS final rule (87 FR 66797 through 66804). In that rule, for example, we responded to commenters' assertions that we violated the Medicare statute, as well as commenters' disagreement with technical concerns, including the inclusion of therapy provision, with our methodology.

One such argument to which we responded in the CY 2023 HH PPS final rule (87 FR 66802) was a theory that we implemented an unauthorized rebasing of the payment rates. The law requires us to determine the difference between assumed versus actual behaviors on estimated aggregate expenditures. Therefore, we continue to believe that the best reading of the law requires us to retrospectively determine if the 30-day payment amount in CYs 2020 through 2022 resulted in the same estimated aggregate expenditures if the 60-day unit of payment and the PDGM case-mix adjustment had not been implemented. As stated previously, the finalized methodology compares the payment rate and aggregate expenditures based on assumed behaviors to what the payment rate and estimated aggregate expenditures would have been using actual behaviors, which we believe is what the law requires.

We thank the commenters for their suggestion that they should be paid more because patient acuity has increased. We 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. It also allows us to be as accurate and up to date as possible when measuring relationships between resource use and functional points, functional threshold levels, comorbidities, LUPA thresholds, and case-mix weights. These aspects of the PDGM capture patient acuity. Further, because our finalized methodology utilizes the most recent claims data (which includes case-mix), patient acuity is reflected in the data.

(d) CY 2020 Results

This section discusses the final results that CMS determined from CY 2020 claims data that was previously published in the CY 2023 HH PPS final rule (87 FR 66804 through 66805). CMS did not do any recalculations for CY 2020 data and this section simply reiterates what was done previously for informative purposes only. Using the methodology described previously, we simulated 60-day episodes using actual CY 2020 30-day periods to determine what the CY 2020 permanent and temporary payment adjustments should be to offset for such increases or decreases in estimated aggregate expenditures. For CY 2020, we began with 8,423,688 30-day periods and dropped 603,157 30-day periods that had a claim occurrence code 50 date after October 31, 2020. We also eliminated 79,328 30-day periods that did not appear to group with another 30-day period to form a 60-day episode if the 30-day period had a ''from date'' before January 15, 2020 or a ''through date'' after November 30, 2020. This was done to ensure a 30-day period would not have been part of a 60-day episode that would have overlapped into CY 2021. Applying the additional exclusions and assumptions as described previously, an additional 14,062 30-day periods were excluded from this analysis. Additionally, we excluded 66,469 simulated 60-day episodes of care where no OASIS information was available in the CCW VRDC or could not be grouped to a HIPPS due to a missing primary diagnosis or other reason. Our simulated 60-day episodes of care produced a distribution of two 30-day periods of care (70.6 percent) and single 30-day periods of care (29.4 percent). This distribution is similar to what we found when we simulated 30-day periods of care for implementation of the PDGM. After all exclusions and assumptions were applied, the final dataset included 7,618,061 actual 30-day periods of care and 4,463,549 simulated 60-day episodes of care for CY 2020.

Using the final dataset for CY 2020 (7,618,061 actual 30-day periods which made up the 4,463,549 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 2020. As described previously in the methodology, we needed to calculate what the actual CY 2020 30-day base payment rate ($1,864.03) should have been to equal the aggregate expenditures that we calculated using the simulated CY 2020 60-day episodes. We determined the CY 2020 30-day base payment rate should have been $1,742.52 based on actual behavior rather than the $1,864.03 based on assumed behaviors. The percent change between the two payment rates (actual and recalculated) would be the permanent adjustment. Next, we calculated the difference in aggregate expenditures for all CY 2020 PDGM 30-day claims using the actual and recalculated payment rates. This difference is the retrospective dollar amount needed to offset payment. Our results are shown in Table B1.

TABLE B1: CY 2020 FINAL PERMANENT AND TEMPORARY ADJUSTMENTS

	Budget-neutral 30-day Payment Rate with Assumed Behavior Changes*	Budget-neutral 30-day Payment Rate with Actual Behavior Changes**	Adjustment
Base Payment Rate	$1,864.03	$1,742.52	**Permanent** - 6.52%
Aggregate Expenditures	$15,170,223,126	$14,297,150,005	**Temporary** - $873,073,121

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021.

*This was the finalized CY 2020 base payment rate.

**This is what we determined the CY 2020 30-day base payment rate should have been.

As shown in Table B1 and in the CY 2023 HH PPS final rule (87 FR 66805), a permanent prospective adjustment of –6.52 percent to the CY 2023 30-day payment rate would be required to offset for such increases in estimated aggregate expenditures in future years. Additionally, we determined that our initial estimate of base payment rates required to achieve budget neutrality resulted in excess expenditures of HHAs of approximately $873 million in CY 2020. This would require a temporary adjustment to offset for such increase in estimated aggregate expenditures for CY 2020.

(e) CY 2021 Results

This section discusses the final results CMS determined from CY 2021 claims data that was previously published in the CY 2023 HH PPS final rule (87 FR 66805 through 66806). CMS did not do any recalculations for CY 2021 data and this section simply reiterates what was done previously for informative purposes only. Using the methodology described previously, we simulated 60-day episodes using actual CY 2021 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. For CY 2021, we began with 9,269,971 30-day periods of care and dropped 570,882 30-day periods of care that had claim occurrence code 50 date after October 31, 2021. We also excluded 968,434 30-day periods of care that had claim occurrence code 50 date before January 1, 2021 to ensure the 30-day period would not be part of a simulated 60-day episode that began in CY 2020. Applying the additional exclusions and assumptions as described previously, an additional 5,868 30-day periods were excluded.

Additionally, we excluded 14,302 simulated 60-day episodes of care where no OASIS information was available in the CCW VRDC or could not be grouped to a HIPPS due to a missing primary diagnosis or other reason. Our simulated 60-day episodes of care produced a distribution of two 30-day periods of care (70.0 percent) and single 30-day periods of care (30.0 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 included 7,703,261 actual 30-day periods of care and 4,529,498 simulated 60-day episodes of care for CY 2021.

Using the final dataset for CY 2021 (7,703,261 actual 30-day periods which made up the 4,529,498 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 2021. As described previously in the methodology, we needed to calculate what the actual CY 2021 30-day base payment rate ($1,901.12) should have been to equal aggregate expenditures that we calculated using the simulated CY 2021 60-day episodes. We determined the CY 2021 30-day base payment rate should have been $1,751.90 based on actual behavior rather than the $1,901.12 based on assumed behaviors. The actual CY 2021 base payment rate of $1,901.12 does not account for any behavior adjustments needed for CY 2020, and therefore to evaluate changes for only CY 2021 we would need to control for the −6.52 percent prospective adjustment that we determined for CY 2020. Therefore, using the recalculated CY 2020 base payment rate of $1,742.52, multiplied by the CY 2021 wage index budget neutrality factor (0.9999) and the CY 2021 home health payment update (1.020), the CY 2021 base payment rate for assumed behaviors would have been $1,777.19. The percent change between the two payment rates would be the annual permanent adjustment for CY 2021 (assuming the −6.52 percent adjustment was already taken). Next, we calculated the difference in aggregate expenditures for all CY 2021 PDGM 30-day claims using the actual ($1,901.12, as this was what CMS actually paid in CY 2021) and recalculated ($1,751.90) payment rates. This difference is the retrospective dollar amount needed to offset payment. Our results are shown in Table B2.

TABLE B2: CY 2021 FINAL PERMANENT AND TEMPORARY ADJUSTMENTS

	Budget-neutral 30-day Payment Rate with Assumed Behavior Changes	Budget-neutral 30-day Payment Rate with Actual Behavior Changes	Adjustment
			Permanent
Base Payment Rate	$1,777.19*	$1,751.90	-1.42%
			Temporary
Aggregate Expenditures	$17,068,503,155**	$15,857,500,202	-$1,211,002,953

Source: CY 2021 Home Health Claims Data, Periods that end in CY 2021 accessed on the CCW March 21, 2022
Notes: *The $1,777.19 is equal to the recalculated budget neutral 30-day base payment rate of $1,742.52 for CY 2020 (shown in Table B2) multiplied by the CY 2021 wage index budget neutrality factor (0.9999) and the CY 2021 home health payment update (1.020).
**The estimated aggregate expenditures for assumed behavior ($17.1 billion), uses the actual CY 2021 payment rate of $1,901.12 as this is what CMS actually paid in CY 2021.

As shown in Table B2 and in the CY 2023 HH PPS final rule (87 FR 66806), a permanent prospective adjustment of −1.42 percent (assuming the −6.52 percent adjustment was already taken) would be required to offset for such increases in estimated aggregate expenditures in future years. Additionally, we determined that our initial estimate of base payment rates required to achieve budget neutrality resulted in excess expenditures of approximately $1.2 billion in CY 2021. This would require a one-time temporary adjustment factor to offset for such increases in estimated aggregate expenditures for CY 2021.

(f) CY 2022 Final Results

We will continue the practice of using the most recent complete home health claims data at the time of rulemaking. The CY 2022 analysis presented in the CY 2024 HH PPS proposed rule was considered ''preliminary'' and as more data became available from the latter half of CY 2022, we updated our results. As we did with the CY 2024 HH PPS proposed rule, the HH PPS limited data set (LDS) file released with this final rule includes two files: the actual CY 2022 30-day periods and the CY 2022 simulated 60-day episodes. We remind readers a data use agreement (DUA) is required to purchase the CY 2024 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 web page for more information.[6] In addition, the final CY 2024 Home Health Descriptive Statistics from the LDS Files spreadsheet is available on the Home Health Prospective Payment System Regulations and Notices web page,[7] 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 2022 that were used to determine the behavior adjustments. The spreadsheet also provides information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments. The CY 2024 final rule utilizes the CY 2022 finalized data for determining the behavior adjustment needed to calculate the CY 2024 payment rate. However, while the claims data and the permanent and temporary behavior adjustment results will be considered complete, any adjustments to future payment rates may be subject to additional considerations such as permanent adjustments taken in previous years.

Using the methodology described previously, we simulated 60-day episodes using actual CY 2022 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. For CY 2022, we began with 8,593,266 30-day periods of care and dropped 539,048 30-day periods of care that had claim occurrence code 50 date after October 31, 2022. We also excluded 894,333 30-day periods of care that had claim occurrence code 50 date before January 1, 2022 to ensure the 30-day period would not be part of a simulated 60-day episode that began in CY 2021. Applying the additional exclusions and assumptions as described previously, an additional 6,105 30-day periods were excluded.

Additionally, we excluded 18,296 simulated 60-day episodes of care where no OASIS information was available in the CCW VRDC or could not be grouped to a HIPPS due to a missing primary diagnosis or other reason. Our simulated 60-day episodes of care produced a distribution of two 30-day periods of care (69.6 percent) and single 30-day periods of care (30.4 percent) that was similar to what we found when we simulated two 30-day periods of care for implementation of the PDGM. After all exclusions and assumptions were applied, the final dataset included 7,124,359 actual 30-day periods of care and 4,199,746 simulated 60-day episodes of care for CY 2022.

Using the final dataset for CY 2022 (7,124,359 actual 30-day periods which made up the 4,199,746 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 as shown in Table B3. This indicates that aggregate expenditures under the PDGM were higher than if the 153-group payment system was still in place in CY 2022. As described previously in the methodology, we needed to calculate what the actual CY 2022 30-day base payment rate should have been to equal aggregate expenditures that we calculated using the simulated CY 2022 60-day episodes. We determined the CY

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

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

2022 30-day base payment rate should have been $1,839.10 based on actual behavior rather than the $2,031.64 based on assumed behaviors. We note, the actual CY 2022 base payment rate of $2,031.64 does not account for any behavior adjustments needed for CYs 2020 and 2021, and therefore to evaluate changes for only CY 2022 we need to account for the −7.85 percent prospective adjustment that we determined for CYs 2020 and 2021. Therefore, using the recalculated CY 2021 base payment rate of $1,751.90 (shown in Table B2), multiplied by the CY 2022 case-mix weights recalibration neutrality factor (1.0396), the CY 2022 wage index budget neutrality factor (1.0019) and the CY 2022 home health payment update (1.026), the CY 2022 base payment rate for assumed behavior would have been $1,872.18. The percent change between the two payment rates would be the additional permanent adjustment (assuming the −7.85 percent adjustment was already taken). Next, we calculated the difference in aggregate expenditures for all CY 2022 PDGM 30-day claims using the actual ($2,031.64) and recalculated ($1,839.10) payment rates. This difference is the retrospective dollar amount needed to offset payment. Our results are shown in Table B3.

TABLE B3: CY 2022 FINAL PERMANENT AND TEMPORARY ADJUSTMENTS

	Budget-neutral 30-day Payment Rate with Assumed Behavior Changes	Budget-neutral 30-day Payment Rate with Actual Behavior Changes	Adjustment
Base Payment Rate	$1,872.18*	$1,839.10	**Permanent** -1.767%
Aggregate Expenditures	$16,554,984,397 **	$15,149,537,108	**Temporary** -$1,405,447,290

Source: CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on the CCW July 15, 2023
Notes: *The $1,872.18 is equal to the recalculated budget neutral 30-day base payment rate of $1,751.90 for CY 2021 (shown in Table B2) multiplied by the CY 2022 recalibration budget neutrality factor (1.0396) and the CY 2022 wage index budget neutrality factor (1.0019) and the CY 2022 home health payment update (1.026).
**The estimated aggregate expenditures for assumed behavior ($16.5 billion), uses the actual CY 2022 payment rate of $2,031.64 as this is what CMS actually paid in CY 2022.

As shown in Table B3, a permanent prospective adjustment of −1.767 percent to the CY 2024 30-day payment rate (assuming the −7.85 percent adjustment was already taken) would be required to offset for such increases in estimated aggregate expenditures in future years. Additionally, we determined that our initial estimate of base payment rates required to achieve budget neutrality resulted in excess expenditures of approximately $1.4 billion in CY 2022. This would require a one-time temporary adjustment factor to offset for such increases in estimated aggregate expenditures for CY 2022.

(g) CY 2024 Final Permanent Adjustment and Temporary Adjustment Calculations

As discussed in the CY 2023 HH PPS final rule (87 FR 66808), to offset fully the increase in estimated aggregate expenditures for CYs 2020 and 2021 based on the impact of the differences between assumed and actual behavior changes, in CY 2023, CMS would have needed to apply a −7.85 percent permanent adjustment to the CY 2023 base payment rate, as well as implement a temporary adjustment of approximately $2.1 billion to reconcile retrospective overpayments in CYs 2020 and 2021. We recognized that applying the full permanent and temporary adjustment immediately would have resulted in a significant negative adjustment in a single year. However, as we noted at the time, and as still is applicable, if the PDGM 30-day base payment rate remained higher than it should be, there will be a compounding effect, potentially creating the need for an even larger reduction to adjust for behavioral changes in future years. After considering all options, CMS proposed and finalized the application of only a permanent adjustment to the CY 2023 base payment rate. We believed, and continue to believe, this mitigates the need for a larger permanent adjustment and reduces the amount of any additional temporary adjustments in future years.

We also recognized the potential hardship to some providers of implementing the full −7.85 percent permanent adjustment in a single year. We exercised our discretion to implement adjustments in a time and manner determined appropriate, under section 1895(b)(3)(D) of the Act, to finalize a −3.925 percent (half of the −7.85[8] percent) permanent adjustment to the CY 2023 30-day payment rate. However, we emphasized that the permanent adjustment needed in CY 2023 to account fully for actual behavior changes in CYs 2020 and 2021 was −7.85 percent and applying a −3.925 percent permanent adjustment to the CY 2023 30-day payment rate would not fully account for differences in behavior changes on estimated aggregate expenditures during those years, as well as CYs 2022 and 2023. We stated we would need to account for that difference (that is, the remaining half not applied to the CY 2023 payment rate) in future rulemaking, and any additional adjustments (for example, CY 2022) needed to the base payment rate, to account for behavior change based on more recent data analysis. We note that the total permanent adjustment based on CY 2022 data did not have any previous behavior adjustments applied.

[8] We initially proposed a −7.69 percent permanent adjustment in the CY 2023 HH PPS proposed rule (87 FR 37620). As more data became available from the latter half of CY 2021, we updated our results.

However, as described later in this section, we recognize for CY 2024 we must account for adjustments made in CY 2023.

The percent change between the actual CY 2022 base payment rate of $2,031.64 (based on assumed behaviors) and the CY 2022 recalculated base payment rate of $1,839.10 (based on actual behaviors) (shown in Table B3) is the total (cumulative) permanent adjustment for CY 2022. The summation of the dollar amount for CYs 2020, 2021, and 2022 is the amount that represents the temporary payment adjustment to offset for increased aggregate expenditures in CYs 2020, 2021, and 2022. Our results are shown in Table B4 and B5.

TABLE B4: TOTAL PERMANENT ADJUSTMENT FOR CYs 2020, 2021, and 2022

Actual CY 2022 Base Payment Rate (Assumed Behavior)	Recalculated CY 2022 Base Payment Rate (Actual Behavior)	Total Permanent Prospective Adjustment
$2,031.64	$1,839.10	-9.48%*

Source: CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on the CCW July 15, 2023. *This is the total permanent adjustment based on CY 2022 data which did not have any previous behavior adjustments applied. However, as described later in this section, we recognize for CY 2024 we must account for adjustments made in CY 2023.

TABLE B5: TOTAL TEMPORARY ADJUSTMENT FOR CYs 2020, 2021, and 2022

CY 2020 Temporary Final Adjustment	CY 2021 Temporary Final Adjustment	CY 2022 Temporary Final Adjustment	Total Temporary Adjustment Dollar Amount for CYs 2020, 2021, and 2022
-$873,073,121	-$1,211,002,953	-$1,405,447,290	-$3,489,523,364

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.

We remind readers when we update the national, standardized 30-day period payment amount (section II.C.4.2) that adjustment factors are multiplied in this payment system and therefore, individual numbers (that is, percentages) do not sum precisely to the permanent adjustment needed to account for the total permanent adjustment in that year. Additionally, as we stated in the CY 2023 HH PPS final rule (87 FR 66808), applying a −3.925 percent permanent adjustment to the CY 2023 30-day payment rate would not adjust the rate fully to account for differences in behavior changes on estimated aggregate expenditures in CYs 2020 and 2021. Therefore, we cannot determine the CY 2024 final permanent adjustment by simply subtracting −3.925 percent from the total permanent adjustment of −9.477 percent (updated from −9.356 percent in the proposed rule as more data became available), as described further below.

Instead, we look at the total permanent adjustment needed for the current year of data and account for any prior permanent adjustments through multiplication and division of factors. In other words, we determined the total permanent adjustment based on CY 2022 data (which had no prior adjustments) is −9.477 percent, which is converted to a 0.90523 factor. We recognize that in CY 2023 we implemented a −3.925 percent permanent behavior adjustment, converted to a 0.96075 factor, and we must account for it in the proposed CY 2024 permanent adjustment. Next, we calculated the CY 2024 permanent adjustment factor by solving (1−x) = 0.90523 (9.477 percent) divided by 0.96075 (3.925 percent). The resulting factor (1−x) is 0.94221, which is converted to a 5.779 percent (updated from 5.653 percent in the CY 2024 HH PPS proposed rule (88 FR 43678) as more data became available) reduction to the CY 2024 national, standardized base payment rate. In other words, 1 minus the factor 0.94221 equals 0.05779 which is equal to a 5.779 percent reduction. Therefore, to offset the increase in estimated aggregate expenditures for CY 2022 based on the impact of the differences between assumed and actual behavior changes, and to account for the permanent adjustment of −3.925 percent taken in CY 2023 rulemaking, CMS would need to apply a −5.779 percent permanent adjustment to the CY 2024 base payment rate.

To calculate the temporary adjustment, we would add the CY 2022 temporary adjustment dollar amount of $1,405,447,290 to the previously finalized CYs 2020 and 2021 dollar amounts for a total of $3,489,523,364. We stated in the CY 2023 HH PPS final rule (87 FR 66804) and the CY 2024 HH PPS proposed rule (88 FR 43678), after we determine the dollar amount to be reconciled, we will calculate a temporary adjustment factor to be applied to the base payment rate for that year. That is, the dollar amount will be converted to a factor. However, in the CY 2023 HH PPS proposed rule (87 FR 37682), we opted to implement only the permanent adjustment and solicit

comments on the implementation of a temporary adjustment, as we believed for that year applying both would result in too significant of a reduction in the payment rate in one year. Given that the magnitude of implementing both the temporary and permanent adjustments for CY 2024 rate setting may also result in a significant reduction of the payment rate, we similarly did not propose to take the temporary adjustment in CY 2024. As we are required by Section 1895(b)(3)(D)(iii) of the Act, we will propose a temporary adjustment factor to the national, standardized 30-day base payment rate when we propose this temporary payment adjustment in future rulemaking.

We received 343 comments on the permanent prospective behavior change adjustment on the CY 2024 home health payment rate which are summarized in this section. Similar to comments received on the CY 2023 permanent adjustment, the majority of commenters disagreed with the proposed permanent adjustment to the CY 2024 payment rate.

Comment: Overall, commenters raised concerns that the proposed rate cut would be a threat to home health access. Further, industry advocates submitted data from hospitals and health systems to support their assertion that HHA referrals for Medicare beneficiaries are increasingly being rejected, and the number of patients referred to home health and subsequently admitted is dropping.

These commenters interpret these trends to be indicative of declining access to home health services and state that CMS's implementation of the PDGM and behavior adjustment resulting in rate cuts are major contributors. Commenters stated that a rate cut will affect beneficiary access by forcing HHAs to close, sell, reduce service areas, reduce admissions, and struggle to retain staff, while many others are operating with, or will operate with, negative margins if the CY 2024 permanent rate adjustment is finalized. These commenters contend that CMS does not have an accurate financial picture of industry stability, as we do not account for overall margins (for example, Medicare Advantage), rather just Medicare Fee-For-Service (FFS) margins when considering margin analyses. A commenter stated that ''the economic model of HHAs necessitates a view consistent with the HHAs' evaluation of its overall financial condition,'' suggesting that it is common for Medicare's FFS payment to subsidize shortfalls from other payers.

Response: We appreciate industry advocates' dedication to ensuring continued access to home health services. We recognize there is always a level of concern that accompanies a payment rate decrease and we remind readers that, by law, as described in section 1895(b)(3)(D) of the Act, we are required to ensure that estimated aggregate expenditures under the HH PPS are equal to our determination of estimated aggregate expenditures that otherwise would have been made under the HH PPS in the absence of the change to a 30-day unit of payment and changes in case-mix adjustment factors. We appreciate providers', beneficiaries', and other stakeholders' commitment to the sustainability of the home health benefit.

As we noted above, we reprice the base payment rate based on actual behavior changes by HHAs, not on how the behavior changes impact HHA margins. In any event, CMS looked closely at our data to ensure the payment rate adequately covers the costs reported by HHAs, without creating unnecessary hardship to providers and maintaining access to quality services for all beneficiaries. Maintaining access is one of CMS's priorities when making policy decisions. We do not intend to obstruct the provision of home health services to any beneficiary who qualifies for this benefit.

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, along with data reported by MedPAC in their annual Medicare payment policy reports to the Congress, 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 profit margins. CMS's analysis, shown in Table B4 of the CY 2024 HH PPS proposed rule, indicates that the CY 2022 national, standardized 30-day period payment rate was approximately 45 percent more than the CY 2022 estimated 30-day period cost (88 FR 43665). MedPAC's 2023 March Report to the Congress [9] found that in 2021, home health agencies' average cost per 30-day period decreased by 2.9 percent and that Medicare's payment per in-person visit increased by 17.7 percent. Medicare margins for freestanding agencies averaged 24.9 percent in 2021, up from 20.2 percent in 2020 and 15.4 percent in 2019. These high margins indicate that the increase in payments in 2021 far exceeded the increase in costs, which undermines commenters' assertion that CMS's modest (by comparison) cuts to the base rate in 2023 would exacerbate any problems with access to care. Further, MedPAC's projected Medicare margin for HHAs for 2023 is 17.0 percent, which includes the statutory adjustment to the base payment rate in accordance with the statutory requirement to determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures in response to the change in case-mix adjustment and the 30-day period payment.

Some commenters pointed to the number of HHAs with negative margins. Using Medicare cost reports with a year end of December 31, 2022, approximately 21 percent of HHAs have margins below zero percent. We are aware that some HHAs face financial difficulties, but the behavior adjustment is an aggregate adjustment that impacts the base payment rates of all HHAs equally. Our analysis, shown in Table B6, indicates that even prior to the PDGM, approximately 20 to 23 percent of freestanding HHAs had margins below zero percent, indicating that this phenomenon pre-dated the PDGM, and are not the result of the rate adjustments related to the initial behavior assumptions applied in CY 2020.

[9] Report to Congress, Medicare Payment Policy. Home Health Care Services, Chapter 8. MedPAC. March 2023 *https://www.medpac.gov/wp-content/uploads/2023/03/Ch8_Mar23_MedPAC_Report_To_Congress_SEC.pdf.*

TABLE B6: NUMBER and PERCENT of FREESTANDING HHAs THAT HAD NEGATIVE MEDICARE MARGINS - CYs 2017-2022

Year	Positive Margin Cost Reports		Negative Margin Cost Reports		Total
	Number	Percent	Number	Percent	Number
2017	6,024	76.5%	1,848	23.5%	7,872
2018	5,851	77.1%	1,738	22.9%	7,589
2019	5,871	79.3%	1,533	20.7%	7,404
2020	5,558	77.0%	1,657	23.0%	7,215
2021	5,532	77.5%	1,605	22.5%	7,137
2022	4,770	78.0%	1,348	22.0%	6,118
Total	33,606	77.6%	9,729	22.5%	43,335

Source: Freestanding cost reports for 2017 through 2022, accessed on the CMS website at https://www.cms.gov/data-research/statistics-trends-and-reports/cost-reports on August 30, 2023.
Notes: We combine multiple cost reports for the same provider if those cost reports cover different months. We excluded HHAs with a Medicare margin in the top or bottom 5 percent in a given year. Therefore, the HHAs included for each year had a margin between the 5th and 95th percentile.

With respect to the comment that CMS must look at the HHAs' overall financial condition (that is, overall margins), we have never endorsed the view that Medicare funds should be used to subsidize reimbursement rates from other payers—a policy that would be inconsistent with our obligation to be responsible stewards of the Medicare Trust Funds and would ultimately increase costs to Medicare beneficiaries, taxpayers, or both. As we noted in the CY 2023 HH PPS final rule we responded to this assertion stating: ''Medicare has never set payments to cross-subsidize other payers. Section 1861(v)(1)(A) of the Act states that under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this title will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs'' (87 FR 66807).

While CMS monitors the payment rate to ensure it is adequate for providing care, MedPAC further assesses access to care by reviewing several indicators to determine the level at which payments will be adequate to cover the costs of providing care of a provider in any given year. Specifically, they examine the supply of home health providers, annual changes in the volume of services, quality of care, and access to capital, in addition to the relationship between Medicare's payments and providers' costs. Their annual reports indicate that prior to and following the implementation of the PDGM, the payment adequacy indicators for home health care have been positive.

Finally, we observed many methodological weaknesses in the analyses submitted by commenters. It is unclear whether the proprietary data on which commenters base their analyses includes referrals from only Medicare FFS beneficiaries or also includes referrals from patients covered by other payers, which means the entire analysis may be inapt for Medicare FFS policy. In addition, the proportion of hospital referrals rejected by HHAs does not equate to the proportion of qualifying beneficiaries who are denied care. The data fails to capture why the beneficiary was rejected—for example, because the analysis focuses on numbers of referrals denied rather than numbers of beneficiaries denied care, the rejection referral proportion could be inflated by a small number of beneficiaries rejected from multiple HHAs, or by beneficiaries rejected from one HHA but who ultimately received care from another HHA. It also fails to indicate that the HHA did in fact reject the referral and why it was rejected (for example, payment or staff related), or whether there was another reason the patient did not receive home health services, such as patient refusal or readmission to an inpatient facility.

Further, the data submitted by the commenters is deficient in analyzing the characteristics of the beneficiaries who are receiving home health services versus those that do not. The usefulness of such analysis would be to potentially show whether HHAs are strategic in accepting certain types of patients over others. In response to a similar home health rate decrease (CY 2011 HH PPS final rule), in which CMS finalized a 3.79 percent rate reduction, a commenter stated that ''HHAs may become more selective in their acceptance of medically difficult patients who are likely to utilize more services'' (75 FR 70375). Additionally, in the CY 2023 HH PPS final rule we quoted an article published in February 2020, in which the National Association for Home Care and Hospice (NAHC) stated ''categorically, across the board, we're going to reduce our therapy services'' because of the PDGM (87 FR 66798). A comment letter received by NAHC on the CY 2023 proposed rule also attempted to outline, how historically, rate cuts to Medicare home health services alter how HHAs provide care. Compellingly, we also received a significant number of comments in response to the CY 2024 HH PPS proposed rule supporting this concept. These comments are discussed below.

Comment: Commenters indicated that HHAs may also choose which patients to accept on service to maximize payment. For example, a patient advocate group noted that ''HHAs self-select the Medicare patients they will serve (or not serve), and then HHAs determine the services they provide, based on their hiring choices and OASIS assessments.'' This commenter stated that home health care has become ''big business,'' and stated that ''HHAs focus

more on profits for shareholders and less on critically needed services for patients.'' Another commenter stated, ''the venture capital backed agencies are using data-mining solutions to ensure a profit is made. This includes everything from the heavily scrutinized referral acceptance procedure to ensure 'profitable' patients are chosen over 'non-profitable' patients and the rationing of care based on what the data shows to create profit from decreasing direct care costs.''

Response: Our previous response related to margins suggests that, as some commenters have claimed, HHAs may be strategically admitting or denying beneficiaries based to maximize their margins. We are concerned by suggestions that the ''referral rejections'' and perceived access to care issue that industry advocates have cited to us are in fact being caused by strategic behavior. We would be interested to receive data and analysis comparing beneficiaries who are receiving home health services versus those who are not, which could help inform future policy proposals. The data we received does not address that issue, and CMS's review of utilization software websites designed to guide HHAs to the most profitable referrals and to identify ways to decrease costs supports these commenters assertions. For these reasons, we cannot credit home health agencies' conclusion that either behavioral adjustments or the PDGM are the root cause of the access issues reported by beneficiaries.

We will continue to monitor home health utilization, claims data, and home health cost reports to identify trends that may indicate vulnerabilities and deficiencies in the home health prospective payment system and potentially affect access to care. Given this monitoring and analyses showing that the home health payment exceeds the cost of providing care, we would expect that providers would not have to reject referrals because of inadequate payment. In fact, due to the newly implemented case-mix system designed to encourage a varied distribution of services, we would not only expect that agencies would not have to reject referrals but be well-positioned to accept a wide range of referrals regardless of the services needed.

We are aware of the changes in the home health industry, including buyouts and increased interest of private equity groups. These shifts will undoubtedly change the landscape of home health; however, we remind stakeholders that Medicare FFS sets rates to cover costs that align with Medicare's principles of reasonable cost determination as set out at 42 CFR 413.9, not to ensure high profit margins. The home health benefit uses a prospective payment system that is inclusive of all care required in a 30-day period of care. This method of payment is made based on a predetermined, base payment amount. The home health case-mix system, the PDGM, was created to align the payment system more closely with patient characteristics and ensure that payment accurately meets the resource needs of various types of patients. This helps HHAs to be paid appropriately for a wide range of patients with varying care needs and improves the likelihood that clinically complex and ill beneficiaries and patients coming from the hospital will have adequate access to home health care. In the CY 2019 HH PPS final rule with comment period (83 FR 56448), where we finalized the implementation of the PDGM, there was some commenter concern that the PDGM may introduce ''inappropriate practice patterns,'' suggesting again that HHAs may change how they operate in accordance with payment. However, our objective then, as well as now, remains to pay for the care provided as required by the statute. As evidenced by the behavior changes described in the CY 2023 HH PPS final rule, we understand that providers do continue to adjust practice patterns in response to payment and case-mix changes. We also understand that venture capital and private equity groups are buying HHAs. This, however, does not mean that overall access to the benefit has been compromised and the analyses presented by commenters fails to show evidence that this is the case. Further, were the data to show definitively that overall access has been affected, there remains no direct link to inadequate payment. It is also important to note that while the commenters' data purports to show an increase in ''referral rejections'' beginning with the implementation of the PDGM and through the beginning of CY 2023, in CY 2020 (beginning of PDGM) and each subsequent year through CY 2023, CMS has instituted a positive rate update for HHAs. It is unclear why HHAs would reject referrals when payment rates have increased each year since the implementation of the PDGM, and as established earlier, have continually exceeded the cost of providing care. Additionally, CMS is statutorily required, under Section 1895(b)(3)(D)(i), 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, by accounting for the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. This requirement under section 1895(b)(3)(D)(i) resulted in the proposed −5.653 percent adjustment for CY 2024.

We do not believe that the percentage of ''referral rejections'' attributable to staffing issues requires a different policy. Commenters did not submit any evidence that staffing shortages are due to changes in the payment rate or case-mix adjustment rather than the widespread staffing shortages that exist across the spectrum of healthcare, and in the general labor market. While we recognize the staffing challenges faced by HHAs and other healthcare providers, we are accounting for those staffing challenges in other ways, such as the market basket increase (which includes labor costs), as explained in section II.C.3 of this final rule.

In conclusion, we appreciate the concerns that a rate decrease may affect access to home health services; however, CMS's analysis of HHA cost reports and margin analysis, as well as MedPAC's analysis of profit margins, the supply of home health providers, annual changes in the volume of services, quality of care, and access to capital shows that access should remain adequate. Our discussion above indicates that any effect on access would not be a result of CMS paying more accurately for the care provided. In addition, the law requires us to evaluate the difference between assumed and actual behavior changes on estimated aggregate expenditures independently for CYs 2020 through 2026. The payment adjustment does not include extenuating factors such as margins. Further, while the analyses submitted by the commenters allegedly show that access to home health services has been compromised, CMS does not have access to the proprietary data used to create the analysis to confirm the validity of the results.

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 acknowledge that taking a large permanent adjustment in a single year, to 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, may be burdensome for some providers. As we have the discretion to implement any behavior adjustment in a time and manner determined appropriate, we are

finalizing only a −2.890 percent (half of the −5.779 [10] percent) permanent adjustment for CY 2024. This approach of applying half of the permanent adjustment is aligned with the approach finalized in the CY 2023 HH PPS final rule (87 FR 66808) where CMS finalized half of the permanent adjustment to the CY 2023 30-day payment rate.

However, we note the permanent adjustment to account for actual behavior changes in CYs 2020, 2021, and 2022, should be −5.779 percent, which includes the remaining ''half'' from the CY 2023 HH PPS final rule and the additional adjustment based on CY 2022 data. Therefore, applying a −2.890 percent permanent adjustment to the CY 2024 30-day payment rate would not adjust the rate fully to account for differences in behavior changes on estimated aggregate expenditures 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 2024 base payment rate using our temporary adjustment authority, as section 1895(b)(3)(D)(iii) 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 (−5.779 percent) in effect, the total temporary dollar amount will likely continue to increase until the permanent adjustment is fully implemented.

2. CY 2024 PDGM LUPA Thresholds and PDGM Case-Mix Weights

(a) CY 2024 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 to set the LUPA thresholds at the 10th percentile of visits or 2 visits, whichever is higher, for each payment group. This means the LUPA threshold for each 30-day period of care may vary 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 CY 2024 per-visit payment amounts as described in section II.C.4.e.3. 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 less visits, payment is made using the per-visit payment amounts.

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

In the CY 2022 HH PPS final rule (86 FR 62249), we discussed the influence of the COVID–19 PHE on home health utilization and finalized a 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 believed the COVID–19 PHE would have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the COVID–19 PHE on the calculation of the case-mix weight would be minimal since the impact would be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight. However, in contrast, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (like what is used to generate the case-mix weight) that would control for the impacts of the COVID–19 PHE. We noted that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. Therefore, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID–19 PHE, we finalized the proposal to maintain the LUPA thresholds finalized and displayed in Table 17 in the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2022 payment purposes.

For CY 2023, we proposed to update the LUPA thresholds using CY 2021 Medicare home health claims (as of March 21, 2022) linked to OASIS assessment data. After reviewing the CY 2022 home health claims utilization data we determined that visit patterns have stabilized. Our data analysis indicated that visits in 2022 were similar to visits in 2020. We believed that CY 2021 data would be more indicative of visit patterns in CY 2023 rather than continuing to use the LUPA thresholds derived from the CY 2018 pre-PDGM data. Therefore, in the CY 2023 HH PPS final rule we finalized a policy to update the LUPA thresholds for CY 2023 using data from CY 2021.

In accordance with our policy, for CY 2024, in the CY 2024 HH PPS proposed rule, we proposed to update the LUPA thresholds using CY 2022 home health claims utilization data (as of March 17, 2023). We solicited public comments on the proposed updates to the LUPA thresholds for CY 2024. These comments and our responses are summarized in this section of the rule.

Comment: A few commenters expressed support for the proposed LUPA thresholds.

Response: We thank the commenters for their support.

Comment: Some commenters continued to disagree with the policy to reevaluate and update the LUPA thresholds annually. A commenter recommended that CMS reduce the LUPA threshold for all case-mix groups to two visits. Another commenter recommended CMS not update the LUPA thresholds for CY 2024 and reassess the impact of using CY 2023 data before making any adjustments. This commenter stated that the change in LUPA visit thresholds from two and three visits to the current four and five visit thresholds narrows the gap between the LUPA visit threshold and the average visits per home health period, and that as the gap narrows, LUPA payments will no longer represent outliers. Lastly, a commenter questioned the methodology used to calculate the LUPA thresholds.

[10] We initially proposed a –5.653 percent permanent adjustment in the CY 2024 HH PPS proposed rule (88 FR 43679). As more data became available from the latter half of CY 2022, we updated our results.

Response: We thank the commenters for their recommendations; however, in the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized the policies to set LUPA thresholds at the 10th percentile of visits or 2 visits, whichever is higher, for each payment group, and reevaluate the LUPA thresholds for each PDGM payment group every year based on the most current utilization data available at the time of rulemaking. We did not propose any changes to our finalized LUPA threshold policy in the CY 2024 HH PPS proposed rule. Further, our policy to reevaluate the LUPA thresholds ensures that they reflect, as accurately as possible, current home health resource use and changes in utilization patterns. As such, we believe that we should update the LUPA thresholds using CY 2022 home health claims utilization data (as of July 15, 2023), to ensure they are representative of the most recent visit patterns.

Final Decision: We are finalizing the proposal to update the LUPA thresholds for CY 2024, using CY 2022 claims data (as of July 15, 2023). The final LUPA thresholds for the CY 2024 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in Table B12 and is also available on the HHA Center web page.[11]

(b) CY 2024 Functional Impairment Levels

Under the PDGM, the functional impairment level is determined by responses to certain OASIS items associated with activities of daily living (ADLs) 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 these points results in a functional score which is used to group home health periods into a functional level with similar resource use. That is, the higher the points, the higher the response is associated with increased resource use. The sum of these points results in a functional impairment score which is used to group home health periods into one of three functional impairment levels with similar resource use. The three functional impairment levels of low, medium, and high were designed so that approximately one-third of home health periods from each of the clinical groups fall within each level. This means home health periods in the low impairment level have responses for the functional OASIS items that are associated with the lowest resource use, on average. Home health periods in the high impairment level have responses for the functional OASIS items that are associated with the highest resource use on average.

For CY 2024, we proposed to use CY 2022 claims data to update the functional points and functional impairment levels by clinical group. The CY 2018 HH PPS proposed rule (82 FR 35320) and the technical report from December 2016, posted on the Home Health PPS Archive web page located at: *https://www.cms.gov/medicare/home-health-pps/home-health-pps-archive,* provides a more detailed explanation as to the construction of these functional impairment levels using the OASIS items. We proposed to use the same methodology previously finalized to update the functional impairment levels for CY 2024.

We solicited public comments on the updates to functional points and the functional impairment levels by clinical group. A summary of these comments and our responses are as follows:

Comment: Several commenters opposed the proposed, updated CY 2024 functional impairment points and levels. A commenter recommended delaying this update until the effect of the CY 2023 functional impairment levels has been assessed. This commenter also suggested that if future updates are warranted that it should occur in CY 2025 using post pandemic CY 2023 claims data.

Response: We thank the commenters for their recommendations; however, performing a yearly recalibration allows us to be as accurate and up to date as possible when measuring the relationship between resource use and functional points, functional threshold levels, comorbidities, LUPA thresholds and case-mix weights. Therefore, we do not believe it would be appropriate to delay updates to the functional impairment points and levels for CY 2024. We continue to believe that updating the functional impairment levels using current data ensures that all variables used as part of the overall case-mix adjustment appropriately align home health payment with the actual cost of providing home health care services.

Comment: A commenter disagreed with the method used for assigning the functional impairment levels, stating that the update in point values appears to be more aimed at achieving an arbitrarily set target of one-third in each level rather than a true categorization of the patients' clinical presentation.

Response: We remind commenters that the functional levels are set so that roughly a third of periods within each clinical group are assigned to low, medium, and high to ensure that the case-mix system pays appropriately for differences in functional impairment level. The structure of categorizing functional impairment into low, medium, and high levels has been part of the home health payment structure since the implementation of the HH PPS. 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. The PDGM functional impairment level structure accounts for the patient characteristics within that clinical group associated with increased resource costs affected by functional impairment. This is to further ensure that payment is more accurately aligned with actual patient characteristics and resource needs.

Comment: Some commenters were concerned that the proposed functional impairment levels do not accurately reflect the actual functional impairment levels of home health patients or the cost to provide care for higher acuity patients, specifically those in the musculoskeletal rehabilitation, neuro rehabilitation, surgical aftercare, and wounds groups, as these individuals often have intense needs for assistance with daily living. A few commenters questioned why it appears there would be a reduction in reimbursement for the highest acuity patients and suggested that this will limit an agency's ability to care for these types of patients. Some commenters indicated that they would see fewer patients with high functional impairment, as several groups changed from high functional impairment to medium functional impairment, while others stated this change will

[11] *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center.*

incentivize for-profit agencies to hand-pick patients based on their predicted case mix grouping. A commenter suggested that the shift of patients from high functional impairment to medium functional impairment indicates by CMS through the HIPPS code that these patients are not as clinically complex and therefore would not require as many resources.

Response: We have noted in past rules that we use the functional impairment level case-mix adjustment, developed as part of the PDGM case-mix, to provide the necessary payment adjustments to ensure that functional care needs are met based on actual patient characteristics. As in any case-mix system, there will be certain case-mix groups where a patient's costs exceed the average as well as where their costs are below the average. However, we do not believe that a patient assignment to a HIPPS category should dictate what care the patient needs. We expect the provision of services to be made to best meet the patient's care needs and in accordance with the home health CoPs at § 484.60 which sets forth the requirements for the content of the individualized home health plan of care which includes the types of services, supplies, and equipment required; the frequency and duration of visits to be made; as well as patient and caregiver education and training to facilitate timely discharge. Therefore, we do not expect HHAs to under-supply care or services; reduce the number of visits in response to payment; or inappropriately discharge a patient receiving Medicare home health services as these would be violations of the CoPs and could also subject HHAs to program integrity measures.

Final Decision: We are finalizing the functional points and functional impairment levels updates for CY 2024 as proposed, using CY 2022 claims data (as of July 15, 2023). The updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2024 are listed in Tables B7 and B8, respectively.

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TABLE B7: FINAL OASIS POINTS TABLE FOR CY 2024

	Responses	Points (2024)	Percent of Periods in 2022 with this Response Category
M1800: Grooming	0 or 1	**0**	**28.0%**
	2 or 3	**3**	**72.0%**
M1810: Current Ability to Dress Upper Body	0 or 1	**0**	**22.9%**
	2 or 3	**5**	**77.1%**
M1820: Current Ability to Dress Lower Body	0 or 1	**0**	**10.5%**
	2	**3**	**66.0%**
	3	**11**	**23.5%**
M1830: Bathing	0 or 1	**0**	**2.6%**
	2	**0**	**10.9%**
	3 or 4	**7**	**50.4%**
	5 or 6	**14**	**36.1%**
M1840: Toilet Transferring	0 or 1	**0**	**62.4%**
	2, 3 or 4	**6**	**37.6%**
M1850: Transferring	0	**0**	**1.4%**
	1	**3**	**20.2%**
	2, 3, 4 or 5	**6**	**78.4%**
M1860: Ambulation/Locomotion	0 or 1	**0**	**3.2%**
	2	**6**	**13.5%**
	3	**4**	**65.5%**
	4, 5 or 6	**20**	**17.8%**
M1033: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	**0**	**61.5%**
	Four or more items marked (Excluding responses 8, 9 or 10)	**11**	**38.5%**

Source: CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed from the CCW on July 15, 2023.
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 B8: FINAL THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, FOR CY 2024

Clinical Group	Level of Impairment	Points (2022)
MMTA – Other	Low	**0-28**
	Medium	**29-41**
	High	**42+**
Behavioral Health	Low	**0-28**
	Medium	**29-41**
	High	**42+**
Complex Nursing Interventions	Low	**0-28**
	Medium	**29-52**
	High	**53+**
Musculoskeletal Rehabilitation	Low	**0-28**
	Medium	**29-41**
	High	**42+**
Neuro Rehabilitation	Low	**0-34**
	Medium	**35-49**
	High	**50+**
Wound	Low	**0-28**
	Medium	**29-49**
	High	**50+**
MMTA - Surgical Aftercare	Low	**0-28**
	Medium	**29-39**
	High	**40+**
MMTA - Cardiac and Circulatory	Low	**0-28**
	Medium	**29-41**
	High	**42+**
MMTA – Endocrine	Low	**0-27**
	Medium	**28-39**
	High	**40+**
MMTA - Gastrointestinal tract and Genitourinary system	Low	**0-31**
	Medium	**32-46**
	High	**47+**
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	**0-28**
	Medium	**29-43**
	High	**44+**
MMTA – Respiratory	Low	**0-29**
	Medium	**30-44**
	High	**45+**

Source: CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed from the CCW on July 15, 2023.

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(c) CY 2024 Comorbidity Subgroups

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

- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.

• *High comorbidity adjustment:* There are two or more secondary diagnoses on the home health-specific comorbidity subgroup interaction list that are associated with higher resource use when both are reported together compared to when they are reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.

• *No comorbidity adjustment:* A 30-day period of care receives no comorbidity adjustment if no secondary diagnoses exist or do not meet the criteria for a low or high comorbidity adjustment.

In the CY 2019 HH PPS final rule with comment period (83 FR 56406), we stated that we would continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements to help ensure that payment is in alignment with the actual costs of providing care. For CY 2024, we proposed to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2022 home health data.

For CY 2024, we proposed to update the comorbidity subgroups to include 22 low comorbidity adjustment subgroups as identified in Table B19 and 101 high comorbidity adjustment interaction subgroups as identified in Table B20 in the CY 2024 HH PPS proposed rule.

We invited comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment interactions for CY 2024. These comments and our responses are summarized as follows.

Comment: A commenter supported the proposed low comorbidity subgroups and the high comorbidity interactions. This commenter stated that the proposed low comorbidity subgroups achieve the goal of ensuring that payment is in alignment with the actual costs of providing care and the high comorbidity adjustment interaction subgroups acknowledge the impact of multiple diagnoses on care delivery complexity and cost.

Response: We thank the commenter for their support.

Comment: A commenter requested clarification on the number of proposed low comorbidity subgroups for CY 2024. This commenter noted that Table B19 included 22 subgroups, but the preamble language listed the number of subgroups as 21.

Response: We thank the commenter for bringing this to our attention. The preamble language inadvertently stated that there were 21 low comorbidity subgroups; however, the 22 subgroups listed in Table B19 are accurate. Furthermore, the number of low comorbidity subgroups remains 22 for this final rule.

Comment: A commenter requested that CMS reassign diseases and disorders, as well as specific ICD–10 CM diagnosis codes, to different comorbidity subgroups and create new high comorbidity interactions. The commenter requested the following reassignments:

• Include the Diabetes with mononeuropathy, E.41 codes in the Neurological 10 grouping.

• Include rheumatic mitral valve diseases I05. codes and aortic rheumatic valve diseases I06 codes in the Heart 9 grouping.

• Add a high comorbidity interaction for Circulatory 1 and Skin 4.

• Add a high comorbidity interaction between Neurological 11 and Skin 4.

• Add a high comorbidity interaction between Skin 1, abscess and Skin 4.

Response: We appreciate the commenter's review of these codes and suggested reassignments and may consider these changes in future rulemaking. As we stated in the CY 2020 final rule with comment period (84 FR 60510), and as described in the technical report ''Overview of the Home Health Groupings Model,'' the home health-specific comorbidity list is based on the principles of patient assessment by body systems and their associated diseases, conditions, and injuries. We used this process to develop categories of conditions that identify clinically relevant relationships associated with increased resource use. We understand the magnitude of clinical conditions and comorbidities, and the interactions that exist between them, in the Medicare home health population; however, we remind commenters that only those subgroups of diagnoses that represent more than 0.1 percent of periods of care and that have at least as high as the median resource use will receive a low comorbidity adjustment. We describe this method for determining statistical significance in the CY 2020 final rule with comment period (84 FR 60510). This is based on the knowledge that the average number of comorbidities in the aggregate becomes the standard within that population for the purpose of payment. However, because we still expect HHAs to report all secondary diagnoses that affect care planning, there will be comorbidity subgroups included in the home health-specific list that do not meet the criteria to receive an adjustment.

Final Decision: We are finalizing the proposal to update the comorbidity adjustment subgroups and the high comorbidity adjustment interactions using CY 2022 home health data. For CY 2024, the final update to the comorbidity adjustment subgroups includes 22 low comorbidity adjustment subgroups as identified in Table B9 and 102 high comorbidity adjustment interaction subgroups as identified in Table B10. The final CY 2024 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments will also be posted on the HHA Center web page at *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

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TABLE B9: FINAL LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2024

Low Comorbidity Subgroup	Description
Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
Circulatory 2	Hemolytic, Aplastic, and Other Anemias
Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
Circulatory 9	Other Venous Embolism and Thrombosis
Circulatory 10	Varicose Veins and Lymphedema
Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
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 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
Neurological 4	Alzheimer's disease and related dementias
Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
Neurological 10	Diabetes with neuropathy
Neurological 11	Disease of the Macula and Blindness/Low Vision
Neurological 12	Nondiabetic neuropathy
Respiratory 10	2019 Novel Coronavirus
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 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on the CCW July 15, 2023.

TABLE B10: FINAL HIGH COMORBIDITY ADJUSTMENT INTERACTIONS FOR CY 2024

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 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
3	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
4	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
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	Circulatory 10	Varicose Veins and Lymphedema
8	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
9	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
10	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 2	Hemolytic, Aplastic, and Other Anemias
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	Neurological 10	Diabetes with neuropathy

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
13	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 11	Disease of the Macula and Blindness/Low Vision
14	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Respiratory 2	Whooping cough
15	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Respiratory 9	Respiratory Failure and Atelectasis
16	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
17	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
18	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
19	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
20	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
21	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
22	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
23	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
24	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
25	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
26	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
27	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
28	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
29	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
30	Circulatory 9	Other Venous Embolism and Thrombosis	Neurological 10	Diabetes with neuropathy
31	Circulatory 9	Other Venous Embolism and Thrombosis	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
32	Circulatory 10	Varicose Veins and Lymphedema	Circulatory 2	Hemolytic, Aplastic, and Other Anemias
33	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
34	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance
35	Circulatory 10	Varicose Veins and Lymphedema	Heart 8	Other Pulmonary Heart Diseases
36	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 3	Joint Pain
37	Circulatory 10	Varicose Veins and Lymphedema	Neurological 10	Diabetes with neuropathy
38	Circulatory 10	Varicose Veins and Lymphedema	Renal 1	Chronic kidney disease and ESRD
39	Circulatory 10	Varicose Veins and Lymphedema	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
40	Circulatory 10	Varicose Veins and Lymphedema	Respiratory 9	Respiratory Failure and Atelectasis
41	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
42	Endocrine 1	Hypothyroidism	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
43	Endocrine 1	Hypothyroidism	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
44	Endocrine 1	Hypothyroidism	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
45	Endocrine 1	Hypothyroidism	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
46	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
47	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
48	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
49	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
50	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
51	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
52	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
53	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
54	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
55	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
56	Heart 8	Other Pulmonary Heart Diseases	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
57	Heart 9	Valve Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
58	Heart 9	Valve Disorders	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
59	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
60	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
61	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
62	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
63	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
64	Heart 11	Heart Failure	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
65	Heart 11	Heart Failure	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
66	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
67	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
68	Heart 12	Other Heart Diseases	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
69	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
70	Infectious 1	C-diff, MRSA, E-coli	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
71	Infectious 1	C-diff, MRSA, E-coli	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
72	Infectious 1	C-diff, MRSA, E-coli	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
73	Infectious 1	C-diff, MRSA, E-coli	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
74	Musculoskeletal 2	Rheumatoid Arthritis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
75	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
76	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
77	Neurological 4	Alzheimer's disease and related dementias	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
78	Neurological 4	Alzheimer's disease and related dementias	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 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Renal 1	Chronic kidney disease and ESRD
82	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
83	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
84	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
85	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Neurological 8	Epilepsy
86	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
87	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
88	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
89	Neurological 8	Epilepsy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
90	Neurological 8	Epilepsy	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
91	Neurological 10	Diabetes with neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
92	Neurological 10	Diabetes with neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
93	Neurological 10	Diabetes with neuropathy	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
94	Neurological 11	Disease of the Macula and Blindness/Low Vision	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
95	Neurological 12	Nondiabetic neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
96	Neurological 12	Nondiabetic neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
97	Neurological 12	Nondiabetic neuropathy	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
98	Renal 1	Chronic kidney disease and ESRD	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
99	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
100	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
101	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
102	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 2022 Home Health Claims Data, Periods that end in CY 2022 accessed from the CCW July 15, 2023.

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(d) CY 2024 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 recalibrate annually 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 2024 case-mix weights for the CY 2024 HH PPS proposed rule, we used CY 2022 home health claims data with linked OASIS data (as of March 17, 2023). These data were the most current and complete data available at the time of rulemaking. We stated that we believe that recalibrating the case-mix weights using data from CY 2022 would be reflective of PDGM utilization and patient resource use for CY 2024 and indicated that the proposed recalibrated case-mix weights would be updated based on more complete CY 2022 claims data for the final rule.

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

Step 1: Estimate a regression model to assign a functional impairment level to each 30-day period. The regression model estimates the relationship between a 30-day period's resource use and the functional status and risk of hospitalization items included in the PDGM, which are obtained from certain OASIS items. We refer readers to Table B7 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 2021 home health cost reports. We use 2021 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 B11 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

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TABLE B11: 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	$140.15	1.0%	0.0919
MMTA - Other - High Functional	$290.02	1.2%	0.1902
MMTA - Surgical Aftercare - Low Functional	-$69.33	1.3%	-0.0455
MMTA - Surgical Aftercare - Medium Functional	$124.31	0.9%	0.0815
MMTA - Surgical Aftercare - High Functional	$316.63	1.1%	0.2076
MMTA - Cardiac and Circulatory - Low Functional	-$23.56	7.2%	-0.0154
MMTA - Cardiac and Circulatory - Medium Functional	$130.16	5.3%	0.0853
MMTA - Cardiac and Circulatory - High Functional	$292.03	5.7%	0.1915
MMTA - Endocrine - Low Functional	$412.90	2.3%	0.2707
MMTA - Endocrine - Medium Functional	$428.07	2.3%	0.2807
MMTA - Endocrine - High Functional	$593.65	2.2%	0.3892
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$79.91	1.7%	-0.0524
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$122.84	1.7%	0.0805
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$260.23	1.5%	0.1706
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$35.20	1.6%	-0.0231
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$109.23	1.4%	0.0716
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$302.83	1.5%	0.1986
MMTA - Respiratory - Low Functional	-$37.80	2.6%	-0.0248
MMTA - Respiratory - Medium Functional	$127.24	2.6%	0.0834
MMTA - Respiratory - High Functional	$295.77	2.7%	0.1939
Behavioral Health - Low Functional	-$62.67	0.8%	-0.0411
Behavioral Health - Medium Functional	$97.32	0.5%	0.0638
Behavioral Health - High Functional	$228.75	0.7%	0.1500
Complex - Low Functional	-$89.83	1.0%	-0.0589
Complex - Medium Functional	$111.26	0.9%	0.0730
Complex - High Functional	$72.42	0.9%	0.0475
MS Rehab - Low Functional	$71.01	7.4%	0.0466
MS Rehab - Medium Functional	$185.37	6.2%	0.1215
MS Rehab - High Functional	$395.82	7.0%	0.2595
Neuro - Low Functional	$211.76	4.0%	0.1388
Neuro - Medium Functional	$381.97	3.5%	0.2504
Neuro - High Functional	$584.77	3.6%	0.3834
Wound - Low Functional	$495.35	4.6%	0.3248
Wound - Medium Functional	$655.27	4.9%	0.4296
Wound - High Functional	$853.01	4.6%	0.5593
Admission Source with Timing (Community Early is excluded)			
Community – Late	-$550.17	63.4%	-0.3607
Institutional – Early	$327.81	19.0%	0.2149
Institutional – Late	$192.72	6.0%	0.1264
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$85.67	54.1%	0.0562
Comorbidity Adjustment - Has at least one interaction from interaction list	$327.85	14.7%	0.2150
Constant	$1,438.07		0.9429
Average Resource Use	1525.158		
Number of 30-day Periods	7,909,806		
Adjusted R-Squared	0.3284		

Source: CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on the CCW July 15, 2023.

The final case-mix weights for CY 2024 are listed in Table B12 and will also be posted on the HHA Center web page [12] upon display of this final rule.

TABLE B12: 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 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1FC11	Behavioral Health – High	Early – Community	0	1.0929	4
1FC21	Behavioral Health – High	Early – Community	1	1.1490	4
1FC31	Behavioral Health – High	Early – Community	2	1.3078	4
2FC11	Behavioral Health – High	Early – Institutional	0	1.3078	3
2FC21	Behavioral Health – High	Early – Institutional	1	1.3640	4
2FC31	Behavioral Health – High	Early – Institutional	2	1.5228	4
3FC11	Behavioral Health – High	Late – Community	0	0.7321	2
3FC21	Behavioral Health – High	Late – Community	1	0.7883	2
3FC31	Behavioral Health – High	Late – Community	2	0.9471	2
4FC11	Behavioral Health – High	Late – Institutional	0	1.2192	3
4FC21	Behavioral Health – High	Late – Institutional	1	1.2754	3
4FC31	Behavioral Health – High	Late – Institutional	2	1.4342	3
1FA11	Behavioral Health – Low	Early – Community	0	0.9018	3
1FA21	Behavioral Health – Low	Early – Community	1	0.9580	3
1FA31	Behavioral Health – Low	Early – Community	2	1.1168	3
2FA11	Behavioral Health – Low	Early – Institutional	0	1.1167	3
2FA21	Behavioral Health – Low	Early – Institutional	1	1.1729	3
2FA31	Behavioral Health – Low	Early – Institutional	2	1.3317	2
3FA11	Behavioral Health – Low	Late – Community	0	0.5411	2
3FA21	Behavioral Health – Low	Late – Community	1	0.5972	2
3FA31	Behavioral Health – Low	Late – Community	2	0.7560	2
4FA11	Behavioral Health – Low	Late – Institutional	0	1.0282	3
4FA21	Behavioral Health – Low	Late – Institutional	1	1.0843	3
4FA31	Behavioral Health – Low	Late – Institutional	2	1.2431	2
1FB11	Behavioral Health – Medium	Early – Community	0	1.0067	4
1FB21	Behavioral Health – Medium	Early – Community	1	1.0629	4
1FB31	Behavioral Health – Medium	Early – Community	2	1.2217	4
2FB11	Behavioral Health – Medium	Early – Institutional	0	1.2216	4
2FB21	Behavioral Health – Medium	Early – Institutional	1	1.2778	4
2FB31	Behavioral Health – Medium	Early – Institutional	2	1.4366	4
3FB11	Behavioral Health – Medium	Late – Community	0	0.6460	2
3FB21	Behavioral Health – Medium	Late – Community	1	0.7021	2
3FB31	Behavioral Health – Medium	Late – Community	2	0.8609	2
4FB11	Behavioral Health – Medium	Late – Institutional	0	1.1331	3
4FB21	Behavioral Health – Medium	Late – Institutional	1	1.1892	3

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

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4FB31	Behavioral Health – Medium	Late – Institutional	2	1.3480	3
1DC11	Complex – High	Early – Community	0	0.9904	2
1DC21	Complex – High	Early – Community	1	1.0465	2
1DC31	Complex – High	Early – Community	2	1.2053	2
2DC11	Complex – High	Early – Institutional	0	1.2053	4
2DC21	Complex – High	Early – Institutional	1	1.2615	3
2DC31	Complex – High	Early – Institutional	2	1.4203	4
3DC11	Complex – High	Late – Community	0	0.6296	2
3DC21	Complex – High	Late – Community	1	0.6858	2
3DC31	Complex – High	Late – Community	2	0.8446	2
4DC11	Complex – High	Late – Institutional	0	1.1167	3
4DC21	Complex – High	Late – Institutional	1	1.1729	3
4DC31	Complex – High	Late – Institutional	2	1.3317	2
1DA11	Complex – Low	Early – Community	0	0.8840	2
1DA21	Complex – Low	Early – Community	1	0.9402	2
1DA31	Complex – Low	Early – Community	2	1.0990	2
2DA11	Complex – Low	Early – Institutional	0	1.0989	3
2DA21	Complex – Low	Early – Institutional	1	1.1551	3
2DA31	Complex – Low	Early – Institutional	2	1.3139	3
3DA11	Complex – Low	Late – Community	0	0.5233	2
3DA21	Complex – Low	Late – Community	1	0.5794	2
3DA31	Complex – Low	Late – Community	2	0.7382	2
4DA11	Complex – Low	Late – Institutional	0	1.0104	3
4DA21	Complex – Low	Late – Institutional	1	1.0665	2
4DA31	Complex – Low	Late – Institutional	2	1.2253	3
1DB11	Complex – Medium	Early – Community	0	1.0158	2
1DB21	Complex – Medium	Early – Community	1	1.0720	2
1DB31	Complex – Medium	Early – Community	2	1.2308	2
2DB11	Complex – Medium	Early – Institutional	0	1.2308	4
2DB21	Complex – Medium	Early – Institutional	1	1.2869	4
2DB31	Complex – Medium	Early – Institutional	2	1.4457	4
3DB11	Complex – Medium	Late – Community	0	0.6551	2
3DB21	Complex – Medium	Late – Community	1	0.7113	2
3DB31	Complex – Medium	Late – Community	2	0.8701	2
4DB11	Complex – Medium	Late – Institutional	0	1.1422	3
4DB21	Complex – Medium	Late – Institutional	1	1.1984	3
4DB31	Complex – Medium	Late – Institutional	2	1.3572	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1HC11	MMTA – Cardiac – High	Early – Community	0	1.1344	4
1HC21	MMTA – Cardiac – High	Early – Community	1	1.1905	4
1HC31	MMTA – Cardiac – High	Early – Community	2	1.3493	4
2HC11	MMTA – Cardiac – High	Early – Institutional	0	1.3493	4
2HC21	MMTA – Cardiac – High	Early – Institutional	1	1.4055	4
2HC31	MMTA – Cardiac – High	Early – Institutional	2	1.5643	4
3HC11	MMTA – Cardiac – High	Late – Community	0	0.7736	2
3HC21	MMTA – Cardiac – High	Late – Community	1	0.8298	2
3HC31	MMTA – Cardiac – High	Late – Community	2	0.9886	3
4HC11	MMTA – Cardiac – High	Late – Institutional	0	1.2607	4
4HC21	MMTA – Cardiac – High	Late – Institutional	1	1.3169	3
4HC31	MMTA – Cardiac – High	Late – Institutional	2	1.4757	4
1HA11	MMTA – Cardiac – Low	Early – Community	0	0.9274	4
1HA21	MMTA – Cardiac – Low	Early – Community	1	0.9836	4
1HA31	MMTA – Cardiac – Low	Early – Community	2	1.1424	3
2HA11	MMTA – Cardiac – Low	Early – Institutional	0	1.1424	4
2HA21	MMTA – Cardiac – Low	Early – Institutional	1	1.1986	4
2HA31	MMTA – Cardiac – Low	Early – Institutional	2	1.3573	4
3HA11	MMTA – Cardiac – Low	Late – Community	0	0.5667	2
3HA21	MMTA – Cardiac – Low	Late – Community	1	0.6229	2
3HA31	MMTA – Cardiac – Low	Late – Community	2	0.7817	2
4HA11	MMTA – Cardiac – Low	Late – Institutional	0	1.0538	3
4HA21	MMTA – Cardiac – Low	Late – Institutional	1	1.1100	3
4HA31	MMTA – Cardiac – Low	Late – Institutional	2	1.2688	3
1HB11	MMTA – Cardiac – Medium	Early – Community	0	1.0282	4
1HB21	MMTA – Cardiac – Medium	Early – Community	1	1.0844	4
1HB31	MMTA – Cardiac – Medium	Early – Community	2	1.2432	4
2HB11	MMTA – Cardiac – Medium	Early – Institutional	0	1.2432	4
2HB21	MMTA – Cardiac – Medium	Early – Institutional	1	1.2993	4
2HB31	MMTA – Cardiac – Medium	Early – Institutional	2	1.4581	5
3HB11	MMTA – Cardiac – Medium	Late – Community	0	0.6675	2
3HB21	MMTA – Cardiac – Medium	Late – Community	1	0.7237	2
3HB31	MMTA – Cardiac – Medium	Late – Community	2	0.8825	3
4HB11	MMTA – Cardiac – Medium	Late – Institutional	0	1.1546	3
4HB21	MMTA – Cardiac – Medium	Late – Institutional	1	1.2108	3
4HB31	MMTA – Cardiac – Medium	Late – Institutional	2	1.3696	4
1IC11	MMTA – Endocrine – High	Early – Community	0	1.3321	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1IC21	MMTA – Endocrine – High	Early – Community	1	1.3883	4
1IC31	MMTA – Endocrine – High	Early – Community	2	1.5471	4
2IC11	MMTA – Endocrine – High	Early – Institutional	0	1.5471	4
2IC21	MMTA – Endocrine – High	Early – Institutional	1	1.6032	4
2IC31	MMTA – Endocrine – High	Early – Institutional	2	1.7620	4
3IC11	MMTA – Endocrine – High	Late – Community	0	0.9714	3
3IC21	MMTA – Endocrine – High	Late – Community	1	1.0276	3
3IC31	MMTA – Endocrine – High	Late – Community	2	1.1864	3
4IC11	MMTA – Endocrine – High	Late – Institutional	0	1.4585	4
4IC21	MMTA – Endocrine – High	Late – Institutional	1	1.5147	4
4IC31	MMTA – Endocrine – High	Late – Institutional	2	1.6735	4
1IA11	MMTA – Endocrine – Low	Early – Community	0	1.2136	4
1IA21	MMTA – Endocrine – Low	Early – Community	1	1.2698	4
1IA31	MMTA – Endocrine – Low	Early – Community	2	1.4286	4
2IA11	MMTA – Endocrine – Low	Early – Institutional	0	1.4286	3
2IA21	MMTA – Endocrine – Low	Early – Institutional	1	1.4847	4
2IA31	MMTA – Endocrine – Low	Early – Institutional	2	1.6435	4
3IA11	MMTA – Endocrine – Low	Late – Community	0	0.8529	3
3IA21	MMTA – Endocrine – Low	Late – Community	1	0.9091	3
3IA31	MMTA – Endocrine – Low	Late – Community	2	1.0678	3
4IA11	MMTA – Endocrine – Low	Late – Institutional	0	1.3400	3
4IA21	MMTA – Endocrine – Low	Late – Institutional	1	1.3962	3
4IA31	MMTA – Endocrine – Low	Late – Institutional	2	1.5549	4
1IB11	MMTA – Endocrine – Medium	Early – Community	0	1.2236	4
1IB21	MMTA – Endocrine – Medium	Early – Community	1	1.2797	4
1IB31	MMTA – Endocrine – Medium	Early – Community	2	1.4385	4
2IB11	MMTA – Endocrine – Medium	Early – Institutional	0	1.4385	4
2IB21	MMTA – Endocrine – Medium	Early – Institutional	1	1.4947	4
2IB31	MMTA – Endocrine – Medium	Early – Institutional	2	1.6535	4
3IB11	MMTA – Endocrine – Medium	Late – Community	0	0.8628	3
3IB21	MMTA – Endocrine – Medium	Late – Community	1	0.9190	3
3IB31	MMTA – Endocrine – Medium	Late – Community	2	1.0778	3
4IB11	MMTA – Endocrine – Medium	Late – Institutional	0	1.3499	4
4IB21	MMTA – Endocrine – Medium	Late – Institutional	1	1.4061	4
4IB31	MMTA – Endocrine – Medium	Late – Institutional	2	1.5649	4
1JC11	MMTA – GI/GU – High	Early – Community	0	1.1135	3
1JC21	MMTA – GI/GU – High	Early – Community	1	1.1697	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1JC31	MMTA – GI/GU – High	Early – Community	2	1.3285	2
2JC11	MMTA – GI/GU – High	Early – Institutional	0	1.3285	4
2JC21	MMTA – GI/GU – High	Early – Institutional	1	1.3846	3
2JC31	MMTA – GI/GU – High	Early – Institutional	2	1.5434	3
3JC11	MMTA – GI/GU – High	Late – Community	0	0.7528	2
3JC21	MMTA – GI/GU – High	Late – Community	1	0.8090	2
3JC31	MMTA – GI/GU – High	Late – Community	2	0.9678	2
4JC11	MMTA – GI/GU – High	Late – Institutional	0	1.2399	3
4JC21	MMTA – GI/GU – High	Late – Institutional	1	1.2961	3
4JC31	MMTA – GI/GU – High	Late – Institutional	2	1.4548	3
1JA11	MMTA – GI/GU – Low	Early – Community	0	0.8905	2
1JA21	MMTA – GI/GU – Low	Early – Community	1	0.9467	2
1JA31	MMTA – GI/GU – Low	Early – Community	2	1.1055	2
2JA11	MMTA – GI/GU – Low	Early – Institutional	0	1.1054	3
2JA21	MMTA – GI/GU – Low	Early – Institutional	1	1.1616	3
2JA31	MMTA – GI/GU – Low	Early – Institutional	2	1.3204	3
3JA11	MMTA – GI/GU – Low	Late – Community	0	0.5298	2
3JA21	MMTA – GI/GU – Low	Late – Community	1	0.5859	2
3JA31	MMTA – GI/GU – Low	Late – Community	2	0.7447	2
4JA11	MMTA – GI/GU – Low	Late – Institutional	0	1.0169	3
4JA21	MMTA – GI/GU – Low	Late – Institutional	1	1.0730	3
4JA31	MMTA – GI/GU – Low	Late – Institutional	2	1.2318	3
1JB11	MMTA – GI/GU – Medium	Early – Community	0	1.0234	3
1JB21	MMTA – GI/GU – Medium	Early – Community	1	1.0796	3
1JB31	MMTA – GI/GU – Medium	Early – Community	2	1.2384	3
2JB11	MMTA – GI/GU – Medium	Early – Institutional	0	1.2384	4
2JB21	MMTA – GI/GU – Medium	Early – Institutional	1	1.2945	4
2JB31	MMTA – GI/GU – Medium	Early – Institutional	2	1.4533	4
3JB11	MMTA – GI/GU – Medium	Late – Community	0	0.6627	2
3JB21	MMTA – GI/GU – Medium	Late – Community	1	0.7189	2
3JB31	MMTA – GI/GU – Medium	Late – Community	2	0.8777	2
4JB11	MMTA – GI/GU – Medium	Late – Institutional	0	1.1498	3
4JB21	MMTA – GI/GU – Medium	Late – Institutional	1	1.2060	3
4JB31	MMTA – GI/GU – Medium	Late – Institutional	2	1.3648	3
1KC11	MMTA – Infectious – High	Early – Community	0	1.1415	2
1KC21	MMTA – Infectious – High	Early – Community	1	1.1976	2
1KC31	MMTA – Infectious – High	Early – Community	2	1.3564	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2KC11	MMTA – Infectious – High	Early – Institutional	0	1.3564	3
2KC21	MMTA – Infectious – High	Early – Institutional	1	1.4126	3
2KC31	MMTA – Infectious – High	Early – Institutional	2	1.5713	3
3KC11	MMTA – Infectious – High	Late – Community	0	0.7807	2
3KC21	MMTA – Infectious – High	Late – Community	1	0.8369	2
3KC31	MMTA – Infectious – High	Late – Community	2	0.9957	2
4KC11	MMTA – Infectious – High	Late – Institutional	0	1.2678	3
4KC21	MMTA – Infectious – High	Late – Institutional	1	1.3240	3
4KC31	MMTA – Infectious – High	Late – Institutional	2	1.4828	3
1KA11	MMTA – Infectious – Low	Early – Community	0	0.9198	2
1KA21	MMTA – Infectious – Low	Early – Community	1	0.9760	2
1KA31	MMTA – Infectious – Low	Early – Community	2	1.1348	2
2KA11	MMTA – Infectious – Low	Early – Institutional	0	1.1347	3
2KA21	MMTA – Infectious – Low	Early – Institutional	1	1.1909	3
2KA31	MMTA – Infectious – Low	Early – Institutional	2	1.3497	3
3KA11	MMTA – Infectious – Low	Late – Community	0	0.5591	2
3KA21	MMTA – Infectious – Low	Late – Community	1	0.6153	2
3KA31	MMTA – Infectious – Low	Late – Community	2	0.7740	2
4KA11	MMTA – Infectious – Low	Late – Institutional	0	1.0462	3
4KA21	MMTA – Infectious – Low	Late – Institutional	1	1.1023	3
4KA31	MMTA – Infectious – Low	Late – Institutional	2	1.2611	3
1KB11	MMTA – Infectious – Medium	Early – Community	0	1.0145	3
1KB21	MMTA – Infectious – Medium	Early – Community	1	1.0707	2
1KB31	MMTA – Infectious – Medium	Early – Community	2	1.2295	2
2KB11	MMTA – Infectious – Medium	Early – Institutional	0	1.2294	3
2KB21	MMTA – Infectious – Medium	Early – Institutional	1	1.2856	3
2KB31	MMTA – Infectious – Medium	Early – Institutional	2	1.4444	4
3KB11	MMTA – Infectious – Medium	Late – Community	0	0.6538	2
3KB21	MMTA – Infectious – Medium	Late – Community	1	0.7100	2
3KB31	MMTA – Infectious – Medium	Late – Community	2	0.8687	2
4KB11	MMTA – Infectious – Medium	Late – Institutional	0	1.1409	3
4KB21	MMTA – Infectious – Medium	Late – Institutional	1	1.1970	3
4KB31	MMTA – Infectious – Medium	Late – Institutional	2	1.3558	3
1AC11	MMTA – Other – High	Early – Community	0	1.1331	4
1AC21	MMTA – Other – High	Early – Community	1	1.1892	4
1AC31	MMTA – Other – High	Early – Community	2	1.3480	3
2AC11	MMTA – Other – High	Early – Institutional	0	1.3480	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2AC21	MMTA – Other – High	Early – Institutional	1	1.4042	4
2AC31	MMTA – Other – High	Early – Institutional	2	1.5629	4
3AC11	MMTA – Other – High	Late – Community	0	0.7723	2
3AC21	MMTA – Other – High	Late – Community	1	0.8285	2
3AC31	MMTA – Other – High	Late – Community	2	0.9873	2
4AC11	MMTA – Other – High	Late – Institutional	0	1.2594	3
4AC21	MMTA – Other – High	Late – Institutional	1	1.3156	3
4AC31	MMTA – Other – High	Late – Institutional	2	1.4744	3
1AA11	MMTA – Other – Low	Early – Community	0	0.9429	3
1AA21	MMTA – Other – Low	Early – Community	1	0.9991	3
1AA31	MMTA – Other – Low	Early – Community	2	1.1579	4
2AA11	MMTA – Other – Low	Early – Institutional	0	1.1578	3
2AA21	MMTA – Other – Low	Early – Institutional	1	1.2140	3
2AA31	MMTA – Other – Low	Early – Institutional	2	1.3728	4
3AA11	MMTA – Other – Low	Late – Community	0	0.5822	2
3AA21	MMTA – Other – Low	Late – Community	1	0.6383	2
3AA31	MMTA – Other – Low	Late – Community	2	0.7971	2
4AA11	MMTA – Other – Low	Late – Institutional	0	1.0693	3
4AA21	MMTA – Other – Low	Late – Institutional	1	1.1254	3
4AA31	MMTA – Other – Low	Late – Institutional	2	1.2842	3
1AB11	MMTA – Other – Medium	Early – Community	0	1.0348	4
1AB21	MMTA – Other – Medium	Early – Community	1	1.0910	4
1AB31	MMTA – Other – Medium	Early – Community	2	1.2497	4
2AB11	MMTA – Other – Medium	Early – Institutional	0	1.2497	4
2AB21	MMTA – Other – Medium	Early – Institutional	1	1.3059	4
2AB31	MMTA – Other – Medium	Early – Institutional	2	1.4647	4
3AB11	MMTA – Other – Medium	Late – Community	0	0.6741	2
3AB21	MMTA – Other – Medium	Late – Community	1	0.7302	2
3AB31	MMTA – Other – Medium	Late – Community	2	0.8890	2
4AB11	MMTA – Other – Medium	Late – Institutional	0	1.1612	3
4AB21	MMTA – Other – Medium	Late – Institutional	1	1.2173	3
4AB31	MMTA – Other – Medium	Late – Institutional	2	1.3761	3
1LC11	MMTA – Respiratory – High	Early – Community	0	1.1368	3
1LC21	MMTA – Respiratory – High	Early – Community	1	1.1930	3
1LC31	MMTA – Respiratory – High	Early – Community	2	1.3518	2
2LC11	MMTA – Respiratory – High	Early – Institutional	0	1.3518	4
2LC21	MMTA – Respiratory – High	Early – Institutional	1	1.4079	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2LC31	MMTA – Respiratory – High	Early – Institutional	2	1.5667	4
3LC11	MMTA – Respiratory – High	Late – Community	0	0.7761	2
3LC21	MMTA – Respiratory – High	Late – Community	1	0.8323	2
3LC31	MMTA – Respiratory – High	Late – Community	2	0.9911	2
4LC11	MMTA – Respiratory – High	Late – Institutional	0	1.2632	3
4LC21	MMTA – Respiratory – High	Late – Institutional	1	1.3194	3
4LC31	MMTA – Respiratory – High	Late – Institutional	2	1.4781	3
1LA11	MMTA – Respiratory – Low	Early – Community	0	0.9181	3
1LA21	MMTA – Respiratory – Low	Early – Community	1	0.9743	3
1LA31	MMTA – Respiratory – Low	Early – Community	2	1.1331	3
2LA11	MMTA – Respiratory – Low	Early – Institutional	0	1.1330	3
2LA21	MMTA – Respiratory – Low	Early – Institutional	1	1.1892	3
2LA31	MMTA – Respiratory – Low	Early – Institutional	2	1.3480	4
3LA11	MMTA – Respiratory – Low	Late – Community	0	0.5574	2
3LA21	MMTA – Respiratory – Low	Late – Community	1	0.6135	2
3LA31	MMTA – Respiratory – Low	Late – Community	2	0.7723	2
4LA11	MMTA – Respiratory – Low	Late – Institutional	0	1.0445	3
4LA21	MMTA – Respiratory – Low	Late – Institutional	1	1.1006	3
4LA31	MMTA – Respiratory – Low	Late – Institutional	2	1.2594	3
1LB11	MMTA – Respiratory – Medium	Early – Community	0	1.0263	4
1LB21	MMTA – Respiratory – Medium	Early – Community	1	1.0825	3
1LB31	MMTA – Respiratory – Medium	Early – Community	2	1.2413	3
2LB11	MMTA – Respiratory – Medium	Early – Institutional	0	1.2413	4
2LB21	MMTA – Respiratory – Medium	Early – Institutional	1	1.2974	4
2LB31	MMTA – Respiratory – Medium	Early – Institutional	2	1.4562	4
3LB11	MMTA – Respiratory – Medium	Late – Community	0	0.6656	2
3LB21	MMTA – Respiratory – Medium	Late – Community	1	0.7218	2
3LB31	MMTA – Respiratory – Medium	Late – Community	2	0.8805	2
4LB11	MMTA – Respiratory – Medium	Late – Institutional	0	1.1527	3
4LB21	MMTA – Respiratory – Medium	Late – Institutional	1	1.2089	3
4LB31	MMTA – Respiratory – Medium	Late – Institutional	2	1.3676	4
1GC11	MMTA – Surgical Aftercare – High	Early – Community	0	1.1505	3
1GC21	MMTA – Surgical Aftercare – High	Early – Community	1	1.2067	2
1GC31	MMTA – Surgical Aftercare – High	Early – Community	2	1.3655	3
2GC11	MMTA – Surgical Aftercare – High	Early – Institutional	0	1.3654	4
2GC21	MMTA – Surgical Aftercare – High	Early – Institutional	1	1.4216	4
2GC31	MMTA – Surgical Aftercare – High	Early – Institutional	2	1.5804	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3GC11	MMTA – Surgical Aftercare – High	Late – Community	0	0.7898	2
3GC21	MMTA – Surgical Aftercare – High	Late – Community	1	0.8459	2
3GC31	MMTA – Surgical Aftercare – High	Late – Community	2	1.0047	2
4GC11	MMTA – Surgical Aftercare – High	Late – Institutional	0	1.2769	3
4GC21	MMTA – Surgical Aftercare – High	Late – Institutional	1	1.3330	3
4GC31	MMTA – Surgical Aftercare – High	Late – Institutional	2	1.4918	4
1GA11	MMTA – Surgical Aftercare – Low	Early – Community	0	0.8974	2
1GA21	MMTA – Surgical Aftercare – Low	Early – Community	1	0.9536	2
1GA31	MMTA – Surgical Aftercare – Low	Early – Community	2	1.1124	2
2GA11	MMTA – Surgical Aftercare – Low	Early – Institutional	0	1.1124	3
2GA21	MMTA – Surgical Aftercare – Low	Early – Institutional	1	1.1685	3
2GA31	MMTA – Surgical Aftercare – Low	Early – Institutional	2	1.3273	4
3GA11	MMTA – Surgical Aftercare – Low	Late – Community	0	0.5367	2
3GA21	MMTA – Surgical Aftercare – Low	Late – Community	1	0.5929	2
3GA31	MMTA – Surgical Aftercare – Low	Late – Community	2	0.7517	2
4GA11	MMTA – Surgical Aftercare – Low	Late – Institutional	0	1.0238	3
4GA21	MMTA – Surgical Aftercare – Low	Late – Institutional	1	1.0800	3
4GA31	MMTA – Surgical Aftercare – Low	Late – Institutional	2	1.2388	3
1GB11	MMTA – Surgical Aftercare – Medium	Early – Community	0	1.0244	2
1GB21	MMTA – Surgical Aftercare – Medium	Early – Community	1	1.0806	2
1GB31	MMTA – Surgical Aftercare – Medium	Early – Community	2	1.2394	2
2GB11	MMTA – Surgical Aftercare – Medium	Early – Institutional	0	1.2393	4
2GB21	MMTA – Surgical Aftercare – Medium	Early – Institutional	1	1.2955	4
2GB31	MMTA – Surgical Aftercare – Medium	Early – Institutional	2	1.4543	5
3GB11	MMTA – Surgical Aftercare – Medium	Late – Community	0	0.6637	2
3GB21	MMTA – Surgical Aftercare – Medium	Late – Community	1	0.7198	2
3GB31	MMTA – Surgical Aftercare – Medium	Late – Community	2	0.8786	2
4GB11	MMTA – Surgical Aftercare – Medium	Late – Institutional	0	1.1508	3
4GB21	MMTA – Surgical Aftercare – Medium	Late – Institutional	1	1.2069	3
4GB31	MMTA – Surgical Aftercare – Medium	Late – Institutional	2	1.3657	4
1EC11	MS Rehab – High	Early – Community	0	1.2024	5
1EC21	MS Rehab – High	Early – Community	1	1.2586	4
1EC31	MS Rehab – High	Early – Community	2	1.4174	4
2EC11	MS Rehab – High	Early – Institutional	0	1.4174	5
2EC21	MS Rehab – High	Early – Institutional	1	1.4735	5
2EC31	MS Rehab – High	Early – Institutional	2	1.6323	5
3EC11	MS Rehab – High	Late – Community	0	0.8417	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3EC21	MS Rehab – High	Late – Community	1	0.8979	2
3EC31	MS Rehab – High	Late – Community	2	1.0567	3
4EC11	MS Rehab – High	Late – Institutional	0	1.3288	4
4EC21	MS Rehab – High	Late – Institutional	1	1.3850	4
4EC31	MS Rehab – High	Late – Institutional	2	1.5437	4
1EA11	MS Rehab – Low	Early – Community	0	0.9895	4
1EA21	MS Rehab – Low	Early – Community	1	1.0456	4
1EA31	MS Rehab – Low	Early – Community	2	1.2044	4
2EA11	MS Rehab – Low	Early – Institutional	0	1.2044	5
2EA21	MS Rehab – Low	Early – Institutional	1	1.2606	5
2EA31	MS Rehab – Low	Early – Institutional	2	1.4194	5
3EA11	MS Rehab – Low	Late – Community	0	0.6287	2
3EA21	MS Rehab – Low	Late – Community	1	0.6849	2
3EA31	MS Rehab – Low	Late – Community	2	0.8437	2
4EA11	MS Rehab – Low	Late – Institutional	0	1.1158	4
4EA21	MS Rehab – Low	Late – Institutional	1	1.1720	4
4EA31	MS Rehab – Low	Late – Institutional	2	1.3308	4
1EB11	MS Rehab – Medium	Early – Community	0	1.0644	5
1EB21	MS Rehab – Medium	Early – Community	1	1.1206	4
1EB31	MS Rehab – Medium	Early – Community	2	1.2794	4
2EB11	MS Rehab – Medium	Early – Institutional	0	1.2794	5
2EB21	MS Rehab – Medium	Early – Institutional	1	1.3355	5
2EB31	MS Rehab – Medium	Early – Institutional	2	1.4943	5
3EB11	MS Rehab – Medium	Late – Community	0	0.7037	2
3EB21	MS Rehab – Medium	Late – Community	1	0.7599	2
3EB31	MS Rehab – Medium	Late – Community	2	0.9187	2
4EB11	MS Rehab – Medium	Late – Institutional	0	1.1908	4
4EB21	MS Rehab – Medium	Late – Institutional	1	1.2470	4
4EB31	MS Rehab – Medium	Late – Institutional	2	1.4058	4
1BC11	Neuro – High	Early – Community	0	1.3263	4
1BC21	Neuro – High	Early – Community	1	1.3825	4
1BC31	Neuro – High	Early – Community	2	1.5413	4
2BC11	Neuro – High	Early – Institutional	0	1.5412	5
2BC21	Neuro – High	Early – Institutional	1	1.5974	5
2BC31	Neuro – High	Early – Institutional	2	1.7562	5
3BC11	Neuro – High	Late – Community	0	0.9656	2
3BC21	Neuro – High	Late – Community	1	1.0217	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3BC31	Neuro – High	Late – Community	2	1.1805	3
4BC11	Neuro – High	Late – Institutional	0	1.4527	4
4BC21	Neuro – High	Late – Institutional	1	1.5088	4
4BC31	Neuro – High	Late – Institutional	2	1.6676	4
1BA11	Neuro – Low	Early – Community	0	1.0817	4
1BA21	Neuro – Low	Early – Community	1	1.1379	4
1BA31	Neuro – Low	Early – Community	2	1.2967	4
2BA11	Neuro – Low	Early – Institutional	0	1.2967	4
2BA21	Neuro – Low	Early – Institutional	1	1.3528	4
2BA31	Neuro – Low	Early – Institutional	2	1.5116	5
3BA11	Neuro – Low	Late – Community	0	0.7210	2
3BA21	Neuro – Low	Late – Community	1	0.7772	2
3BA31	Neuro – Low	Late – Community	2	0.9360	2
4BA11	Neuro – Low	Late – Institutional	0	1.2081	3
4BA21	Neuro – Low	Late – Institutional	1	1.2643	4
4BA31	Neuro – Low	Late – Institutional	2	1.4231	4
1BB11	Neuro – Medium	Early – Community	0	1.1933	4
1BB21	Neuro – Medium	Early – Community	1	1.2495	4
1BB31	Neuro – Medium	Early – Community	2	1.4083	4
2BB11	Neuro – Medium	Early – Institutional	0	1.4083	5
2BB21	Neuro – Medium	Early – Institutional	1	1.4644	5
2BB31	Neuro – Medium	Early – Institutional	2	1.6232	5
3BB11	Neuro – Medium	Late – Community	0	0.8326	2
3BB21	Neuro – Medium	Late – Community	1	0.8888	2
3BB31	Neuro – Medium	Late – Community	2	1.0476	2
4BB11	Neuro – Medium	Late – Institutional	0	1.3197	4
4BB21	Neuro – Medium	Late – Institutional	1	1.3759	4
4BB31	Neuro – Medium	Late – Institutional	2	1.5347	4
1CC11	Wound – High	Early – Community	0	1.5022	4
1CC21	Wound – High	Early – Community	1	1.5584	4
1CC31	Wound – High	Early – Community	2	1.7171	4
2CC11	Wound – High	Early – Institutional	0	1.7171	5
2CC21	Wound – High	Early – Institutional	1	1.7733	4
2CC31	Wound – High	Early – Institutional	2	1.9321	4
3CC11	Wound – High	Late – Community	0	1.1415	3
3CC21	Wound – High	Late – Community	1	1.1976	3
3CC31	Wound – High	Late – Community	2	1.3564	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2024	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4CC11	Wound – High	Late – Institutional	0	1.6286	4
4CC21	Wound – High	Late – Institutional	1	1.6847	4
4CC31	Wound – High	Late – Institutional	2	1.8435	4
1CA11	Wound – Low	Early – Community	0	1.2677	4
1CA21	Wound – Low	Early – Community	1	1.3239	4
1CA31	Wound – Low	Early – Community	2	1.4826	4
2CA11	Wound – Low	Early – Institutional	0	1.4826	4
2CA21	Wound – Low	Early – Institutional	1	1.5388	4
2CA31	Wound – Low	Early – Institutional	2	1.6976	4
3CA11	Wound – Low	Late – Community	0	0.9070	2
3CA21	Wound – Low	Late – Community	1	0.9631	3
3CA31	Wound – Low	Late – Community	2	1.1219	3
4CA11	Wound – Low	Late – Institutional	0	1.3940	3
4CA21	Wound – Low	Late – Institutional	1	1.4502	4
4CA31	Wound – Low	Late – Institutional	2	1.6090	4
1CB11	Wound – Medium	Early – Community	0	1.3725	4
1CB21	Wound – Medium	Early – Community	1	1.4287	4
1CB31	Wound – Medium	Early – Community	2	1.5875	4
2CB11	Wound – Medium	Early – Institutional	0	1.5875	4
2CB21	Wound – Medium	Early – Institutional	1	1.6436	5
2CB31	Wound – Medium	Early – Institutional	2	1.8024	4
3CB11	Wound – Medium	Late – Community	0	1.0118	3
3CB21	Wound – Medium	Late – Community	1	1.0680	3
3CB31	Wound – Medium	Late – Community	2	1.2268	3
4CB11	Wound – Medium	Late – Institutional	0	1.4989	4
4CB21	Wound – Medium	Late – Institutional	1	1.5551	4
4CB31	Wound – Medium	Late – Institutional	2	1.7139	4

Source: CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on the CCW July 15, 2023.

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Changes to the PDGM case-mix weights are implemented in a budget neutral manner by multiplying the CY 2024 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 2024, we will continue the practice of using the most recent complete home health claims

data at the time of rulemaking, which is CY 2022 data (as of July 15, 2023). The case-mix budget neutrality factor is calculated as the ratio of 30-day base payment rates such that total payments when the CY 2024 PDGM case-mix weights (developed using CY 2022 home health claims data) are applied to CY 2022 utilization (claims) data are equal to total payments when CY 2023 PDGM case-mix weights (developed using CY 2021 home health claims data) are applied to CY 2022 utilization data. This produces a case-mix budget neutrality factor for CY 2024 of 1.0124.

We invited comments on the proposed CY 2024 case-mix weights, case-mix weight budget neutrality factor and these are summarized as follows.

Comment: A commenter expressed support for the annual recalibration of the case-mix weights using CY 2022 utilization data.

Response: We thank the commenter for their support.

Comment: Several commenters opposed recalibrating the PDGM case-mix weights for CY 2024. Some commenters expressed concern with the frequency of recalibration stating that annual updates create instability for home health agencies. Other commenters stated that CMS should delay recalibrating the case-mix weights until the impact of previous recalibrations on access and care has been reviewed. A commenter suggested that an independent analysis should be conducted to verify the reliability of the regression model used to set case-mix weights during a period of budget neutrality measurement. Lastly, a commenter requested transparency as to why and how CMS makes changes to the PDGM case-mix weights.

Response: We recognize that commenters have had concerns regarding annual recalibration since we finalized this policy previously; however, we continue to believe that annual recalibration of the PDGM case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use, changes in utilization patterns, and reflects the types of patients currently receiving home health services. We believe that prolonging recalibration, rather than recalibrating annually, could lead to more significant variation in the case-mix weights than what is observed using the most recent utilization data. Therefore, we believe that utilizing CY 2022 data to recalibrate the CY 2024 case-mix weights is appropriate and do not agree that an independent analysis is necessary. Regarding the comment requesting transparency, we direct commenters to review the CY 2019 HH PPS final rule with comment period (83 FR 56502) for the finalized case-mix adjustment methodology, as well as the previously discussed steps we take to determine the case-mix weight for each of the 432 different PDGM payment groups which are outlined in this final rule.

Comment: A few commenters requested that CMS analyze the cumulative impact of the proposed recalibration of the PDGM case-mix weights, as well as the updates to the wage index prior to finalizing any changes.

Response: 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 so that changes to the case-mix weights, functional impairment levels, comorbidity adjustments, as well as updated wage data do not impact payments in the aggregate.

Comment: A commenter had general concerns regarding the diagnosis codes included in the clinical grouping case-mix variable. This commenter stated that there continues to be no assignment of many diagnoses that drive home health need, citing non-specific diagnosis codes such as debility and weakness. The commenter stated that while there may be no specific medical diagnoses causing these conditions, the patient would still greatly benefit from home health care. The commenter recommended that CMS allow codes such as R29.6 Repeated falls, R54 Age related physical debility, R26.89 Abnormalities of gait, M62.81 Muscle weakness, and generalized R41.82 Altered Mental Status for home health services.

Response: As we stated in the CY 2019 HH PPS final rule with comment period (83 FR 56473), we believe that the majority of the R-codes (codes that describe signs and symptoms, as opposed to diagnoses) are not appropriate as principal diagnosis codes for grouping home health periods into clinical groups. We believe that the use of symptoms, signs, and abnormal clinical and laboratory findings would make it difficult to meet the requirements of an individualized plan of care as required at 42 CFR 484.60. Likewise, we believe that clinically it is important for home health providers to have a clear understanding of the patients' diagnoses in order to safely and effectively furnish home health services. Interventions and treatment aimed at mitigating signs and symptoms of a condition may vary depending on the cause. Anecdotally, we have heard that a home health referral may be nonspecific or that a physician or allowed practitioner may be in the process of determining a more definitive diagnosis. However, with respect to patient safety and quality of care, we believe it is important for a clinician to investigate the cause of the signs and/or symptoms for which the referral was made. This may involve calling the referring physician or allowed practitioner to gather more information. We note that HHAs are required under the home health CoPs at § 484.60 to participate in care coordination to assure the identification of patient needs and factors that could affect patient safety and treatment efficacy. ICD–10–CM coding guidelines are clear that R-codes are to be used when no more specific diagnosis can be made even after all the facts bearing on the case have been investigated. Therefore, while these codes should not be used as a principal diagnosis for the provision of home health services, they can be reported as secondary diagnoses to provide a more complete clinical picture of the patient. By the time the patient is referred to home health and meets the qualifications of eligibility, we would expect that a more definitive code would substantiate the need for services.

Final Decision: We are finalizing the proposal to recalibrate the HH PPS case-mix weights for CY 2024. The proposed recalibrated case-mix weights were updated based on more complete CY 2022 claims data (as of July 15, 2023) for this final rule. 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 2024 national, standardized 30-day period payment rate. As stated previously, the final case-mix budget neutrality factor for CY 2024 will be 1.0124.

3. Rebase and Revise the Home Health Market Basket and Revise the Labor-Related Share

(a) Background

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2024 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. Effective for cost reporting periods beginning on or after July 1, 1980, we developed and adopted an HHA input price index (that is, the home health ''market basket''). Although ''market basket'' technically describes

the mix of goods and services used to produce home health care, this term is also commonly used to denote the input price index derived from that market basket. Accordingly, the term ''home health market basket'' used in this document refers to the HHA input price index.

The percentage change in the home health market basket reflects the average change in the price of goods and services purchased by HHAs in providing an efficient level of home health care services. We first used the home health market basket to adjust HHA cost limits by an amount that reflected the average increase in the prices of the goods and services used to furnish reasonable cost home health care. This approach linked the increase in the cost limits to the efficient utilization of resources. For a greater discussion on the home health market basket, see the notice with comment period published in the February 15, 1980 **Federal Register** (45 FR 10450, 10451), the notice with comment period published in the February 14, 1995 **Federal Register** (60 FR 8389, 8392), and the notice with comment period published in the July 1, 1996 **Federal Register** (61 FR 34344, 34347). Beginning with the FY 2002 HH PPS payments, we have used the growth in a home health market basket to update payments under the HH PPS.

We have rebased and revised the home health market basket periodically through the years since FY 2002. We rebased the home health market basket effective with the FY 2005 update (69 FR 31251–31255), with the CY 2008 update (72 FR 25435–25442), and with the CY 2013 update (77 FR 67081). We last rebased and revised the home health market basket effective with the CY 2019 update (83 FR 56425 through 56435) reflecting a 2016 base year. Beginning with CY 2024, we proposed to rebase and revise the home health market basket to reflect a 2021 base year. In the following discussion, we provide an overview of the proposed home health market basket and describe the methodologies used to determine the 2021-based home health market basket.

The home health market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to the base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (for the proposed home health market basket, we proposed to use 2021 as the base period) and total base period costs are estimated for a set of mutually exclusive and exhaustive cost categories. Each category is calculated as a proportion of total costs. These proportions are called cost weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the cost weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted previously, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide HHA services. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, an HHA hiring more nurses after the base period to accommodate the needs of patients would increase the volume of goods and services purchased by the HHA but would not be factored into the price change measured by a fixed-weight home health market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the home health market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that HHAs purchase to furnish inpatient care between base periods.

(b) Rebasing and Revising of the Home Health Market Basket

We believe that it is technically appropriate to rebase the home health market basket periodically so that the cost category weights reflect changes in the mix of goods and services that HHAs purchase in furnishing home health care. For the CY 2024 HH PPS proposed rule, we proposed to rebase and revise the home health market basket to reflect a 2021 base year using 2021 Medicare cost report data for Medicare-participating freestanding HHAs, the latest available and most complete data on the actual structure of HHA costs at the time of this rulemaking. In prior rulemaking, commenters have expressed concern that recent cost pressures and the impact of the COVID–19 PHE have impacted input price inflation in providing home health services. We proposed to use 2021 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available for developing the home health market basket that captures recent cost trends. Given the potential impact of the COVID–19 PHE on the Medicare cost report data, we will continue to monitor these data going forward and any changes to the home health market basket will be proposed in future rulemaking.

The terms ''rebasing'' and ''revising,'' while often used interchangeably, denote different activities. The term ''rebasing'' means moving the base year for the structure of costs of an input price index (that is, in this exercise, we proposed to move the base year cost structure from 2016 to 2021) without making any other major changes to the methodology. The term ''revising'' means changing data sources, cost categories, and price proxies used in the input price index. For the CY 2024 HH PPS proposed rule, we proposed to rebase and revise the home health market basket to reflect a 2021 base year.

(c) Derivation of the 2021-Based Home Health Market Basket Major Cost Weights

We proposed to derive the major cost weights for the revised and rebased home health market basket from the Medicare cost reports (CMS Form 1728–20, OMB No. 0938–0022) for freestanding HHAs whose cost reporting period began on or after October 1, 2020 and before October 1, 2021. Of the 2021 Medicare cost reports for freestanding HHAs, approximately 84 percent of the reports had a begin date on January 1, 2021, approximately 5 percent had a begin date on July 1, 2021, and approximately 3 percent had a begin date on October 1, 2020. The remaining 8 percent had a begin date within the specified range. Using this methodology allowed our sample to include HHAs with varying cost report years including, but not limited to, the Federal fiscal or calendar year.

We proposed to maintain our policy of using data from freestanding HHAs,

which account for about 93 percent of HHAs (87 FR 66882), as our analysis has determined that they better reflect HHAs' actual cost structure. Cost data for hospital-based HHAs can be affected by the allocation of overhead costs over the entire institution.

We proposed to derive seven major cost categories (Wages and Salaries, Benefits, Transportation, Professional Liability Insurance (PLI), Fixed Capital, Movable Capital, and Medical Supplies) from the 2021 HHA Medicare cost reports. The residual cost category, ''All Other'', reflects all remaining costs not captured in the seven major cost categories. Each of the major cost categories and the residual are based on those cost centers that are reimbursable under the HH PPS, specifically cost centers 16 through 25 (Skilled Nursing Care—RN, Skilled Nursing Care—LPN, Physical Therapy, Physical Therapy Assistant, Occupational Therapy, Certified Occupational Therapy Assistant, Speech-Language Pathology, Medical Social Services, Home Health Aide, and Medical Supplies Charged to Patients). While the cost centers have changed in CMS Form 1728–20, these generally coincide with those cost centers from CMS Form 1728–94 that were used to derive the 2016-based home health market basket (83 FR 56425). The cost centers used from CMS Form 1728–94 were cost centers 6 through 12 (Skilled Nursing Care, Physical Therapy, Occupational Therapy, Speech Pathology, Medical Social Services, Home Health Aide, and Supplies). Total costs for the HH PPS reimbursable services reflect overhead allocation. We note that Medical Supplies was not considered to be a major cost category in the 2016-based home health market basket because it was not derived directly from Medicare cost report data and was instead derived from the residual ''All Other'' category using Benchmark Input-Output (I–O) data published by the Bureau of Economic Analysis (BEA). Next, we provide details on the proposed calculations for the total Medicare allowable costs and each of the seven major cost categories derived from the Medicare cost report data. Unless otherwise specified, calculations are consistent with 2016 methodology.

(1) Total Medicare Allowable Costs

We proposed that total Medicare allowable costs for HHAs would be equal to the sum of total costs for the Medicare allowable cost centers as reported on Worksheet B, column 10, lines 16 through 25. We proposed that these total Medicare allowable costs for the HHA will be the denominator for the cost weight calculations for the Wages and Salaries, Benefits, Transportation, Professional Liability Insurance, Fixed Capital, Movable Capital, and Medical Supplies cost weights. With this work complete, we then set about deriving cost levels for the seven major cost categories.

(2) Costs for the Seven Major Cost Categories Derived From the Medicare Cost Report Data

(a) Wages and Salaries

We proposed that wages and salaries costs reflect direct patient care wage and salary costs, overhead wage and salary costs (associated with the following overhead cost centers: Plant Operations and Maintenance, Transportation, Telecommunications Technology, Administrative and General, Nursing Administration, Medical Records, and Other General Service cost centers), and a portion of direct patient care contract labor costs. The estimation of the wage and salary costs is derived using a similar methodology to that which was implemented for the 2016-based home health market basket, with the primary difference being the specific cost report line items now available on the HHA cost report form.

(i) Direct Patient Care

We proposed to calculate direct patient care wages and salaries by summing costs from Worksheet A, column 1, lines 16 through 25.

(ii) Overhead

We proposed to calculate overhead wages and salaries by summing costs from Worksheet B, columns 3 through 9, lines 16 through 25 multiplied by the percentage of costs in the overhead cost centers that were reported as salaries. This ratio is calculated as the sum of costs on Worksheet A, column 1, lines 3 through 9, divided by the sum of costs on Worksheet A, columns 1 through 5, lines 3 through 9.

(iii) Wages and Salaries Portion of Direct Patient Care Contract Labor

Contract labor costs allocated to wages and salaries costs reflect a portion of the direct patient care contract labor costs. Specifically, we proposed to calculate direct patient care contract labor costs by first summing costs from Worksheet A, column 4, lines 16 through 25. These contract labor costs are then multiplied by each provider's ratio of direct patient care wages and salaries costs to total direct patient care wages and salaries and benefits costs. This ratio is calculated as the sum of costs on Worksheet A, column 1, lines 16 through 25, divided by the sum of costs on Worksheet A, columns 1 and 2, lines 16 through 25. Similarly, the 2016 method for deriving the wages and salaries costs multiplied the combined salaries and benefits (both Direct Patient Care (DPC) and non-DPC) and DPC contract labor, by the ratio of combined DPC and non-DPC salaries to total DPC and non-DPC salaries and benefits.

(b) Benefits

Benefits costs reflect direct patient care benefit costs, overhead benefit costs (associated with the following overhead cost centers: Plant Operations and Maintenance, Transportation, Telecommunications Technology, Administrative and General, Nursing Administration, Medical Records, and Other General Service) and a portion of direct patient care contract labor costs. Similarly, the 2016 method for deriving the benefits costs multiplied the combined salaries and benefits (both DPC and non-DPC) and DPC contract labor, by the ratio of combined DPC and non-DPC benefits to total DPC and non-DPC salaries and benefits.

(i) Direct Patient Care

We proposed to calculate the cost of the direct patient care benefit costs by summing costs from Worksheet A, column 2, lines 16 through 25.

(ii) Overhead

We proposed to calculate overhead benefit costs by summing costs from Worksheet B, columns 3 through 9, lines 16 through 25 multiplied by the percentage of costs in the overhead cost centers that were reported as benefits. This percentage is calculated as the sum of costs on Worksheet A, column 2, lines 3 through 9, divided by the sum of costs on Worksheet A, columns 1 through 5, lines 3 through 9.

(iii) Benefits Portion of Direct Patient Care Contract Labor

Contract labor costs allocated to Benefits costs reflect a portion of the direct patient care contract labor costs. Specifically, we proposed to first calculate direct patient care contract labor costs by summing costs from Worksheet A, column 4, lines 16 through 25. These contract labor costs are then multiplied by each provider's ratio of direct patient care benefits costs to total direct patient care wages and salaries and benefits costs. This ratio is calculated as the sum of costs on Worksheet A, column 2, lines 16 through 25, divided by the sum of costs on Worksheet A, columns 1 and 2, lines 16 through 25.

(c) Transportation

Transportation costs reflect direct patient care costs as well as transportation costs associated with Capital Expenses, Plant Operations and Maintenance, and Administrative and General cost centers. Specifically, we proposed to calculate transportation costs by summing costs from Worksheet A, column 3, lines 16 through 25; Worksheet A, column 3, lines 1 through 3; and costs on Worksheet B, column 4, lines 16 through 25 multiplied by a ratio that reflects the non-salary and benefits portion of these costs. Specifically, this ratio was calculated as 1 minus the sum of costs on Worksheet A, columns 1 and 2, line 4, divided by the sum of costs on Worksheet A, columns 1 through 5, line 4.

(d) Professional Liability Insurance

Professional Liability Insurance reflects premiums, paid losses, and self-insurance costs. Specifically, we proposed to calculate Professional Liability Insurance by summing costs from Worksheet S–2 Part I, line 14, columns 1 through 3.

(e) Fixed Capital

Fixed Capital-related costs reflect the portion of Medicare-allowable costs reported in Capital Related Buildings and Fixtures (Worksheet A, column 5, line 1). We proposed to calculate this Medicare allowable portion by first calculating a ratio for each provider that reflects fixed capital costs as a percentage of HHA reimbursable services. Specifically, this ratio was calculated as the sum of costs from Worksheet B, column 1, lines 16 through 25 divided by the sum of costs from Worksheet B, column 1, line 1 minus lines 3 through 9. This percentage is then applied to the costs from Worksheet A, column 5, line 1.

(f) Movable Capital

Movable Capital-related costs reflect the portion of Medicare allowable costs reported in Capital Related Movable Equipment (Worksheet A, column 5, line 2). We proposed to calculate this Medicare allowable portion by first calculating a ratio for each provider that reflects movable capital costs as a percentage of HHA reimbursable services. Specifically, this ratio was calculated as the sum of costs from Worksheet B, column 2, lines 16 through 25 divided by the sum of costs from Worksheet B, column 2, line 2 minus lines 3 through 9. This percentage is then applied to the costs from Worksheet A, column 5, line 2.

(g) Medical Supplies

Medical Supplies costs reflect the cost of supplies furnished to individual patients and for which a separate charge is made, as well as minor medical and surgical supplies not expected to be specifically identified in the plan of treatment or for which a separate charge is not made. Specifically, we proposed to calculate Medical Supplies as the sum of Worksheet A, column 5, line 25; and Worksheet B, column 6, line 25 multiplied by a ratio that reflects the non-salary and benefits portion of these costs. Specifically, this ratio was calculated as 1 minus the sum of costs on Worksheet A, columns 1 and 2, line 6, divided by the sum of costs on Worksheet A, columns 1 through 5, line 6. We note that in the 2016-based home health market basket, the Medical Supplies cost weight was derived from the ''All Other'' residual cost weight.

(3) Derivation of the Major Cost Weights

After we derive costs for each of the seven major cost categories and total Medicare allowable costs for each provider using the Medicare cost report data, we proposed to address data outliers using the following steps. First, for each of the seven major cost categories, we divide the costs in that category by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of HHA providers. We proposed to trim the data to remove outliers (a standard statistical process) by: (1) requiring that major costs (such as wages and salaries costs) and total Medicare allowable costs be greater than zero and requiring that category costs are less than the total Medicare allowable costs; and (2) excluding the top and bottom five percent of the major cost weight (for example, wages and salaries costs as a percent of total Medicare allowable costs). We note that missing values are assumed to be zero consistent with the methodology for how missing values were treated in the 2016-based home health market basket. After these outliers have been excluded, we sum the costs for each category across all remaining providers. We then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the 2021-based home health market basket for the given category.

Finally, we proposed to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the other categories listed by subtracting the major cost weight percentages (Wages and Salaries, Benefits, Transportation, Professional Liability Insurance, Fixed Capital, Movable Capital, and Medical Supplies) from 1. We note that non-direct patient care contract labor costs (such as contract labor costs reported in the Administrative and General cost center of the Medicare cost report) are captured in the ''All Other'' residual cost weight and later disaggregated into more detail as described later in this section.

Table B13 shows the major cost categories and their respective cost weights as derived from the Medicare cost reports.

TABLE B13 – MAJOR COST WEIGHTS AS DERIVED FROM THE MEDICARE COST REPORTS

Major Cost Categories	2021-based	2016-based
Wages and Salaries	64.2	65.1
Benefits	10.7	10.9
Transportation	2.3	2.6
Professional Liability Insurance	0.4	0.3
Fixed Capital	1.3	1.4
Movable Capital	0.5	0.6
Medical Supplies	2.0	n/a[1]
"All Other" residual	18.6	19.0

Note: Figures may not sum to 100.0 due to rounding

[1] In the 2016-based home health market basket, the Medical Supplies cost category is part of the "All Other" residual cost weight.

The decrease in the wages and salaries cost weight of 0.9 percentage point and the decrease in the benefits cost weight of 0.2 percentage point is primarily attributable to direct patient care contract labor costs as reported on the Medicare cost report data, as shown in Table B14. Our analysis of the Medicare cost report data shows that a decrease in the compensation cost weight from 2016 to 2021 occurred, in aggregate, among for-profit, nonprofit, and government providers and among providers serving only rural beneficiaries, only urban beneficiaries, or both rural and urban beneficiaries.

TABLE B14 – COST WEIGHTS FOR DIRECT PATIENT CARE CONTRACT LABOR AND WAGES AND SALARIES AND EMPLOYEE BENEFITS THAT EXCLUDE DIRECT PATIENT CARE CONTRACT LABOR

Major Cost Categories	2021-Based Home Health Market Basket	2016-Based Home Health Market Basket
Wages and Salaries, excluding Direct Patient Care Contract Labor	58.3	58.1
Employee Benefits, excluding Directing Patient Care Contract Labor	9.8	9.8
Direct Patient Care Contract Labor	6.8	8.1

Additionally, the Medicare cost report data shows that decreased contract labor utilization has occurred over most occupational categories, including higher-paid specialties, and that utilization of direct patient care contract labor has been trending downward since 2010. We also note that over the 2016 to 2021 time period, the average number of full-time equivalents per provider decreased considerably.

(4) Derivation of the Detailed Cost Weights

We proposed to divide the ''All Other'' residual cost weight estimated from the 2021 Medicare cost report data into more detailed cost categories. To divide this cost weight, we proposed to use the 2012 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for North American Industrial Classification System (NAICS) 621600, Home Health Agencies, published by the BEA. These data are publicly available at *http://www.bea.gov/industry/io_annual.htm.* For the 2016-based home health market basket, we used the 2007 Benchmark I–O data, the most recent data available at the time (83 FR 56427).

The BEA Benchmark I–O data are generally scheduled for publication every five years with the most recent data available for 2012. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[13] Besides Benchmark I–O estimates, BEA also produces Annual I–O estimates. While based on a similar methodology, the Annual I–O estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we proposed to inflate the detailed 2012 Benchmark I–O data forward to 2021 by applying the annual price changes for each year from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. Then, we calculated the cost shares that each cost category represents of the 2012 I–O data inflated to 2021. These resulting 2021 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the 2021-based home health market basket. For example, the cost for Utilities represents 11.0 percent of the sum of the ''All Other'' 2012 Benchmark I–O HHA costs inflated to 2021. Therefore, the Utilities cost weight represents 11.0 percent of the 2021-based home health market basket's ''All Other'' cost category (18.6 percent), yielding a Utilities cost weight

[13] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

of 2.0 percent in the 2021-based home health market basket (0.110 × 18.6 percent = 2.0 percent). For the 2016-based home health market basket, we used the same methodology while basing it on the 2007 Benchmark I–O data (aged to 2016).

Using this methodology, we proposed to derive eight detailed cost categories from the 2021-based home health market basket ''All Other'' residual cost weight (18.6 percent). These categories are: (1) Utilities; (2) Administrative Support; (3) Financial Services; (4) Rubber and Plastics; (5) Telephone; (6) Professional Fees; (7) Other Products; and (8) Other Services. We note that the Utilities cost category is currently referred to as Operations & Maintenance in the 2016-based home health market basket; however, the methodology and data sources underlying this cost category remain the same.

Table B15 compares the cost categories and weights for the 2021-based home health market basket compared to the 2016-based home health market basket. In cases where a cost category has been recategorized in the 2021-based home health market basket, we have entered ''n/a'' to maintain correct totals as they appear in the CY 2019 HH PPS final rule with comment period (83 FR 56428).

TABLE B15: 2021-BASED HOME HEALTH MARKET BASKET COST WEIGHTS COMPARED TO 2016-BASED HOME HEALTH MARKET BASKET COST WEIGHTS

Cost Categories	2021-based	2016-based
Compensation	74.9	76.1
Wages and Salaries	64.2	65.1
Benefits	10.7	10.9
Medical Supplies	2.0	n/a
Operations & Maintenance	n/a	1.5
Professional Liability Insurance	0.4	0.3
Transportation	2.3	2.6
All Other[1]	18.6	17.4
Administrative Support	1.2	1.0
Financial Services	1.1	1.9
Medical Supplies[2]	n/a	0.9
Rubber & Plastics	2.0	1.6
Telephone	0.6	0.7
Professional Fees	5.9	5.3
Utilities[3]	2.0	n/a
Other Products	2.9	2.8
Other Services	2.9	3.2
Capital-Related	1.9	2.1
Fixed Capital	1.3	1.4
Movable Capital	0.5	0.6
Total	**100.0**	**100.0**

Note: Figures may not sum due to rounding.
1. The 2016-based home health market basket refers to this cost category as Administrative & General.
2. The 2016-based home health market basket estimated these costs as a component of Administrative & General.
3. The 2016-based home health market basket refers to this cost category as Operations & Maintenance.

(d) Selection of Price Proxies

After developing the cost weights for the 2021-based home health market basket, we select the most appropriate wage and price proxies currently available to represent the rate of price change for each cost category. With the exception of the price index for Professional Liability Insurance costs, the proposed price proxies are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs

are based on the Standard Occupational Classification System (SOC).

- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.
- *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

The following is a detailed explanation of the price proxies we proposed for each cost category weight.

(e) 2021-Based Home Health Market Basket Price Proxies

As part of the revising and rebasing of the home health market basket, we proposed to rebase and revise the home health blended Wages and Salaries index and the home health blended Benefits index. We proposed to use these blended indexes as price proxies for the Wages and Salaries and the Benefits categories of the 2021-based home health market basket, as we did in the 2016-based home health market basket. The following is a more detailed discussion.

(1) Wages and Salaries

For measuring price growth in the 2021-based home health market basket, we proposed to apply six price proxies to six occupational subcategories within the Wages and Salaries cost weight, which would reflect the 2021 occupational mix in HHAs. This is a similar approach that was used for the 2016-based market basket. We proposed to use a blended wage proxy because there is not a published wage proxy specific to the home health industry.

We proposed to continue to use the National Industry-Specific Occupational Employment and Wage estimates for NAICS 621600, Home Health Care Services, published by the BLS Office of Occupational Employment and Wage Statistics (OEWS) as the data source for the cost shares of the home health blended wage and benefits proxy. We note that in the spring of 2021, the Occupational Employment Statistics (OES) program began using the name Occupational Employment and Wage Statistics (OEWS) to better reflect the range of data available from the program. Data released on or after March 31, 2021 reflect the new program name. This is the same data source that was used for the 2016-based HHA blended wage and benefit proxies; however, we proposed to use the May 2021 estimates in place of the May 2016 estimates. Detailed information on the methodology for the national industry-specific occupational employment and wage estimates survey can be found at *http://www.bls.gov/oes/current/oes_tec.htm.*

The six occupational subcategories (Health-Related Professional and Technical, Non- Health-Related Professional and Technical, Management, Administrative, Health and Social Assistance Service, and Other Service Occupations) for the Wages and Salaries cost weight were tabulated from the May 2021 OEWS data for NAICS 621600, Home Health Care Services. Table B16 compares the 2021 occupational assignments to the 2016 occupational assignments of the six CMS designated subcategories. Data that are unavailable in the OEWS occupational classification for 2016 or 2021 are shown in Table B16 as ''n/a.''

TABLE B16: 2021 OCCUPATIONAL ASSIGNMENTS COMPARED TO 2016 OCCUPATIONAL ASSIGNMENTS FOR CMS HOME HEALTH WAGES AND SALARIES PROXY BLEND

2021 Occupational Groupings		2016 Occupational Groupings	
Group 1	**Health-Related Professional and Technical**	**Group 1**	**Health-Related Professional and Technical**
29-1021	Dentists, General	n/a	n/a
29-1031	Dietitians and Nutritionists	29-1031	Dietitians and Nutritionists
29-1051	Pharmacists	29-1051	Pharmacists
n/a	n/a	29-1062	Family and General Practitioners
n/a	n/a	29-1063	Internists, General
n/a	n/a	29-1065	Pediatricians, General
n/a	n/a	29-1066	Psychiatrists
n/a	n/a	29-1069	Physicians and Surgeons, All Other
29-1071	Physician Assistants	29-1071	Physician Assistants
29-1122	Occupational Therapists	29-1122	Occupational Therapists
29-1123	Physical Therapists	29-1123	Physical Therapists
29-1125	Recreational Therapists	29-1125	Recreational Therapists
29-1126	Respiratory Therapists	29-1126	Respiratory Therapists
29-1127	Speech-Language Pathologists	29-1127	Speech-Language Pathologists
29-1129	Therapists, All Other	29-1129	Therapists, All Other
29-1141	Registered Nurses	29-1141	Registered Nurses
29-1171	Nurse Practitioners	29-1171	Nurse Practitioners
n/a	n/a	29-1199	Health Diagnosing and Treating Practitioners, All Other
29-1215	Family Medicine Physicians	n/a	n/a
29-1216	General Internal Medicine Physicians	n/a	n/a
29-1229	Physicians, All Other	n/a	n/a
29-1292	Dental Hygienists	n/a	n/a
29-1299	Healthcare Diagnosing or Treating Practitioners, All Other	n/a	n/a
Group 2	**Non Health Related Professional and Technical**	**Group 2**	**Non Health Related Professional and Technical**
13-0000	Business and Financial Operations Occupations	13-0000	Business and Financial Operations Occupations
15-0000	Computer and Mathematical Occupations	15-0000	Computer and Mathematical Occupations
19-0000	Life, Physical, and Social Science Occupations	19-0000	Life, Physical, and Social Science Occupations
23-0000	Legal Occupations	n/a	n/a
25-0000	Educational Instruction and Library Occupations	25-0000	Education, Training, and Library Occupations
27-0000	Arts, Design, Entertainment, Sports, and Media Occupations	27-0000	Arts, Design, Entertainment, Sports, and Media Occupations
Group 3	**Management**	**Group 3**	**Management**
11-0000	Management Occupations	11-0000	Management Occupations
Group 4	**Administrative**	**Group 4**	**Administrative**
43-0000	Office and Administrative Support Occupations	43-0000	Office and Administrative Support Occupations
Group 5	**Health and Social Assistance Services**	**Group 5**	**Health and Social Assistance Services**
21-0000	Community and Social Service Occupations	21-0000	Community and Social Service Occupations
29-2010	Clinical Laboratory Technologists and Technicians	n/a	n/a
n/a	n/a	29-2011	Medical and Clinical Laboratory Technologists
n/a	n/a	29-2012	Medical and Clinical Laboratory Technicians
n/a	n/a	29-2021	Dental Hygienists
29-2031	Cardiovascular Technologists and Technicians	n/a	n/a
29-2032	Diagnostic Medical Sonographers	29-2032	Diagnostic Medical Sonographers
29-2034	Radiologic Technologists and Technicians	29-2034	Radiologic Technologists
n/a	n/a	29-2041	Emergency Medical Technicians and Paramedics
29-2051	Dietetic Technicians	29-2051	Dietetic Technicians
29-2052	Pharmacy Technicians	29-2052	Pharmacy Technicians
29-2053	Psychiatric Technicians	29-2053	Psychiatric Technicians
n/a	n/a	29-2054	Respiratory Therapy Technicians
n/a	n/a	29-2055	Surgical Technologists
29-2061	Licensed Practical and Licensed Vocational Nurses	29-2061	Licensed Practical and Licensed Vocational Nurses
n/a	n/a	29-2071	Medical Records and Health Information Technicians
29-2072	Medical Records Specialists	n/a	n/a
29-2099	Health Technologists and Technicians, All Other	29-2099	Health Technologists and Technicians, All Other

We proposed to calculate total costs by occupation by taking the OEWS number of employees multiplied by the OEWS annual average salary for each subcategory, and then calculating the proportion of total wage costs that each subcategory represents of the total industry wage costs. The proportions listed in Table B17 represent the wages and salaries blend weights for 2021, and the ECIs for each occupational category within the Wages and Salaries price proxy blend, as well as the 2016 weights. We note that the current ECI series also reflect the 2021 occupational mix of workers. We also note that 2018 updates to the Standard Occupational Classification (SOC) system included a reclassification of Personal Care Aides from SOC code 39–9021 to 31–1122, which is reflected in the updated weights and represents the major reason for the higher weight for health care and

social assistance services and lower weight for other service occupations.[14]

29-9021	Health Information Technologists and Medical Registrars	n/a	n/a
29-9099	Healthcare Practitioners and Technical Workers, All Other	29-9099	Healthcare Practitioners and Technical Workers, All Other
31-0000	Healthcare Support Occupations	31-0000	Healthcare Support Occupations
Group 6	**Other Service Occupations**	**Group 6**	**Other Service Occupations**
33-0000	Protective Service Occupations	33-0000	Protective Service Occupations
35-0000	Food Preparation and Serving Related Occupations	35-0000	Food Preparation and Serving Related Occupations
37-0000	Building and Grounds Cleaning and Maintenance Occupations	37-0000	Building and Grounds Cleaning and Maintenance Occupations
39-0000	Personal Care and Service Occupations	39-0000	Personal Care and Service Occupations
41-0000	Sales and Related Occupations	41-0000	Sales and Related Occupations
n/a	n/a	47-0000	Construction and Extraction Occupations
49-0000	Installation, Maintenance, and Repair Occupations	49-0000	Installation, Maintenance, and Repair Occupations
51-0000	Production Occupations	51-0000	Production Occupations
53-0000	Transportation and Material Moving Occupations	53-0000	Transportation and Material Moving Occupations

TABLE B17: COMPARISON OF THE 2021-BASED HOME HEALTH WAGES AND SALARIES PROXY BLEND AND THE 2016-BASED HOME HEALTH WAGES AND SALARIES PROXY BLEND

Cost Subcategory	2021 Weight	2016 Weight	Price Proxy	BLS Series ID
Non Health-Related Professional and Technical	2.9	2.3	ECI for Wages and salaries for Private industry workers in Professional, scientific, and technical services	CIU2025400000000I
Health-Related Professional and Technical	29.7	33.7	ECI for Wages and salaries for All Civilian workers in Hospitals	CIU1026220000000I
Management	6.7	7.6	ECI for Wages and salaries for Private industry workers in Management, business, and financial	CIU2020000110000I
Administrative	5.9	6.7	ECI for Wages and salaries for Private industry workers in Office and administrative support	CIU2020000220000I
Health and Social Assistance Services	53.5	35.3	ECI for Wages and salaries for All Civilian workers in Health care and social assistance	CIU1026200000000I
Other Service Occupations	1.4	14.4	ECI for Wages and salaries for Private industry workers in Service occupations	CIU2020000300000I
Total *	**100.0**	**100.0**		

*Totals may not sum due to rounding.

A comparison of the yearly changes from CY 2021 to CY 2024 for the 2016-based home health Wages and Salaries proxy blend and the 2021-based home health Wages and Salaries proxy blend is shown in Table B18. The annual increases in the wages and salaries price proxy is 0.3 percentage point lower in 2021 and 2022 relative to the 2016-based price proxy, and the increases are equal in 2023 and 2024. The differences are primarily driven by the aforementioned reclassification of Personal Care Aides, which caused a shift in the relative share from the Other Service Occupations to Health and Social Assistance Services as illustrated previously in Table B17.

[14] *https://www.bls.gov/soc/2018/soc_2018_whats_new.pdf.*

TABLE B18: ANNUAL CY GROWTH IN 2021-BASED AND 2016-BASED HOME HEALTH WAGES AND SALARIES PROXY BLENDS

	2021	2022	2023	2024
Wage Proxy Blend 2021	3.6	5.6	5.2	3.8
Wage Proxy Blend 2016	3.9	5.9	5.2	3.8

Source: IHS Global Inc. 3rd Quarter 2023 forecast with historical data through 2nd Quarter 2023

(2) Benefits

For measuring Benefits price growth in the 2021-based home health market basket, we proposed to apply applicable price proxies to the six occupational subcategories that are used for the Wages and Salaries price proxy blend. The six categories in Table B19 are the same as those in the 2016-based home health market basket and include the same occupational mix as listed in Table B17.

TABLE B19: COMPARISON OF THE 2021-BASED HOME HEALTH BENEFITS PROXY BLEND AND 2016-BASED HOME HEALTH BENEFITS PROXY BLEND

Cost Category	2021 Weight	2016 Weight	Price Proxy
Non-Health-Related Professional and Technical	2.8	2.3	ECI for Benefits for Private industry workers in Professional, scientific, and technical services
Health-Related Professional and Technical	30.1	33.9	ECI for Benefits for All Civilian workers in Hospitals
Management	6.5	7.3	ECI for Benefits for Private industry workers in Management, business, and financial
Administrative	5.8	6.7	ECI for Benefits for Private industry workers in Office and administrative support
Health and Social Assistance Services	53.5	35.5	ECI for Benefits for All Civilian workers in Health care and social assistance
Other Service Occupations	1.3	14.2	ECI for Benefits for Private industry workers in Service occupations
Total *	**100.0**	**100.0**	

*Totals may not sum due to rounding.

There is no available data source that exists for benefit costs by occupation for the home health industry. Thus, to construct weights for the home health benefits blend we calculated the ratio of benefits to wages and salaries for 2021 for the six ECI series we proposed to use in the blended 'wages and salaries' and 'benefits' indexes. To derive the relevant benefits weight, we applied the benefit-to-wage ratios to the 2021 OEWS wage and salary weights for each of the six occupational subcategories and normalized. For example, the 2021 ECI data shows a ratio of benefits to wages for the health-related professional & technical category of 1.010. We applied this ratio to the 2021 OEWS weight for wages and salaries for health-related professional & technical (29.7 percent) to get an unnormalized weight of 30.0 (29.7 times 1.010), and then normalized those weights relative to the other five benefit occupational categories to obtain a final benefit weight for health-related professional & technical (30.1 percent).

A comparison of the yearly changes from CY 2021 to CY 2024 for the 2016-based home health Benefits proxy blend and the 2021-based home health Benefits proxy blend is shown in Table B20. With the exception of a 0.2 percentage point difference in 2022, the annual increases in the two price proxies are the same when rounded to one decimal place.

TABLE B20: ANNUAL GROWTH IN THE 2021-BASED HOME HEALTH BENEFITS PROXY BLEND AND THE 2016-BASED HOME HEALTH BENEFITS PROXY BLEND

	2021	2022	2023	2024
Benefits Proxy Blend 2021	2.6	4.8	4.1	3.5
Benefits Proxy Blend 2016	2.6	5.0	4.1	3.5

Source: IHS Global Inc. 3rd Quarter 2023 forecast with historical data through 2nd Quarter 2023

(3) Medical Supplies

We proposed to use a 75/25 blend of the PPI Commodity data for Surgical and Medical Instruments (BLS series code #WPU1562) and the PPI Commodity data for Personal Safety Equipment and Clothing (BLS series code #WPU1571), which would replace the current price proxy of the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code #WPU156). The PPI Commodity data for Personal Safety Equipment and Clothing would reflect personal protective equipment (PPE) including but not limited to face shields and protective clothing. The 2012 Benchmark I–O data does not provide specific costs for the two categories we proposed to blend. In absence of such data, we have based the weights of this blend on the change in the medical supplies weight as reported in the Medicare cost reports in the years prior to and after the COVID–19 PHE. Specifically, analysis of Medicare cost report data found that the average weight for medical supplies for the 2016–2019 period (stable around 1.5 percent) was about 75 percent of the weight observed for the 2020–2021 period (roughly 2.0 percent). Thus, we believe that it was likely that the increase in the cost weight was mainly attributable to costs such as those associated with personal safety equipment and clothing, and we based the 75/25 blend on that analysis. We believe this change will more closely proxy the rate of change of the underlying costs, including increased utilization of personal protective equipment.

(4) Professional Liability Insurance

We proposed to use the CMS Physician Professional Liability Insurance price index to measure price growth of this cost category. To generate this index, we collect commercial insurance premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). The same proxy was used for the 2016-based home health market basket.

(5) Transportation

We proposed to use the CPI U.S. city average for Transportation (BLS series code #CUUR0000SAT) to measure price growth of this category. The same proxy was used for the 2016-based home health market basket.

(6) Administrative and Support

We proposed to use the ECI for Total compensation for Private industry workers in Office and administrative support (BLS series code #CIU2010000220000I) to measure price growth of this cost category. The same proxy was used for the 2016-based home health market basket.

(7) Financial Services

We proposed to use the ECI for Total compensation for Private industry workers in financial activities (BLS series code #CIU201520A000000I) to measure price growth of this cost category. The same proxy was used for the 2016-based home health market basket.

(8) Rubber and Plastics

We proposed to use the PPI Commodity data for Rubber and plastic products (BLS series code #WPU07) to measure price growth of this cost category. The same proxy was used for the 2016-based home health market basket.

(9) Telephone

We proposed to use CPI U.S. city average for Telephone services (BLS series code #CUUR0000SEED) to measure price growth of this cost category. The same proxy was used for the 2016-based home health market basket.

(10) Professional Fees

We proposed to use the ECI for Total compensation for Private industry workers in Professional and related (BLS series code #CIS2010000120000I) to measure price growth of this category. The same proxy was used for the 2016-based home health market basket.

(11) Utilities

We proposed to use CPI–U U.S. city average for Fuel and utilities (BLS series code #CUUR0000SAH2) to measure price growth of this cost category. The same proxy was used for the 2016-based home health market basket.

(12) Other Products

We proposed to use the PPI Commodity data for Final Demand-Finished goods less foods and energy (BLS series code #WPUFD4131) to measure price growth of this category. The same proxy was used for the 2016-based home health market basket.

(13) Other Services

We proposed to use the ECI for Total compensation for Private industry workers in Service occupations (BLS series code #CIU2010000300000I) to measure price growth of this category. The same proxy was used for the 2016-based home health market basket.

(14) Fixed Capital

We proposed to use the CPI U.S. city average for Owners' equivalent rent of residences (BLS series code #CUUS0000SEHC) to measure price growth of this cost category. The same proxy was used for the 2016-based home health market basket.

(15) Movable Capital

We proposed to use the PPI Commodity data for Machinery and equipment (BLS series code #WPU11) to measure price growth of this cost category. The same proxy was used for the 2016-based home health market basket.

(f) Summary of Price Proxies of the 2021-Based Home Health Market Basket

Table B21 shows the price proxies for the 2021-based home health market basket.

TABLE B21: PRICE PROXIES FOR THE 2021-BASED HOME HEALTH MARKET BASKET

Cost Description	Price Proxy	Weight
Total		**100.0**
Compensation		**74.9**
Wages and Salaries (W&S)		**64.2**
Non-Health-Related Professional and Technical (P&T) W&S	ECI for Wages and salaries for Private industry workers in Professional, scientific, and technical services	**1.8**
Health-Related Professional and Technical (P&T) W&S	ECI for Wages and salaries for All Civilian workers in Hospitals	**19.1**
Managerial / Supervisory W&S	ECI for Wages and salaries for Private industry workers in Management, business, and financial	**4.3**
Administrative / Clerical W&S	ECI for Wages and salaries for Private industry workers in Office and administrative support	**3.8**
Other Service Occupations W&S	ECI for Wages and salaries for Private Industry workers in Service occupations	**0.9**
Health and Social Assistance Services W&S	ECI for Wages and salaries for All Civilian workers in Health care and social assistance	**34.3**
Benefits		**10.7**
Non-Health-Related Professional and Technical (P&T) Benefits	ECI for Total benefits for Private industry workers in Professional, scientific, and technical services	**0.3**
Health-Related Professional and Technical (P&T) Benefits	ECI for Total benefits for All Civilian workers in Hospitals	**3.2**
Managerial / Supervisory Benefits	ECI for Total benefits for Private industry workers in Management, business, and financial	**0.7**
Administrative / Clerical Benefits	ECI for Total benefits for Private industry workers in Office and administrative support	**0.6**
Other Service Occupations Benefits	ECI for Total benefits for Private industry workers in Service occupations	**0.1**
Health and Social Assistance Services Benefits	ECI for Total Benefits for All Civilian workers in Health care and social assistance	**5.7**
Medical Supplies	75/25 blend: PPI Commodity data for Surgical and Medical Instruments, and PPI Commodity data for Personal Safety Equipment and Clothing	**2.0**
Professional Liability Insurance	CMS Professional Liability Insurance Index, physicians	**0.4**
Transportation	CPI for Transportation	**2.3**
All Other		**18.6**
Administrative Support	ECI for Total compensation for Private industry workers in Office and administrative support	**1.2**
Financial Services	ECI for Total compensation for Private industry workers in Financial activities	**1.1**
Rubber & Plastics	PPI for Rubber and plastic products	**2.0**
Telephone	CPI for Telephone Services	**0.6**
Professional Fees	ECI for Total compensation for Private industry workers in Professional and related	**5.9**
Utilities	CPI for Fuels and Utilities	**2.0**
Other Products	PPI for Finished goods less foods and energy	**2.9**
Other Services	ECI for Total compensation for Private industry workers in Service occupations	**2.9**
Capital Costs		**1.9**
Fixed Capital	CPI for Owners' equivalent rent of residences	**1.3**
Movable Capital	PPI for Machinery and equipment	**0.5**

Note: Totals may not sum to 100.0 percent due to rounding.

We invited public comment on our proposal to rebase and revise the home health market basket to reflect a 2021 base year. The following is a summary of the public comments received and our responses.

Comment: Several commenters supported the rebasing and revising of the home health market basket from a 2016 base year to a 2021 base year. Some commenters, while supporting moving forward with a rebasing, asked CMS to consider rebasing the home health market basket to a later base year, such as 2022 or 2023, when the data become available, to more fully incorporate changes to HHA cost structures. They stated that there is a significant gap between 2021 and what home health providers are experiencing now, and that data from 2021 cost reports neglects to capture the rapid rise in labor costs starting in 2022, and, therefore, using CY 2023 in future rulemaking would better align permanent changes that have occurred in more recent years. A commenter recommended that CMS delay rebasing and revising until this data is further explored, perhaps using a technical expert panel.

Response: We appreciate the commenters' support to rebase and revise the home health market basket. As discussed in section II.C.3 of this final rule, the market basket used to update HH PPS payments has been periodically rebased and revised over the history of the HH PPS to reflect more recent data on HHA cost structures. We proposed to rebase and revise the home health market basket using 2021 Medicare cost reports, the most recent year of complete data available at the time of CY 2024 rulemaking, which showed a decrease in the compensation cost weight between 2016 and 2021. While Medicare cost report data for 2022 and 2023 are incomplete at this time, we note that preliminary 2022 data suggest that a decline in the compensation weight may have continued. Accordingly, we believe it is more appropriate to update the base year cost weights to 2021 to reflect changes since 2016 rather than to delay the rebasing. It has been our longstanding practice to rebase the market basket on a regular basis to ensure it reflects the input cost structure of HHAs. As stated in the CY 2024 HH PPS proposed rule (88 FR 43703), given the potential impact of the COVID–19 PHE on the Medicare cost report data, we will continue to monitor the Medicare cost report data as they become available and, if appropriate, propose any changes to the home health market basket in future rulemaking.

CMS appreciates hearing from stakeholders, through rulemaking or by sending an email to *cmsdnhs@cms.hhs.gov,* about any data or analyses available to achieve the shared goal of ensuring that the home health market basket and its underlying data are technically appropriate. As required by statute, any proposed changes to improve and/or update the home health market basket occur through the rulemaking process and stakeholders have an opportunity to publicly comment and make recommendations regarding the appropriateness of proposed changes.

Comment: A few commenters noted that the rebasing and revising of the home health market basket utilizes Medicare cost report data from freestanding HHAs, and questioned whether providers that are part of health systems are being fairly compensated as a result. A commenter noted that if CMS did include data for hospital-based HHAs, their analysis of Medicare cost report data indicates that the labor-related share would be approximately 76 percent.

Response: CMS has discussed the CY 2019 HH PPS final rule with comment period (83 FR 56425) and explained in the CY 2024 HH PPS proposed rule (88 FR 43704), that we believe data from freestanding HHAs, which account for over 90 percent of HHAs, better reflect HHAs' actual cost structure, as expense data for hospital-based HHAs can be affected by the allocation of overhead costs over the entire institution. This is a result of freestanding HHAs using an HHA-specific cost report while HHAs that are hospital-based use the HHA component of the hospital cost report. Therefore, we believe that the 2021-based home health market basket reflects the most current and accurate mix of goods and services for the majority of home health providers.

Final Decision: After consideration of public comments, we are finalizing the 2021-based home health market basket as proposed without modification.

4. CY 2024 Home Health Payment Rate Updates

(a) CY 2024 Home Health Market Basket Percentage Increase

Based on IHS Global Inc.'s (IGI's) first quarter 2023 forecast, the proposed CY 2024 home health market basket percentage increase was 3.0 percent based on the 2021-based home health market basket. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the market basket percentage increase in the final rule.

Based on IGI's third quarter 2023 forecast with historical data through the second quarter of 2023, the 2021-based home health market basket percentage increase for CY 2024 is 3.3 percent. Table B22 provides a comparison of the yearly percent changes from CY 2019 to CY 2026 for the 2016-based home health market basket and the 2021-based home health market basket based on IGI's third quarter 2023 forecast.

TABLE B22: COMPARISON OF THE 2016-BASED HOME HEALTH MARKET BASKET AND THE 2021-BASED HOME HEALTH MARKET BASKET, PERCENT CHANGE, 2019-2026

	2016-based Home Health Market Basket	2021-based Home Health Market Basket	Difference (2021-based less 2016-based)
Historical data:			
CY 2019	2.6	2.4	-0.2
CY 2020	2.2	2.1	-0.1
CY 2021	4.1	3.9	-0.2
CY 2022	6.3	6.2	-0.1
Average CYs 2019-2022	3.8	3.7	-0.1
Forecast:			
CY 2023	4.6	4.6	0.0
CY 2024	3.4	3.3	-0.1
CY 2025	3.0	3.0	0.0
CY 2026	2.8	2.8	0.0
Average CYs 2023-2026	3.5	3.4	-0.1

Source: IHS Global Inc. 3rd Quarter 2023 forecast with historical data through 2nd Quarter 2023

Table B22 shows that the forecasted percentage increase for CY 2024 of the 2021-based home health market basket is 3.3 percent, or 0.1 percentage point lower than growth estimated using the 2016-based home health market basket. The average historical estimates of the growth in the 2021-based and 2016-based home health market baskets over CY 2019 through CY 2022 differ by an average of 0.1 percentage point. As discussed previously, this is primarily driven by a reclassification of Personal Care Aides, which caused a shift in the relative weight of the Wages and Salaries and Benefits blended price proxies from Other Service Occupations to Health and Social Assistance Services, which over this period grew relatively slower. On average, the two indexes produce similar updates to one another over the forecasted period. We invited public comment on our proposals for the CY 2024 home health market basket update. The following is a summary of the public comments received on the proposed CY 2024 home health market basket update.

Comment: Several commenters supported the proposed payment update for CY 2024 and the use of the latest available data but expressed concern that the CY 2024 payment update does not adequately factor in the effects of many challenges faced by HHAs. These challenges included the impact of the COVID–19 PHE, increased costs of labor due to workforce-shortages, and other increased costs associated with infection control, medical supplies, and transportation. Multiple commenters reported offering bonuses to attract and retain staff, and that it is increasingly difficult to compete with other medical providers in their market, such as hospitals and SNFs. A commenter stated that they believe the home health market basket update should roughly coincide with the CPI and if it does not coincide, CMS should explain why it is different.

A few commenters expressed concern over the accuracy of the forecast underlying the proposed market basket update for CY 2024. They requested that CMS reexamine the forecasting approach or consider other methods and data sources to calculate a final rule market basket update that better reflects the rapidly increasing input prices and costs facing HHAs.

Response: 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) 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) is determined and applied to the mix of goods and services comprising inpatient hospital services for the fiscal year or year. As the law specifies which specific update factors to use, comparisons to general inflation are not relevant to the determination of the home health market basket update.

In the CY 2024 HH PPS proposed rule, we proposed to rebase and revise the current 2016-based home health market basket to reflect a 2021 base year. See section II.C.3 of this final rule for a description of this proposal, the comments received, and the final 2021-based home health market basket. 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 or any shifts between contract and staff nurses. We note that cost changes (that is, the product of price and quantities) would only be reflected when a market basket is rebased and the base year weights are updated to a more recent time period. We believe the increase in the 2021-based home health market basket adequately reflects the average change in the price of goods and services HHAs purchase in order to provide home health services and is technically appropriate to use as the home health payment update factor. As stated previously, we are finalizing a home health market basket that reflects a 2021

base year and, therefore, any change in the cost structure for HHAs that occurred between 2016 and 2021 is now reflected in the cost weights for this rebased market basket.

In response to the commenters' request that we reexamine the current forecasting approach for determining the HH PPS market basket update, IHS Global Inc. is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. We believe that basing the prospective update on these forecasts is an appropriate method, while also acknowledging that these are expectations of expected trends and may differ from actual experience. Thus, we do acknowledge that CY 2022 compensation price growth for the 2016-based home health market basket was higher (5.8 percent) than was forecasted at the time of the CY 2022 HH PPS final rule (3.3 percent). We note that the lower projected CY 2024 home health market basket percent increase relative to the CY 2022 historical increase and the CY 2023 projected increase reflects the expectation that wage, and price pressures will lessen in CY 2024 relative to recent history.

Comment: A commenter stated the proposed market basket update does not reflect the increased cost of giving care and suggested that CMS give home health providers a full market basket adjustment that recognizes the dramatic increases in the cost of care. The commenter referenced a high inflation period prior to the implementation of the PPS and noted that cost limits were updated by higher amounts than what CMS had proposed for the CY 2024 update.

Response: As stated previously, the home health market basket measures price changes (like other CMS market baskets) over time and appropriately would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. In FY 2002, CMS began using the growth in a home health market basket to update payments under the HH PPS as stated in section 1895(b)(4)(B) of the Act, and effective beginning with 2015, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Comment: Several commenters requested that CMS deviate from its usual update and consider making a one-time adjustment to the market basket update or apply a forecast error adjustment to account for underpayments in CY 2021 through CY 2023.

Response: As most recently discussed in the CY 2023 HH PPS final rule (87 FR 66848), the HH PPS market basket updates are set prospectively, which means that the market basket 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 2024 market basket update in this final rule reflects historical data through the second quarter of CY 2023 and forecasted data through the fourth quarter of CY 2024. The forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. In evaluating the difference between the forecasted increase and later acquired actual data for the period from CY 2012 through CY 2020 (excluding CYs 2018 and CY 2020, which were set by statute), we found the forecasted market basket updates for each payment year for HHAs were higher than the actual market basket updates. 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 2024.

Final Decision: In accordance with section 1895(b)(3)(B)(iii) of the Act, we are finalizing our policy to use the most recent data to determine the home health market basket update for CY 2024 in this final rule. The final CY 2024 home health market basket percentage increase is 3.3 percent.

(b) CY 2024 Productivity Adjustment

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 BLS publishes the official measures of productivity for the United States economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as ''private nonfarm business total factor productivity''. We refer readers to *https://www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.* Based on IGI's first quarter 2023 forecast, the proposed productivity adjustment (the 10-year moving average of TFP for the period ending December 31, 2024) for CY 2024 was 0.3 percent. We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the productivity adjustment in the CY 2024 HH PPS final rule. Using IGI's third quarter 2023 forecast, the 10-year moving average growth of TFP for CY 2024 is projected to be 0.3 percent.

The following is a summary of the public comments received on the proposed CY 2024 productivity adjustment:

Comment: Several commenters expressed concern about the continued application of the productivity adjustment to HHAs. They stated that services provided through the home health benefit are hands-on, labor-intensive services and do not lend themselves to the productivity gains realized in other sectors. A commenter noted that CMS has acknowledged that health providers, due to the nature of their service, lack the ability to add efficiencies in the way other sectors do.[15] They asked CMS to use its

[15] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/*

authority to account for the lack of parity in this adjustment when considering its overall payment adjustment to home health providers. A commenter recognized that the productivity adjustment is required by statute and urged CMS to work with Congress to eliminate it permanently. In absence of that elimination, they believe that the home health rate increase should include an additional amount equal to the productivity adjustment to offset it.

Response: Section 1895(b)(3)(B) of the Act requires the market basket percentage under the HHA prospective payment system, as described in section 1895(b)(3)(B) of the Act, be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). We acknowledge the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, we are required pursuant to Section 1895(b)(3)(B) of the Act to apply the specific productivity adjustment described here. In addition, with respect to providing feedback to Congress, we note that MedPAC monitors various factors for Medicare providers in terms of profitability and beneficiary access to care and reports the findings to Congress on an annual basis. MedPAC did a full analysis of payment adequacy for home health care providers in its March 2023 Report to Congress (*https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/*). MedPAC stated that given the positive payment adequacy indicators for HHAs, they recommended that the home health base payment rate be reduced by 7 percent for CY 2024.

Final Decision: We are finalizing the CY 2024 productivity adjustment of 0.3 percent. Therefore, the final CY 2024 home health payment update percentage is 3.0 percent (3.3 percent home health market basket percentage increase, reduced by 0.3 percentage point productivity adjustment). 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, the CY 2024 final home health payment update percentage is 1.0 percent (3.0 percent minus 2 percentage points).

(c) Labor-Related Share

In the CY 2024 HH PPS proposed rule (88 FR 43715), we proposed to update the labor-related share to reflect the 2021-based home health market basket Compensation (Wages and Salaries plus Benefits, which include direct patient care contract labor costs) cost weight. The current labor-related share is based on the Compensation cost weight of the 2016-based home health market basket. Based on the 2021-based home health market basket, the proposed labor-related share was 74.9 percent, and the proposed non-labor-related share was 25.1 percent. The labor-related share for the 2016-based home health market basket was 76.1 percent and the non-labor-related share was 23.9 percent. As explained earlier, the decrease in the compensation cost weight of 1.2 percentage points is primarily attributable to a lower cost weight of direct patient care contract labor costs as reported in the Medicare cost report data. Table B23 details the components of the labor-related share for the 2016-based and 2021-based home health market baskets.

TABLE B23: LABOR-RELATED SHARE OF 2016-BASED AND 2021-BASED HOME HEALTH MARKET BASKETS

Cost Category	2016-Based Market Basket Weight	2021-Based Market Basket Weight
Total Labor-Related	**76.1**	**74.9**
Wages and Salaries	65.1	64.2
Employee Benefits	10.9	10.7
Total Non-Labor-Related	**23.9**	**25.1**

The revised labor-related share will be implemented in a budget neutral manner through the use of labor-related share budget neutrality factor (as described in section II.C.4.e.(2)) so that the aggregate payments do not increase or decrease due to changes in the labor-related share values.

We invited public comments on the proposed labor-related share. The following is a summary of the public comments received and our responses.

Comment: A few commenters opposed the proposal to decrease the labor-related share based on the updated cost weights from the 2021 Medicare cost report data. The commenters state that a drop in the compensation cost weight for HHAs is in direct contradiction to their real-time experience that labor and associated costs continue to increase. A commenter indicated that they believe the decrease in the labor-related share is a direct result of factors related to COVID–19, and they are concerned a shortage of staff may be artificially decreasing the labor-related share based on the 2021 Medicare cost report data. They believe that contract labor utilization by HHAs has normalized and increased relative to the period CMS proposed to use to establish the labor-related share due to increased availability of contract staff.

A commenter stated they are concerned that the 2021 data precedes the time period when much of the dramatic growth in labor costs occurred, or that the result may have been influenced by inaccuracies in the underlying reported costs, including how providers reported contract labor costs (for example, in the Administrative and General cost center, which would not be captured in the compensation costs weight or in direct salaries which would). They suggested that CMS ensure the accuracy of the

ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf.

compensation weight and underlying 2021 cost report data, including ensuring that it is consistent with available 2022 data.

Response: The labor-related share is composed of the Wages & Salaries and Benefits cost weights (which include direct patient care contract labor) from the 2021-based home health market basket. These cost weights were calculated using the 2021 Medicare cost report data (form CMS–1728–20), which is submitted by both rural and urban freestanding home health agencies and was the most comprehensive data source available for determining the CY 2024 labor-related share at the time of rulemaking. We note that the labor-related share has been trending downward since 2010, and preliminary Medicare cost report data from 2022 (which reflects approximately 80 percent of home health agencies) suggest that this trend may continue despite recent increases in utilization of contract labor. We understand that these findings may appear to conflict with the firsthand experiences of many providers who are experiencing increased costs of labor, but the labor-related share is intended to reflect the national average and a decrease in the labor-related share does not suggest that the cost of labor is decreasing, but rather that aggregate labor-related costs have increased at a slower rate than aggregate non-labor-related costs since 2016.

While we will continue to analyze the home health Medicare cost report data on a regular basis to ensure it accurately reflects the costs structures facing home health providers, we believe the proposed 74.9 percent labor-related share reflects the most recent and comprehensive data source available and, therefore, is a technical improvement to the 2016-based labor-related share, which was based on CY 2016 Medicare cost report data.

Final Decision: After consideration of public comments, we are finalizing the labor related share of 74.9 percent and the non-labor- related share of 25.1 percent, as proposed. We did not receive any comments on our proposal to implement the revised labor-related share in a budget neutral manner. Therefore, we are finalizing our proposal to implement the revised labor-related share in a budget neutral manner using a labor-related share budget neutrality factor. The labor-related share budget neutrality factor for CY 2024 is 0.9998.

(d) CY 2024 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 2024, as it is our belief that in the absence of home health-specific wage data accounting for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS.

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, where the estimated reduction in a geographic area's wage index would be capped at 5-percent in CY 2021 only, meaning no cap would be applied to wage index decreases for the second year (CY 2022). Therefore, we finalized the use of the FY 2022 pre-floor, pre-reclassified hospital wage index with no 5-percent cap on decreases as the CY 2022 wage adjustment to the labor portion of the HH PPS rates (86 FR 62285). However, as described in the CY 2023 HH PPS final rule (87 FR 66851 through 66853), for CY 2023 and each subsequent year, we finalized a policy that the CY HH PPS wage index would include a 5-percent cap on wage index decreases. 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 that a geographic area's wage index for CY 2023 would not be less than 95 percent of its final wage index for CY 2022, regardless of whether the geographic area is part of an updated CBSA, and that for subsequent years, a geographic area's wage index would not be less than 95 percent of its wage index calculated in the prior calendar year. For CY 2024, we proposed to base the HH PPS wage index on the FY 2024 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2019 and before October 1, 2020 (FY 2020 cost report data). The proposed CY 2024 HH PPS wage index would not take into account any geographic reclassification of hospitals, including those in accordance with section 1886(d)(8)(B) or 1886(d)(10) of the Act, but would include the 5-percent cap on wage index decreases. We would apply the appropriate wage index value to the revised labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2024 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 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. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity of almost all of Puerto Rico's various urban and non-urban areas to one another, this methodology would produce a wage index for rural Puerto Rico that is higher than half of its urban areas). Instead, we proposed to continue to use the most recent wage index previously available for that area. The most recent wage index previously available for rural Puerto Rico is 0.4047. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. For CY 2024, 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 proxy, the final CY 2024 wage index value for Hinesville, GA will be 0.8622.

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted OMB's area delineations using a 1-year transition.

On August 15, 2017, OMB issued Bulletin No. 17–01 in which it announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area. The new CBSA (46300) comprises the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. The CY 2022 HH PPS wage index value for CBSA 46300, Twin

Falls, Idaho is 0.8707. Bulletin No. 17–01 is available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2017/b-17-01.pdf*.

On April 10, 2018 OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at: *https://www.bls.gov/bls/omb-bulletin-18-04-revised-delineations-of-metropolitan-statistical-areas.pdf.*

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 2018. (For a copy of this bulletin, we refer readers to *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area, one new component of an existing Combined Statistical Area and changes to New England City and Town Area (NECTA) delineations. In the CY 2021 HH PPS final rule (85 FR 70298), we stated that if appropriate, we would propose any updates from OMB Bulletin No. 20–01 in future rulemaking. After reviewing OMB Bulletin No. 20–01, we have determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare home health wage index for CY 2022. Specifically, the updates consisted of changes to NECTA delineations and the re-designation of a single rural county into a newly created Micropolitan Statistical Area. The Medicare home health wage index does not utilize NECTA definitions, and, as most recently discussed in the CY 2021 HH PPS final rule (85 FR 70298) we include hospitals located in Micropolitan Statistical areas in each State's rural wage index. In other words, these OMB updates did not affect any geographic areas for purposes of the HH PPS wage index calculation for CY 2024.

The following is a summary of the comments received on the CY 2024 wage index and our responses:

Comment: A few commenters recommended more far-reaching revisions and reforms to the wage index methodology used under Medicare fee-for-service. Some commenters recommended that CMS create a home health specific wage index. These commenters stated that it is no longer reasonable to believe that the cost of labor is comparable between hospitals and home health agencies, and therefore, the IPPS wage index is no longer a sufficient proxy for the home health wage index. MedPAC recommended that Congress repeal the existing Medicare wage index statutes, including current exceptions, and require the Secretary to phase in new Medicare wage index systems for hospitals and other types of providers that use all-employer, occupation-level wage data with different occupation weights for the wage index of each provider type; reflect local-area-level differences in wages between and within metropolitan statistical areas and statewide rural areas; and smooth wage index differences across adjacent local areas.

Response: We appreciate the commenters' recommendations; however, these comments are outside the scope of the proposed rule. Any changes regarding the adjustment of home health payments to account for geographic wage differences, beyond the wage index proposals discussed in the CY 2024 HH PPS proposed rule, would have to go through notice and comment rulemaking. While CMS and other interested parties, such as MedPAC, have explored potential alternatives to the current home health wage index, no consensus has been achieved regarding a replacement system. Further, it seems some of these recommendations are more appropriate for Congress to consider. Therefore, we believe that in the absence of home health specific wage data, using the pre-floor, pre-reclassified hospital wage data is appropriate and reasonable for home health payments. This position is longstanding and consistent with other Medicare payment systems (for example, SNF PPS, IRF PPS, and Hospice).

Comment: Several commenters recommended that CMS adopt wage index policies for home health that are allowed under other Medicare payment areas such as IPPS and hospice. A few commenters recommended that CMS allow home health providers to utilize geographic reclassification and the rural floor. Another commenter recommended that CMS create a home health specific floor like the hospice floor. Other commenters recommended that CMS adopt, for home health, the low wage index policy finalized in the CY 2020 IPPS final rule. Finally, a commenter requested that CMS calculate non-hospital wage indexes using the post-floor, post-reclassified hospital wage index.

Response: We thank the commenters for their recommendations. However, we do not believe that any of these policies are applicable to the home health wage index. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification. The reclassification provision found in section 1886(d)(10) of the Act is specific to IPPS hospitals only. Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) 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 is the rural floor provision and it is also specific only to IPPS hospitals. Additionally, the low wage index hospital policy increases the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. This policy is specific to IPPS hospitals and does not apply to home health agencies. Finally, 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. Because the reclassification provision, the hospital rural floor, and the hospital low wage policy each apply only to hospitals, and the hospice floor applies only to hospices, 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.

Comment: A commenter suggested that the HH PPS wage index should be based on the hospital wage index adjusted for population density. This commenter believes that in areas with lower population densities such as rural areas, travel costs are increased because of the time and mileage involved for home health personnel to travel between patients to provide services and that the current method of adjusting labor costs does not accurately account for the increased travel costs and lost productivity when serving lower population density areas. Another commenter recommended that CMS implement an out-migration adjustment for non-hospital providers. This commenter stated that due to the nature of their work, home health workers not only travel extensively to visit patients in their homes, but they also tend to live and work across a broad geographic area. The commenter believes this causes disparities between provider types because acute care hospitals have the option to increase their wage index if at least 10% of a county's hospital-employed residents commute to work in higher wage index areas and home health providers do not have this option.

Response: We thank the commenters for their recommendations. However, currently there are no mechanisms in place that would allow population density or out migration adjustments in the home health wage index and we did not propose such changes in the CY 2024 HH PPS proposed rule.

Comment: A few commenters recommended refinements to the 5-percent cap policy on wage index decreases finalized in the CY 2023 HH PPS final rule (87 FR 66853). A commenter recommended that CMS lower the cap threshold to 3 percent. This commenter believes that a 3-percent cap on wage index decreases would protect HHAs who are still experiencing negative consequences due to the COVID–19 pandemic, such as increased costs and loss of staff. Another commenter recommended that in addition to the 5-percent cap on wage index decreases, CMS should implement a 10-percent cap (2x the decrease cap) on the amount any geographic area's wage index can increase from one year to the next.

Response: We thank the commenters for their recommendations; however, we did not propose changes to the 5-percent cap policy in the CY 2024 HH PPS proposed rule. We remind commenters that we stated in the CY 2023 HH PP final rule (87 FR 66852) that we believe that the 5-percent cap on wage index decreases is an adequate safeguard against any significant payment reductions and that the 5-percent threshold effectively mitigates any significant decreases in an HHA's wage index for future calendar years, while still balancing the importance of ensuring that area wage index values accurately reflect relative differences in area wage levels. Additionally, we stated that the purpose of the wage index cap on wage index decreases is to support increased predictability about home health payments for providers, enabling them to more effectively budget and plan their operations. That is, we believe that a provider will be able to more effectively budget and plan when there is awareness regarding expected minimum level of home health payments in the upcoming calendar year. We did not propose to limit wage index increases because we do not believe such a policy would enable HHAs to more effectively budget and plan their operations.

Comment: A commenter questioned whether the 2020 cost report data collected during the first year of the COVID–19 pandemic is accurate and if it adequately reflects current relative labor costs given the unique nature of that period. This commenter suggested that CMS validate the 2020 cost report wage data collected during the COVID–19 pandemic to ensure it does not reflect aberrant trends.

Response: The FY 2020 cost report data was reviewed and audited by the MACs and CMS did not identify any significant issues with the FY 2020 wage data itself in terms of our audits of this data. Therefore, we continue to believe the FY 2020 wage data is the best available wage data to use for FY 2024. A full discussion on this process can be found in section III.C ''Verification of Worksheet S–3 Wage Data'' located in the FY 2024 IPPS final rule (87 FR 58961–58965).

Comment: A few commenters expressed concern that the proposed revised labor-related shares would negatively impact the home health wage index and in turn home health payments. A commenter stated that the proposed wage index changes from CY 2023 to CY 2024, combined with the decrease in the labor-related share, results in substantial payment variances and a greater impact on home health providers than in past years.

Response: As noted in the proposed rule, the decrease in the compensation cost weight of 1.2 percentage points is primarily attributable to a lower cost weight of direct patient care contract labor costs as reported in the Medicare cost report data. The decreased labor-related share is implemented in a budget neutral manner, which is consistent with the policies for implementing the annual recalibration of the case-mix weights and update of the home health wage index in a budget neutral manner.

Final Decision: After considering the comments received in response to the proposed rule, and for the reasons discussed previously, we are finalizing as proposed our proposal to use the FY 2024 pre-floor, pre-reclassified hospital wage index data as the basis for the CY 2024 HH PPS wage index. The final CY 2024 wage index is available on the CMS website at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

(e) CY 2024 Home Health Payment Update

(1) Background

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

As set forth in § 484.220, we adjust the national, standardized prospective payment rates by a case-mix relative weight and a wage index value based on the site of service for the beneficiary. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. In the CY 2019 HH PPS final rule with comment period (83 FR 56435), we finalized rebasing the home health market basket to reflect 2016 Medicare cost report data. We also finalized a revision to the labor-related share to reflect the 2016-based home health market basket Compensation (Wages and Salaries plus Benefits) cost weight. We finalized that for CY 2019 and subsequent years, the labor-related share would be 76.1 percent and the non-labor related share would be 23.9 percent. As discussed in section II.C.3 of this final rule, for CY 2024, we are finalizing the proposal to rebase the home health market basket using 2021 Medicare cost

report data. We are also finalizing that the labor-related share based on the 2021-based home health market basket 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 2024:

- Multiply the national, standardized 30-day period rate by the patient's applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (74.9 percent) and a non-labor portion (25.1 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 30-day period payment amount, subject to any additional applicable adjustments.

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

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

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

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

(2) CY 2024 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 2024 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 2022 claims data for CY 2024 payment rate updates. We apply a permanent behavioral adjustment factor, a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor, a labor-related share budget neutrality factor and the home health payment update percentage to update the CY 2024 payment rate. As discussed in section II.C.1 of this final rule, we finalized a permanent behavior adjustment of −2.890 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 behavior adjustment factor is 0. 97110. 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 2024 national, standardized 30-day period payment rate. The final case-mix weight budget neutrality factor for CY 2024 is 1.0124.

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 2024 wage index, so those total payments are equivalent to the total payments for non-LUPA 30-day periods using the CY 2023 wage index and the CY 2023 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 2024 wage index with a 5-percent cap on wage index decreases by the payment rate for non-LUPA 30-day periods using the CY 2023 wage index with a 5-percent cap on wage index decreases, we obtain a wage index budget neutrality factor of 1.0012. We then apply the wage index budget neutrality factor of 1.0012 to the 30-day period payment rate. After we apply the wage index budget neutrality factor, we also apply a labor-related share budget neutrality factor so that aggregate payments do not increase or decrease due to changes in the labor-related share values. In order to calculate the labor-related share budget neutrality factor, we simulate total payments using CY 2022 home health utilization claims data with the CY 2024 HH PPS wage index and the CY 2024 labor-related share (labor-related share of 74.9 percent and non-labor-related share of 25.1 percent) and compare it to our simulation of total payments using the CY 2024 HH PPS wage index with the CY 2023 labor-related share (labor-related share of 76.1 percent and non-labor-related share of 23.9 percent). By dividing the base payment amount using the finalized labor-related share and CY 2024 wage index and payment rate by the base payment amount using the CY 2023 labor-related share and CY 2024 wage index and payment rate, we obtain a labor-related share budget neutrality factor of 0.9998.

Next, we update the 30-day period payment rate by the final CY 2024 home health payment update percentage of 3.0 percent. The CY 2024 national, standardized 30-day period payment rate is calculated in Table B24.

TABLE B24: CY 2024 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2023 National Standardized 30-Day Period Payment	CY 2024 Permanent BA Adjustment Factor	CY 2024 Case-Mix Weights Recalibration Neutrality Factor	CY 2024 Wage Index Budget Neutrality Factor	CY 2024 Labor-Related Share Neutrality Factor	CY 2024 HH Payment Update	CY 2024 National, Standardized 30-Day Period Payment
$2,010.69	0.97110	1.0124	1.0012	0.9998	1.030	$2,038.13

The CY 2024 national, standardized 30-day period payment rate for an HHA that does not submit the required quality data is updated by the final CY 2024 home health payment update percentage of 1.0 percent (3.0 percent minus 2 percentage points) and is shown in Table B25.

TABLE B25: CY 2024 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAs THAT DO NOT SUBMIT THE QUALITY DATA

CY 2023 National Standardized 30-Day Period Payment	CY 2024 Permanent BA Adjustment Factor	CY 2024 Case-Mix Weights Recalibration Neutrality Factor	CY 2024 Wage Index Budget Neutrality Factor	CY 2024 Labor-Related Share Neutrality Factor	CY 2024 HH Payment Update Minus 2 Percentage Points	CY 2024 National, Standardized 30-Day Period Payment
$2,010.69	0.97110	1.0124	1.0012	0.9998	1.010	$1,998.56

(3) CY 2024 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 2024 national per-visit rates, we started with the CY 2023 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 2024 wage index with a 5-percent cap on wage index decreases and comparing it to simulated total payments for LUPA 30-day periods of care using the CY 2023 wage index with 5-percent cap. By dividing the total payments for LUPA 30-day periods of care using the CY 2024 wage index by the total payments for LUPA 30-day periods of care using the CY 2023 wage index, we obtained a wage index budget neutrality factor of 1.0012. We apply the wage index budget neutrality factor to calculate the CY 2024 national per-visit rates. In order to calculate the labor-related share budget neutrality factor for the national per visit amounts, we simulate total payments for LUPA 30-day periods using CY 2022 home health utilization claims data with the CY 2024 HH PPS wage index and the CY 2024 labor-related share (labor-related share of 74.9 percent and non-labor-related share of 25.1 percent) and compare it to our simulation of total payments for LUPA 30-day periods using the CY 2024 HH PPS wage index with the CY 2023 labor-related share (labor-related share of 76.1 percent and non-labor-related share of 23.9 percent). By dividing the payment amounts for LUPA 30-day periods using the CY 2024 labor-related share and CY 2024 wage index and payment rate by the payment amounts for LUPA 30-day periods using the CY 2023 labor-related share and CY 2024 wage index and payment rate, we obtain a labor-related share budget neutrality factor of 0.9999.

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 2024 home health payment update percentage of 3.0 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2024 national per-visit rates for HHAs that submit the required quality data are updated by the finalized CY 2024 home health payment update percentage of 3.0 percent and are shown in Table B26.

TABLE B26: CY 2024 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2023 Per-Visit Payment Amount	CY 2024 Wage Index Budget Neutrality Factor	CY 2024 Labor-Related Share Neutrality Factor	CY 2024 HH Payment Update	CY 2024 Per-Visit Payment Amount
Home Health Aide	$73.93	1.0012	0.9999	1.030	$76.23
Medical Social Services	$261.72	1.0012	0.9999	1.030	$269.87
Occupational Therapy	$179.70	1.0012	0.9999	1.030	$185.29
Physical Therapy	$178.47	1.0012	0.9999	1.030	$184.03
Skilled Nursing	$163.29	1.0012	0.9999	1.030	$168.37
Speech-Language Pathology	$194.00	1.0012	0.9999	1.030	$200.04

The CY 2024 per-visit payment rates for HHAs that do not submit the required quality data are updated by the CY 2024 home health payment update percentage of 3.0 percent minus 2 percentage points and are shown in Table B27.

TABLE B27: CY 2024 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAs THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2023 Per-Visit Payment Amount	CY 2024 Wage Index Budget Neutrality Factor	CY 2024 Labor-Related Share Neutrality Factor	CY 2024 HH Payment Update Minus 2 Percentage Points	CY 2024 Per-Visit Payment Amount
Home Health Aide	$73.93	1.0012	0.9999	1.010	$74.75
Medical Social Services	$261.72	1.0012	0.9999	1.010	$264.63
Occupational Therapy	$179.70	1.0012	0.9999	1.010	$181.70
Physical Therapy	$178.47	1.0012	0.9999	1.010	$180.45
Skilled Nursing	$163.29	1.0012	0.9999	1.010	$165.10
Speech-Language Pathology	$194.00	1.0012	0.9999	1.010	$196.16

We did not receive any comments on the CY 2024 30-day home health payment rates or the per-visit payment rates.

Final Decision: We are finalizing the updates to the CY 2024 national, standardized 30-day period payment rates and the CY 2024 national per-visit payment amounts as proposed.

(4) LUPA Add-On Factors

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

In the CY 2019 HH PPS final rule with comment period (83 FR 56440), in addition to finalizing a 30-day unit of payment, we finalized our policy of continuing to multiply the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in LUPA periods that occur as the only period of

care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM. For example, using the final CY 2024 per-visit payment rates for HHAs that submit the required quality data, for LUPA periods that occur as the only period or an initial period in a sequence of adjacent periods, if the first skilled visit is SN, the payment for that visit would be $310.66 (1.8451 multiplied by $168.37), subject to area wage adjustment.

(5) Occupational Therapy LUPA Add-On Factor

In order to implement Division CC, section 115, of CAA, 2021, in the CY 2022 HH PPS final rule (86 FR 62289) CMS finalized changes to regulations at § 484.55(a)(2) and (b)(3) that allowed occupational therapists to conduct initial and comprehensive assessments for all Medicare beneficiaries under the home health benefit when the plan of care does not initially include skilled nursing care, but either PT or SLP (86 FR 62351). This change, led to us establishing a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled occupational therapy (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.

As stated in the CY 2022 HH PPS final rule with comment period (86 FR 62289) since 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, we finalized the use of the PT LUPA add-on factor of 1.6700 as a proxy. We also stated that we would use the PT LUPA add-on factor as a proxy until we have CY 2022 data to establish a more accurate OT add-on factor for the LUPA add-on payment amounts (86 FR 62289). At this time, we are analyzing the CY 2022 data and will continue to use the PT LUPA add-on factor for OT LUPAs and plan to propose a LUPA add-on factor specific to OT in future rulemaking.

(6) Payments for High-Cost Outliers Under the HH PPS

(a) 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 partial payment adjustment defined as the 30-day day period payment or partial payment adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the home health FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost that surpasses the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

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

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

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

In the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, the per unit rates used to estimate an episode's cost were updated by the home health update percentage each year, meaning we would start with the national per visit amounts for the same calendar year when calculating the

cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We will continue to monitor the visit length by discipline as more recent data becomes available and may propose to update the rates as needed in the future.

In the CY 2019 HH PPS final rule with comment period (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of PDGM beginning in CY 2020 and calculated payment for high-cost outliers based upon 30-day period of care. Upon implementation of the PDGM and 30-day unit of payment, we finalized the FDL ratio of 0.56 for 30-day periods of care in CY 2020. Given that CY 2020 was the first year of the PDGM and the change to a 30-day unit of payment, we finalized maintaining the same FDL ratio of 0.56 in CY 2021 as we did not have sufficient CY 2020 data at the time of CY 2021 rulemaking to propose a change to the FDL ratio for CY 2021. In the CY 2022 HH PPS final rule with comment period (86 FR 62292), we estimated that outlier payments would be approximately 1.8 percent of total HH PPS final rule payments if we maintained an FDL of 0.56 in CY 2022. Therefore, in order to pay up to, but no more than, 2.5 percent of total payments as outlier payments we finalized an FDL of 0.40 for CY 2022. In the CY 2023 HH PPS final rule (87 FR 66875), using CY 2021 claims utilization data, we finalized an FDL of 0.35 in order to pay up to, but no more than, 2.5 percent of the total payment as outlier payments in CY 2023.

(b) Fixed-Dollar Loss (FDL) Ratio for CY 2024

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 more complete CY 2022 claims data (as of July 15, 2023) and given the statutory requirement that total outlier payments do not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we are finalizing an FDL ratio of 0.27 percent for CY 2024.

5. Disposable Negative Pressure Wound Therapy

(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. Applying continued or intermittent vacuum pressure helps to increase blood flow to the area and draw out excess fluid from the wound. This promotes wound healing by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and removing exudate and infectious material. The wound type and the location of the wound determine whether the vacuum can either be applied continuously or intermittently. NPWT can be utilized for varying lengths of time, as indicated by the severity of the wound, from a few days, up to a span of several months.

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. To be eligible for Medicare home health services, as set out in sections 1814(a) and 1835(a) of the Act, a physician, nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA) (that is, allowed practitioner) must certify that the Medicare beneficiary (patient) meets the following criteria:

- Is confined to the home.
- Needs skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or have a continuing need for occupational therapy.
- Is under the care of a physician or allowed practitioner.
- Receive services under a plan of care established and reviewed by a physician or allowed practitioner.
- Has had a face-to-face encounter related to the primary reason for home health care with a physician or allowed provider type within a required timeframe.

Coverage for dNPWT is determined based upon a physician or allowed practitioner's order as well as patient preference. Treatment decisions as to whether to use a dNPWT system versus a conventional NPWT DME system are determined by the characteristics of the wound, as well as patient goals and preferences discussed with the ordering physician or allowed practitioner to best achieve wound healing.

(2) Current Payment for Negative Pressure Wound Therapy Using a Disposable Device

Prior to CY 2017, a dNPWT system was considered a non-routine supply and thus payment for the disposable device was included in the episode payment amount under the previous home health payment system. However, section 504 of the CAA, 2016 (Pub. L. 114–113) amended both section 1834 of the Act (42 U.S.C. 1395m) and section 1861(m)(5) of the Act (42 U.S.C. 1395x(m)(5)), and required a separate payment for an applicable disposable device when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit. Therefore, in the CY 2017 HH PPS final rule (81 FR 76736), we finalized the implementation of several changes in payment for furnishing dNPWT for a patient under a home health plan of care beginning in CY 2017, and each subsequent year. These payment changes included the implementation of a separate payment amount for dNPWT that was set equal to the amount of the payment that would be made under the Medicare Hospital Outpatient Prospective Payment System (OPPS) using the CPT codes 97607 and 97608. This separate payment amount included furnishing the service as well as the dNPWT device. As a reminder, codes 97607 and 97608 are defined as follows:

- HCPCS 97607—Negative pressure wound therapy, (for example, vacuum assisted drainage collection), utilizing disposable, non-durable medical

equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.

- HCPCS 97608—Negative pressure wound therapy, (for example, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.

We also finalized that for instances where the sole purpose of a home health visit is to furnish dNPWT, Medicare would not consider this a visit for purposes of determining full episode payments, LUPAs or other adjustments, under the HH PPS. Visits performed solely for the purposes of furnishing a new dNPWT device are not reported on the HH PPS claim (TOB 32x). Where a home health visit is exclusively for the purpose of furnishing dNPWT, the HHA submits only a TOB 34x. However, if the home health visit includes the provision of other home health services in addition to, and separate from, furnishing dNPWT, the HHA submits 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. Payment for home health visits related to wound care, but not requiring the furnishing of an entirely new dNPWT device, are covered by the HH PPS 30-day period payment and must be billed using the home health claim.

(3) CAA, 2023

Division FF, section 4136 of the CAA, 2023 (Pub. L. 117–328) amends section 1834 of the Act (42 U.S.C. 1395m) and mandates several amendments to the Medicare separate payment for dNPWT devices beginning in CY 2024. Section 4136(a) of the CAA, 2023 amends 1834(s)(3) of the Act by adding subparagraph (A) which outlines the calculation of the payment amounts for (i) years prior to CY 2024, (ii) CY 2024, (iii) CY 2025; and each subsequent year. As discussed previously, for a year prior to CY 2024, the amount of the separate payment was set equal to the amount of the payment that would be made under the Medicare Hospital OPPS using the CPT codes 97607 and 97608 and included the professional service as well as the furnishing of the device. For CY 2024, the CAA, 2023 requires that the separate payment amount for an applicable dNPWT device would be 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 specified adjustment described in subparagraph (B) for such year. For 2025 and each subsequent year, the CAA, 2023 requires that the separate payment amount will be set equal to the payment amount established for the device in the previous year, updated by the specified adjustment described in subparagraph (B) for such year.

Division FF section 4136 of the CAA, 2023 adds a new subparagraph 1834(s)(3)(B), which requires that the separate payment amount to be adjusted by the percent increase in the CPI–U for the 12-month period ending with June of the preceding year minus the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) for such year. Accordingly, this may result in a percentage being less than 0.0 for a year and may result in payment being less than such payment rates for the preceding year.

Section 1834(s)(3)(C) of the Act, as added by Division FF, section 4136 of the CAA, 2023, specifies that the separate payment amount for applicable devices furnished on or after January 1, 2024, would no longer include payment for nursing or therapy services described in section 1861(m) of the Act. Payment for such nursing or therapy services would now be made under the prospective payment system established under section 1895 of the Act, the HH PPS, and is no longer separately billable.

Division FF, section 4136 of the CAA, 2023 also added a new paragraph 1834(s)(4) of the Act that mandates a change in claims processing for the separate payment amount for an applicable disposable device. Beginning in CY 2024 and each subsequent year, claims for the separate payment amount of an applicable dNPWT device would now be accepted and processed on 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 (TOB 32X). That is, claims with a date of service on or after January 1, 2024 for an applicable dNPWT device will no longer be submitted on TOB 34X.

(4) Payment Policies for dNPWT Devices for CY 2024 and Subsequent Years

For the purposes of paying for a dNPWT device for a patient under a Medicare home health plan of care, CMS proposed that the payment amount for CY 2024 would be equal to the supply price of the applicable disposable device under the Medicare PFS (as of January 1, 2022) updated by the specified adjustment as mandated by the CAA, 2023. The supply price of an applicable disposable device under the Medicare PFS for January 1, 2022 listed in the supporting documentation files for the CY 2022 PFS final rule (86 FR 64966) is $263.25. Therefore, the payment amount for CY 2024 will be set equal to the amount of $263.25 updated by the percent increase in the CPI–U for the 12-month period ending in June of 2023 minus the productivity adjustment. The CPI–U for the 12-month period ending in June of 2023 is 3.0 percent and the corresponding productivity adjustment is 0.4 percent based on IHS Global Inc.'s third-quarter 2023 forecast of the CY 2024 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, 2023).[16] Therefore, the final update percentage will be 2.6 percent.

[16] Note: This productivity adjustment is different from home health as the timeframe for the home health productivity adjustment is calculated using the 10-year moving average of changes in annual economy-wide private nonfarm business TFP for the period ending December 31, 2024.

TABLE B28: CY 2024 DISPOSABLE NEGATIVE PRESSURE WOUND THERAPY (dNPWT)

Supply Price for dNPWT (as of January 1, 2022)	CY2024 dNPWT Payment Update (12 month CPI-U ending in June 2023 (3.0%) minus Productivity Adjustment (0.4%))	CY2024 dNPWT Payment Rate
$263.25	1.026	$270.09

We also proposed that the separate payment for CY 2025 and each subsequent year would be based on the established payment amount for the previous calendar year updated by the percentage increase in the CPI–U minus the productivity adjustment for the 12-month period ending in June of the previous year. The application of 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 under this subsection for an applicable device for a year being less than such separate payment amount for such device for the preceding year.

In accordance with the changes made by the CAA, 2023, we proposed that claims reported for a dNPWT device would no longer be reported on TOB 34X. Instead, for dates of service beginning on or after January 1, 2024, the HHA would report the Healthcare Common Procedure Coding System (HCPCS) code A9272 (for the device only) on the home health TOB 32X. The code HCPCS A9272 is defined as a wound suction, disposable, includes dressing, all accessories and components, any type, each. We will provide education and develop materials outlining the new billing procedures for dNPWT under the home health benefit including MLN Matters® articles and manual guidance after publication of the CY 2024 HH PPS final rule.

Finally, we proposed that the services related to the application of the device would be included in the HH PPS and would be excluded from the separate payment amount for the device. Only the home health services for the administration of the device would be geographically adjusted and the payment amount for HCPCS A9272 would not be subject to geographic adjustment.

We solicited public comment on all aspects of the proposed payment policies for furnishing a dNPWT device as articulated in this section, as well as the corresponding proposed regulations text changes at § 409.50 and § 484.202.

The following is a summary of the public comments received regarding the new payment policies for dNPWT.

Comment: Commenters were generally supportive of the proposals to codify the statutorily mandated changes to dNPWT for beneficiaries under a home health plan of care, stating that the new policies will promote clarity regarding these services and facilitate collaboration between providers. A few commenters also requested guidance materials as soon as possible to ensure that HHAs and vendors have ample time to make the necessary adjustments in their claim reporting processes.

Response: We thank the commenters for their support. We will issue a Change Request (CR) outlining the new billing procedures for dNPWT under the home health benefit and provide educational materials, including MLN Matters® articles and manual guidance after publication of this final rule.

Comment: A commenter requested clarification regarding which practitioners are authorized to order dNPWT. This commenter noted that in the preamble language CMS references the pre-CARES Act requirements that these functions are limited to a physician and wanted to ensure that nurse practitioners (NPs), clinical nurse specialists (CNSs) and physician assistants (PAs) are authorized to establish, review, and certify home health plans of care that include dNPWT, and that home health beneficiaries receiving dNPWT are authorized to be under the care of an NP, CNS, or PA.

Response: We thank the commenter for their comment. The term ''allowed practitioner'' was inadvertently omitted from the dNPWT preamble language. However, the regulations at parts 409, 424, and 484 were amended to implement section 3708 of the CARES Act, which included defining a nurse practitioner (NP), a clinical nurse specialist (CNS), and a physician's assistant (PA) (as such qualifications are defined at §§ 410.74 through 410.76) as ''allowed practitioners'' (85 FR 27572). Allowed practitioners in addition to physicians, can certify and recertify beneficiaries for eligibility, order home health services (including dNPWT), and establish and review the plan of care.

Comment: A commenter requested further clarification regarding the billing process for dNPWT. This commenter submitted several questions regarding how claims should be billed beginning in CY 2024 including, whether payment for the device would still occur under OPPS and continue to be captured on TOB 34X; whether CPT codes 97607 and 97608 would continue to be utilized; whether the co-payment would still apply to the device; how visits would be captured on TOB 32X; if visits related to the application of the device are required to be identified as dNPWT visits; and whether wound care centers would be able to initially apply the dNPWT device.

Response: In the CY 2024 HH PPS proposed rule, we clarified that HHAs will no longer submit claims on TOB 34X or utilize CPT codes 97607 and 97608 for home health beneficiaries receiving dNPWT. Instead, when a home health beneficiary receives dNPWT, for dates of service beginning on or after January 1, 2024, the HHA will report the HCPCS code A9272 on TOB 32X for the device only. The deductible and coinsurance will still apply when the dNPWT device is billed using HCPCS code A9272. Claims for dNPWT sent on TOB 34X with HCPCS codes 97607 or 97608 and claim through dates on or after January 1, 2024 will be returned to the provider. In addition, services related to the application of the device will be reported on TOB 32X and are included in the home health bundled payment. That is, visits for home health services, including visits for the application for dNPWT, would be reported as they currently are based on the discipline providing the service. Therefore, visits for services related to the application of the dNPWT device are excluded from the separate payment amount for the device. In situations where wound care centers initially apply the dNPWT device to beneficiaries who are then referred to

home health for the continuation of the treatment with dNPWT, the wound care center would apply the device and bill the appropriate CPT code (as the patient is not yet under a HH plan of care). However, if the patient is already under a home health plan of care and goes to the wound care center for application of the device, then the device should be billed by the HHA on the TOB 32X and the services would be considered home health services under the HH PPS.

Final Decision: We are finalizing our proposal to codify the statutory requirements for dNPWT as proposed. Beginning January 1, 2024, a separate payment for the disposable device will be made to an HHA for an individual who is under a home health plan of care using HCPCS code A9272. The CY 2024 payment amount for the device under a home health plan of care will be $270.09, which is equal to the supply price of an applicable disposable device under the Medicare PFS for January 1, 2022, which is $263.25 updated by the final update of 2.6 percent. For 2025 and each subsequent year, the separate payment amount will be set equal to the payment amount established for the device in the previous year, updated by the percentage increase in the CPI–U minus the productivity adjustment for the 12-month period ending in June of the previous year. Claims reported for a dNPWT device will no longer be reported on TOB 34X. Instead, for dates of service beginning on or after January 1, 2024, the HHA would report the HCPCS code A9272 (for the device only) on the home health TOB 32X. The services related to the application of the device will be included in the home health payment and will be excluded from the separate payment amount for the device. We note that only the home health services for the administration of the device will be geographically adjusted and the payment amount for HCPCS A9272 (for the device only) will not be subject to geographic adjustment. We will issue a CR and provide educational materials outlining the new billing procedures for dNPWT under the home health benefit including MLN Matters® articles and manual guidance after publication of the CY 2024 HH PPS final rule.

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 home health 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.

In this final rule, we are adopting two new measures and removing one existing measure. Second, we are finalizing the removal of two OASIS items. Third, we are finalizing a requirement for public reporting of four measures in the HH QRP. Fourth, we are providing an update on our efforts to close the health equity gap. Fifth, we are codifying our 90 percent data submission threshold policy in the Code of Federal Regulations. Lastly, we discuss responses to our request for information on principles we could use to select and prioritize HH QRP quality measures in future years. These proposals are further discussed as follows.

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

For a detailed discussion of the considerations we historically use for measure selection for the HH QRP quality, resource use, and 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 20 measures for the CY 2024 program year, as described in Table C1.

TABLE C1: MEASURES CURRENTLY ADOPTED FOR THE CY 2024 HH QRP

Short Name	Measure Name & Data Source
QM Name	**OASIS-based**
Ambulation	Improvement in Ambulation/Locomotion (CBE #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #0674).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (CBE #2631).
Bathing	Improvement in Bathing (CBE #0174).
Bed Transferring	Improvement in Bed Transferring (CBE # 0175).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
Dyspnea	Improvement in Dyspnea.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (CBE #0176).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation Of Care (CBE #0526).
TOH -Provider	Transfer of Health Information to Provider-Post-Acute Care[1]
TOH -Patient	Transfer of Health Information to Patient-Post-Acute Care[1]
QM Name	**Claims-based**
ACH	Acute Care Hospitalization During the First 60 Days of HH (CBE #0171).
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (CBE #3477)
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (CBE #0173).
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
PPH	Home Health Within Stay Potentially Preventable Hospitalization
QM Name	**HHCAHPS-based**
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (CBE #0517)[2] - How often the HH team gave care in a professional way. - How well did the HH team communicate with patients. - Did the HH team discuss medicines, pain, and home safety with patients. - How do patients rate the overall care from the HHA. - Will patients recommend the HHA to friends and family.

NOTES:

1 Data collection delayed due to the COVID-19 public health emergency for the TOH-Patient and TOH-Provider.

2 The HHCAHPS has five components that together are used to represent one CBE-endorsed measure.

D. HH QRP Quality Measure Proposals Beginning With the CY 2025 HH QRP

1. Discharge Function Score Measure Beginning With the CY 2025 HH QRP

a. Background

Eligibility for Medicare's home health benefit stipulates that beneficiaries must need part-time (fewer than eight hours per day) or intermittent skilled care for their medical conditions and be unable to leave their homes without considerable effort. Unlike skilled nursing facilities, a proceeding hospital stay is not required for beneficiaries to access the Medicare home health benefit.[17] HH patients frequently have complex medical issues, including cardiac, circulatory and respiratory conditions, and between 30–40 percent of HH patients begin their episode of care with a high level of functional debility.[18] Measuring functional status of HH patients can provide valuable information about an HHA's quality of care. A patient's functional status is associated with institutionalization,[19] higher risk of falls and falls-related hip fracture and death,[20] [21] greater risk of undernutrition,[22] higher emergency department admissions,[23] higher risk of readmissions following home care,[24] [25] and higher prevalence of hypertension and diabetes.[26] Predictors of poorer recovery in function include greater age, complications after hospital discharge, and residence in a nursing home.[27] Understanding factors associated with poorer functional recovery facilitates the ability to estimate expected functional outcome recovery for patients, based on their personal characteristics.

Home health care can positively impact functional outcomes. There is evidence the provision of home care services can lead to statistically significant improvements in function and successful discharge into the community.[28] In stroke patients, home-based rehabilitation programs administered by home health clinicians significantly improved function.[29] Home health services, delivered by a registered nurse positively impacted patient Quality of Life (QOL) and clinical outcomes, including significant improvement in dressing lower body and bathing activities of daily living, meal preparation, shopping, and housekeeping instrumental activities of daily living.[30] In addition, a retrospective study, using data abstracted from the Minimum Data Set and OASIS, reported that nursing home admissions were delayed in the study population receiving home health services by an average of eight months [31] and for a similar population, community dwelling adults receiving community-based services supporting aging in place, health and functional outcomes were enhanced, and improved cognition and lower rates of depression, function assistance, and incontinence were noted.[32]

To satisfy the requirement of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185) to develop and implement standardized quality measures from five quality measure domains, including the domain of functional status, cognitive function, and changes in function and cognitive function, across the post-acute care (PAC) settings, CMS adopted the ''Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function'' (Application of Functional Assessment/Care Plan) measure in the CY 2018 HH PPS final rule (82 FR 51722 through 51727). This cross-setting process measure allowed for the standardization of functional assessments across assessment instruments and facilitated cross-setting data collection, quality measurement, and interoperable data exchange.

However, performance on this measure across the PAC settings, including the range of HHAs, is so high and unvarying across most HH providers that the measure no longer offers meaningful distinctions in performance. Several measures addressing functional status are currently part of the PAC QRPs. None of the existing functional outcome measures are cross-setting in nature, in that they are either: (a) not implemented in all four settings (for instance, the ''Discharge Mobility and Self-Care Score'' measures are reported for SNFs and IRFs but not for LTCHs and HHAs); or (b) rely on functional status items not collected in all settings (for instance, the ''Discharge Mobility and Self-Care Score'' measures rely on items not collected in LTCHs). In contrast, a cross-setting functional outcome measure will include the HH setting. Moreover, the measure specifications will be aligned across settings, including the use of a common set of standardized functional assessment data elements, thereby

[17] Medicare Payment Advisory Commission. (2022). March 2022 report to the congress: Medicare payment policy. *Washington, DC: Medicare Payment Advisory Commission.*

[18] Medicare Payment Advisory Commission. (2022). March 2022 report to the congress: Medicare payment policy. *Washington, DC: Medicare Payment Advisory Commission.*

[19] Hajek, A., Brettschneider, C., Lange, C., Posselt, T., Wiese, B., Steinmann, S., Weyerer, S., Werle, J., Pentzek, M., Fuchs, A., Stein, J., Luck, T., Bickel, H., Mösch, E., Wagner, M., Jessen, F., Maier, W., Scherer, M., Riedel-Heller, S.G., König, H.H., & AgeCoDe Study Group. (2015). Longitudinal Predictors of Institutionalization in Old Age. PLoS One, 10(12):e0144203.

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satisfying the requirements of the IMPACT Act.

Measure Importance

Maintenance or improvement of physical function among older adults is increasingly an important focus of healthcare. Worldwide, close to 20 percent of older adults living at home report needing some form of assistance with their ADLs, and in the US 29 percent of older adults report difficulties completing their activities of daily living (ADLs).[33] Adults aged 65 years and older constitute the most rapidly growing population in the United States, and functional capacity in physical (non-psychological) domains has been shown to decline with age.[34] Moreover, impaired functional capacity is associated with poorer quality of life and an increased risk of all-cause mortality, postoperative complications, and cognition, the latter of which can complicate the return of a patient to the community from post-acute care if the patient exhibits cognitive deficits.[35 36 37] Nonetheless, evidence suggests that physical functional abilities, including mobility and self-care, are modifiable predictors of patient outcomes across PAC settings, including functional recovery or decline after post-acute care,[38 39 40 41 42] rehospitalization rates,[43 44 45] discharge to community,[46 47] and falls.[48]

The implementation of interventions that improve patients' functional outcomes and reduce the risks of associated undesirable outcomes as a part of a patient-centered care plan is essential to maximizing functional improvement. For many people, the overall goals of HH care may include optimizing functional improvement, returning to a previous level of independence, maintaining functional abilities, or avoiding institutionalization. Studies have suggested that HH care has the potential to improve patients' functional abilities including the performance of ADLs at discharge through the provision of physical and occupational therapy services for community dwelling older adult patients with various diagnoses, including dementia.[49 50 51 52 53 54] Assessing functional status as a health outcome in HH can thus provide valuable information in determining treatment decisions throughout the care continuum, the need for therapy service, and discharge planning,[55 56 57] as well as

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provide information to consumers about the effectiveness of the care delivered. Because evidence shows that older adults experience aging heterogeneously and require individualized and comprehensive health care, functional status can serve as a vital component in informing the provision of health care and thus indicate HH quality of care.[58] [59] [60] [61]

We are finalizing the adoption of the Discharge Function Score (DC Function) measure[62] in the HH QRP beginning with the CY 2025 HHQRP. This assessment-based outcome measure evaluates functional status by calculating the percentage of HH patients' quality episodes who meet or exceed an expected discharge function score. We are finalizing that this measure will replace the topped-out, cross-setting Application of Functional Assessment/Care Plan process measure. Like the cross-setting process measure it is replacing, the final measure is calculated using standardized patient assessment data from the current HH assessment tool.

In addition to meeting the requirements of the Act, the DC Function measure supports current CMS priorities. Specifically, the measure aligns with the Streamline Quality Measurement domain in CMS's Meaningful Measures 2.0 framework[63] in two ways. First, the final outcome measure will further CMS's objective to increase the proportion of outcome measures in the HH QRP by replacing the Application of Functional Assessment/Care Plan cross-setting process measure with an outcome measure (see Section III.2 of this final rule). Second, this measure adds no additional provider burden since it will be calculated using data from the OASIS that are already reported to the Medicare program for quality reporting purposes.

The final DC Function measure will also follow a calculation approach similar to the existing functional outcome measures. Specifically, the measure (1) considers two dimensions of function (that is, self-care and mobility activities) and (2) accounts for missing data by using statistical imputation to improve the validity of measure performance. The statistical imputation recodes missing functional status data to a *likely value* had the status been assessed, whereas the current imputation approach implemented in existing function outcome measures recodes missing data to the *lowest* functional status.

b. Measure Testing

Measure testing was conducted on the DC Function measure to assess validity, reliability, and reportability, all of which informed stakeholder feedback and Technical Expert Panel (TEP) input (See the *Stakeholder and Technical Expert Panel (TEP) Input* section of this final rule). Validity was assessed for the measure performance, the risk adjustment model, face validity, and statistical imputation models. Validity testing of measure performance entailed determining Spearman's rank correlations between the final measure's performance and the performance of other publicly reported HH quality measures. Results indicated that the measure captures the most probable determination of actual outcomes based on the directionalities and strengths of correlation coefficients and are further detailed in Table C2.

TABLE C2. SPEARMAN'S RANK CORRELATION RESULTS OF DC FUNCTION MEASURE WITH PUBLICLY REPORTED HH QUALITY MEASURES

Measure – Long Name	Measure – Short Name	ρ
Discharge to Community – PAC HH QRP (CBE ID #3477)	Discharge to Community	0.25
Improvement in Ambulation – Locomotion (CBE ID #0167)	Improvement in Ambulation	0.25
Improvement in Bed Transferring (CBE ID #0175)	Improvement in Bed Transferring	0.31
Improvement in Bathing (CBE ID #0174)	Improvement in Bathing	0.26
Improvement in Dyspnea (CBE ID #0179)	Improvement in Dyspnea	0.26
Improvement in Management of Oral Medications (CBE ID #0176)	Improvement in Management of Oral Medications	0.23

Validity testing of the risk adjustment model showed good model discrimination, as the measure model has the predictive ability to distinguish patients with low expected functional capabilities from those with high expected functional capabilities.[64] The ratios of observed-to-predicted discharge function score across eligible episodes, by deciles of expected functional capabilities, ranged from 0.98 to 1.01. Both the Cross-Setting Discharge Function TEPs and patient-family feedback showed strong support for the face validity and importance of the final measure as an indicator of quality of care. Lastly, validity testing of the measure's statistical imputation models indicated that the models demonstrate good discrimination and produce more precise and accurate estimates of function scores for items with missing scores when compared to adopting the current imputation approach implemented in the SNF QRP functional outcome measures, specifically Change in Self-Care Score measure, Change in Mobility Score measure, Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (CBE ID #2635) (Discharge Self-Care Score) measure, and Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (CBE ID #2636) (Discharge

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[62] Discharge Function Score for Home Health Agencies (HHAs) Technical Report, which is available at *https://www.cms.gov/files/document/hh-discharge-function-score-measure-technical-report.pdf.*

[63] *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization,* accessed February 1, 2023.

[64] ''Expected functional capabilities'' is defined as the predicted discharge function score.

Mobility Score) measure. The current imputation approach involves recoding ''Activity Not Attempted'' (ANA) codes to ''1'' or ''most dependent.''

Reliability and reportability testing also yielded results that support the measure's scientific acceptability. Split-half testing revealed the final measure's excellent reliability, indicating an intraclass correlation coefficient value of 0.94. Reportability testing indicated good reportability (79 percent) of providers meeting the public reporting threshold of 20 eligible episodes. For additional measure testing details, we refer readers to the document titled *Discharge Function Score for Home Health Agencies (HHAs) Technical Report,* which is available at *https://www.cms.gov/files/document/hh-discharge-function-score-measure-technical-report.pdf*.

c. Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, measures specified under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a). In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The final DC Function measure is not CBE-endorsed, so we considered whether there are other available measures that (1) assess both functional domains of self-care and mobility in HHAs and (2) satisfy the requirement of the Act to develop and implement standardized quality measures from the quality measure domain of functional status, cognitive function, and changes in function and cognitive function across the PAC settings. While the Application of Functional Assessment/Care Plan measure assesses both functional domains and satisfies the Act's requirement, this cross-setting process measure is not CBE-endorsed and the performance on this measure among HHAs is so high and unvarying across most providers that the measure does not offer meaningful distinctions in performance. Additionally, after review of the CBE's consensus-endorsed measures, we were unable to identify any CBE-endorsed measures for HHAs that meet the aforementioned requirements.

Therefore, after consideration of other available measures, we find that the exception under section 1899B(e)(2)(B) of the Act applies and propose to adopt the DC Function measure beginning with the CY 2025 HH QRP. We intend to submit the final measure to the CBE for consideration of endorsement when feasible.

d. Interested Parties and Technical Expert Panel (TEP) Input

In our development and specification of this measure, we employed a transparent process in which we sought input from stakeholders and national experts and engaged in a process that allowed for pre-rulemaking input, in accordance with section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: a Patient and Family Engagement Listening Session, two TEPs, and public comments through a request for information (RFI).

First, the measure development contractor convened a Patient and Family Engagement Listening Session, during which patients and caregivers provided views on the measure concept. Participants expressed support and emphasized the importance of measuring functional outcomes and found self-care and mobility to be critical aspects of care. Additionally, they expressed a strong interest in metrics assessing the number of patients discharged from particular agencies or facilities with improvements in self-care and mobility, and their views of self-care and mobility aligned with the functional domains captured by the final measure. All feedback was used to inform measure development efforts.

The measure development contractor subsequently convened TEPs on July 14–15, 2021, and January 26–27, 2022, to obtain expert input on the development of DC Function measure for use in the HH QRP. The TEPs consisted of stakeholders with a diverse range of expertise, including HH and PAC subject matter knowledge, clinical expertise, patient and family perspectives, and measure development experience. The TEPs supported the final measure concept and provided substantive feedback regarding the measure's specifications and measure testing data. First, the TEP was asked whether they prefer a cross-setting measure that is modeled after the Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (CBE ID #2636) (Discharge Mobility Score) and IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (CBE ID #2635) (Discharge Self-Care Score) measures, or one that is modeled after the IRF Functional Outcome Measure: Change in Mobility for Medical Rehabilitation Patients (CBE ID #2634) (Change in Mobility Score) and IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (CBE ID #2633) (Change in Self-Care Score). With the Discharge Mobility Score and Change in Mobility Score measures and the Discharge Self-Care Score and Change in Self-Care Score measures being both highly correlated and not appearing to measure unique concepts, the TEP favored the Discharge Mobility Score and Discharge Self-Care Score measures over the Change in Mobility Score and Change in Self-Care Score measures and recommended moving forward with the Discharge Mobility Score and Discharge Self-Care Score measures for the cross-setting measure. Second, in deciding on the standardized functional assessment data elements to include in the cross-setting measure, the TEP recommended removing redundant data elements. Strong correlations between scores of functional items within the same functional domain suggested that certain items may be redundant in eliciting information about patient function and inclusion of these items could lead to overrepresentation of a particular functional area. Subsequently, our measure development contractor focused on the Discharge Mobility Score measure as a starting point for cross-setting development due to the greater number of cross-setting standardized functional assessment data elements for mobility while also identifying redundant functional items that could be removed from a cross-setting functional measure.

Additionally, the TEP supported including the cross-setting self-care items such that the cross-setting function measure captures both self-care and mobility. Panelists agreed that self-care items added value to the measure and are clinically important to function. Lastly, the TEP provided refinements to imputation strategies to more accurately represent function performance across all PAC settings, including the support of using statistical imputation over the current imputation approach implemented in existing functional outcome measures in the PAC QRPs. We considered all the TEP's recommendations for developing a cross-setting function measure and applied those recommendations where technically feasible and appropriate. Summaries of the TEP proceedings

titled *Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report* (July 2021 TEP) available at *https://mms-test.battelle.org/sites/default/files/TEP-Summary-Report-PAC-Function.pdf* and *Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report* (January 2022 TEP) available at *https://mms-test.battelle.org/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf*.

e. Measure Application Partnership (MAP) Review

Our pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the MUC List, that the Secretary is considering adopting through the Federal rulemaking process for use in Medicare programs. This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list.

We included the DC Function measure under the HH QRP in the publicly available MUC List for December 1, 2022,[65] and the CBE received five comments from industry-connected interested parties on the 2022 MUC List. Three commenters were supportive of the measure and two were not. Among the commenters in support of the measure, one commenter stated that function scores are the most meaningful outcome measure in the HH setting, as they not only assess patient outcomes but also can be used for clinical improvement processes. Additionally, the commenter noted the measure's good reliability and validity and that the measure is feasible to implement. The second commenter supported the measure; however, the comments did not appear to be directly related to any aspect of the measure itself. The third commenter supported the measure without providing additional detailed comments.

Among the two commenters who did not support the DC Function measure, a commenter raised the following concerns: the ''gameability'' of the expected discharge score, the measure's complexity, and the difficulty of implementing a composite functional score. CMS was able to address these concerns during the MAP PAC/LTC Workgroup Meeting held on December 12, 2022. Specifically, CMS clarified that the expected discharge scores are not calculated using self-reported functional goals and are simply calculated by risk-adjusting the observed discharge scores (see the Quality Measure Calculation section III.C.1.e of this final rule). Therefore, CMS believes that these scores cannot be ''gamed'' by reporting less-ambitious functional goals. CMS also pointed out that the measure is highly usable as it is similar in design and complexity to existing function measures (for example, Discharge Mobility Score and Discharge Self-Care Score for IRF) and that the data elements used in this measure are already in use.

The other commenter who did not support the DC Function measure raised the following concerns: its performance for stabilization patients; and its ability to account for patients that change payer during a HH episode. CMS was able to address the first concern during the MAP PAC/LTC Workgroup Meeting held on December 12, 2022. Specifically, CMS clarified that an episode will contribute to the numerator of DC Function if the observed discharge score meets or exceeds the expected discharge score, a value determined using clinical comorbidity and setting-specific parameters at the start or resumption of care. These parameters can and do predict no improvement among stabilization patients, that is, the expected discharge score can and does occasionally equal the observed admission score if clinical comorbidity and setting-specific parameters indicate no expected improvement in the risk adjustment model.

The second concern was not raised during the MAP PAC/LTC Workgroup Meeting; however, we do not find any convincing evidence that it influences HHA-level performance for the majority of HHAs. Payer changes will only affect episodes ending between December 31 and March 31. By comparing HHA-level performance calculated using the full calendar year versus using a dataset that excludes the dates with possibly affected episodes (January 1 through March 31 and December 31), we assessed the degree to which this requirement influences performance. The Spearman correlation coefficient between the two scenarios is 0.97, and the changes in reliability and validity are smaller than one percentage point. The results imply that including or excluding affected episodes does not appear to influence HHA-level performance for the majority of HHAs. We will continue to monitor this concern in the future, and we will address it accordingly in the future if necessary.

Shortly after, several CBE-convened MAP workgroups met virtually to provide input on the DC Function measure. First, the MAP Health Equity workgroup convened on December 6–7, 2022. The workgroup did not share any health equity concerns related to the implementation of the DC Function measure, and only asked for clarification regarding measure specifications from measure developers. The MAP Rural Health workgroup met on December 8–9, 2022, during which two members provided support for the DC Function measure and other workgroup members did not express rural health concerns regarding the measure. The MAP Post-Acute Care/Long-Term Care (PAC–LTC) workgroup met virtually on December 12, 2022 and provided input on the DC Function measure. The workgroup voted to support the staff recommendation of conditional support for rulemaking.

In response to the MAP PAC/LTC Workgroup's preliminary recommendation, the CBE received one supportive comment and one non-supportive comment regarding the DC Function measure. The former commenter supported the measure under the condition that it be reviewed and refined so that its implementation would support patient autonomy, and would result in care that would align with patients' personal functional goals. The latter commenter was concerned with the applicability of the measure to the different patient populations served by the various PAC settings. CMS clarified that the DC Function measure was not designed to compare function across PAC settings, and that this feature is not a requirement of the IMPACT Act.

Finally, the MAP Coordinating Committee convened on January 24–25, 2023. The CBE received no comments on the PAC/LTC workgroup's preliminary recommendation for conditional support of the DC Function measure. The MAP Coordinating Committee upheld the PAC/LTC workgroup's recommendation of conditional support for rulemaking with 20 votes in support and one against. We refer readers to the final MAP recommendations, titled *2022–2023 MAP Final Recommendations* available at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

f. Quality Measure Calculation

The final outcome measure estimates the percentage of HH patients who meet

[65] Centers for Medicare & Medicaid Services. Overview of the List of Measures Under Consideration for December 1, 2022. *https://mmshub.cms.gov/sites/default/files/2022-MUC-List-Overview.pdf.*

or exceed an expected discharge score during the reporting period. The final measure's numerator is the number of HH episodes with an observed discharge function score that is equal to or higher than the calculated expected discharge function score. The observed discharge function score is the sum of individual function items at discharge. The expected discharge function score is computed by risk adjusting the SOC/ROC observed discharge function score for each HH episode. Risk adjustment controls for patient characteristics such as SOC/ROC function score, age, and clinical conditions. The denominator is the total number of HH episodes in the measure target period (four rolling quarters) that do not meet the measure exclusion criteria. For additional details regarding the numerator, denominator, risk adjustment, and exclusion criteria, refer to the *Discharge Function Score for Home Health Agencies (HHAs) Technical Report* available at *https://www.cms.gov/files/document/hh-discharge-function-score-measure-technical-report.pdf*.

The final measure implements a statistical imputation approach for handling ''missing'' standardized functional assessment data elements. The coding guidance for standardized functional assessment data elements allows for using ANA codes, resulting in ''missing'' information about a patient's functional ability on at least some items, at SOC/ROC and/or discharge, for a substantive portion of HH patients. Statistical imputation replaces these missing values with a variable based on the values of other, non-missing variables in the data and which are otherwise similar to the assessment with a missing value. In this case, statistical imputation allows missing values (for example, the ANA codes) to be replaced with any value from 1 to 6, based on a patient's clinical characteristics and codes assigned on other standardized functional assessment data element. The measure implements separate imputation models for each standardized functional assessment data element used in measure construction at SOC/ROC and discharge. Relative to the current simple imputation method, this statistical imputation approach increases precision and accuracy and reduces the bias in estimates of missing item scores. We refer readers to the *Discharge Function Score for Home Health Agencies (HHAs) Technical Report* available at *https://www.cms.gov/files/document/hh-discharge-function-score-measure-technical-report.pdf* for measure specifications and additional details on measure testing, including the method for comparing the statistical imputation approach to the current simple imputation method.

We solicited public comment on our proposal to adopt the Discharge Function Score measure. The following is a summary of the comments we received on our proposal to adopt the DC Function measure, beginning with the CY 2025 HH QRP, and our responses.

Comment: Most commenters supported the adoption of the proposed measure, noting its improvement over the current functional process measure.

Response: We thank commenters for their support of the adoption of the DC Function measure.

Comment: A commenter supported the addition of the DC Function measure and urged CMS to consider using the measure to assess the adequacy of RN staffing.

Response: CMS appreciates the support and will consider future uses for the measure, including evaluating the adequacy of RN staffing in home health.

Comment: Some commenters believed the measure's imputation and risk-adjustment approach were complex and difficult to understand. A commenter supported the addition of the DC Function measure, though encouraged greater transparency on how the DC Function measure was calculated, and requested that HHAs have immediate access to expected score calculations. Another commenter suggested that CMS provide greater transparency on the ''expected'' discharge function score and/or the imputation method. Two additional commenters opposed the adoption of the DC Function measure and expressed concern with the proposed imputation approach. A commenter noted that the measure could vary significantly from the other metrics currently being reported. Another commenter expressed concerns that publicly reported measures should be reflective of actual data gathered and calculated.

Response: We thank the commenter for supporting the adoption of the DC Function measure, and we appreciate the concerns about transparency of the imputation calculation. We appreciate that statistical imputation adds additional steps to the measure's calculation; however, understanding the technical details of imputation and, separately, the construction of the expected scores, is not needed to correctly interpret the measure scores. For those who are interested in the technical details, the methodology and specifications are available in the Discharge Function Score for Home Health Agencies (HHAs) Technical Report.[66] CMS anticipates baseline performance for CY 2023 will be shared in July 2024 as part of the HH VBP Model.

The imputation approach implemented in the proposed DC Function measure uses each patient's available functional and clinical information to estimate each ANA value had the item been completed. An alternative imputation method currently in place for similarly designed, CBE-endorsed measures under IRF QRP and SNF QRP imputes all ANA codes to 1 (dependent). Unlike DC Function, as proposed, this alternative uses no actual data to impute. Additionally, relative to this alternative, testing demonstrates that the statistical imputation approach used in the DC Function measure increases precision and accuracy and reduces bias in estimates of missing item values.

Comment: Some commenters opposed to the adoption of the DC Function measure expressed concern that the measure only includes a subset of function items from the assessment instrument and is concerned that these items are not necessarily the best indicators of patient functional success when discharged; for example, functional abilities and goals that better reflect self-care included upper body dressing and lower body dressing.

Response: We acknowledge that the cross-setting applicability was a motivating factor in determining function items captured in the proposed DC Function measure, and the ''upper body dressing'' and ''lower body dressing'' function items were not available across settings. Nonetheless, the proposed DC Function measure does reflect the progress of a patient across both the mobility and selfcare domains. As stated in section III.D.1.b. of this final rule, the TEP supported the inclusion of both functional domains, since self-care items impact mobility items and are clinically relevant to function.

Comment: A commenter opposed to the adoption of the DC Function measure expressed concern with the amount of compliance burden on HHA staff to become familiar with the new measure.

Response: We disagree that the adoption of the proposed measure would result in additional burden or require additional training. We are not proposing changes to the number of

[66] *https://www.cms.gov/files/document/hh-discharge-function-score-measure-technical-report.pdf.*

items required or the reporting frequency of the items reported in the OASIS in order to report this measure. In fact, this measure requires the same set of items that are already reported by HHAs in the OASIS. Additionally, we calculate this measure and provide HHAs with various resources to review and monitor their HHA performance on this measure, including provider preview reports. Therefore, HHAs are not required to update software to successfully report or monitor performance. Regarding the commenter's concerns about education, we do plan to provide educational resources to HHAs about the DC Function measure.

Comment: A few commenters opposed to the adoption of the DC Function measure noted that the CBE is generally required to endorse the measure.

Response: We direct readers to section III.D.1.b. of this final rule, where we discuss the topic of CBE endorsement in detail. Despite the current absence of CBE endorsement for this measure, we still believe it is important to adopt the DC Function measure into the HH QRP because, unlike the Discharge Self-Care Score and Discharge Mobility Score measures found in both IRF QRP and SNF QRP, the DC Function measure relies on functional status items collected in all PAC settings, satisfies the requirement of a cross-setting quality measure set forth in sections 1888(e)(6)(B)(i)(II) and 1899B(c)(1)(A) of the Act, and assesses both domains of function. We also acknowledge the importance of the CBE endorsement process and plan to submit the proposed measure for CBE endorsement in the future. We direct readers to section III.D.1.a. of this final rule and the technical report for detailed measures testing results demonstrating that the measure provides meaningful information which can be used to improve quality of care, and to the TEP report summaries [67] [68] which detail TEP support for the proposed measure concept.

Comment: A few commenters encouraged the incorporation of maintenance care into the measure. One broadly supportive commenter suggested CMS examine measure(s) that would better capture both maintenance and improvement in functional status. Another commenter opposed the adoption of the DC Function measure due to the belief that this measure encourages HHAs to favor patients with the potential for improvement at discharge over those in need of maintenance care. For this reason, the commenter recommended excluding beneficiaries who do not have improvement goals.

Response: The DC Function measure does not solely reflect improvement of patients at discharge. The measure estimates the percentage of patients who meet, as well as exceed, an expected discharge function score. In other words, if a patient, based on their own demographic and clinical characteristics, is expected to maintain, as opposed to improve in, function, then they will still meet the numerator criteria for this measure. For many patients, the overall goals of HHA care may include optimizing functional improvement, returning to a previous level of independence, maintaining functional abilities, or avoiding institutionalization. For additional details regarding risk adjustment, please refer to the Discharge Function Score for Home Health Agencies (HHAs) Technical Report.[69]

Comment: A commenter urged CMS to consider alternative assessments that better incorporate cognition and communication into the measure calculation.

Response: We agree that cognition and communication are critically important and related to the safety and independence of patients. Although not directly assessed for the purpose of measure calculation, this measure does indirectly capture an HHA's ability to impact a patient's cognition and communication to the extent that these factors are correlated to improvements in self-care and mobility. That said, we agree that communication and cognition are important to assess directly, and HHAs currently do so through completion of the Brief Interview for Mental Status (BIMS) and Confusion Assessment Method (CAM©) items in section C of the OASIS. Additionally, we regularly assess the measures in the HH QRP for measurement gaps, and we will use feedback technical experts and empirical analyses to determine how to measure communication and cognition going forward.

Comment: A commenter expressed concern about the inconsistency of PAC providers' recording of functional assessment information, especially if the items are used for payment, where incentives may encourage providers to report codes that are advantageous for financial reasons. This commenter discouraged CMS reliance on OASIS-based measures of function for payment or quality measurement until their accuracy or integrity are improved.

Response: CMS has processes in place to ensure reported patient data are accurate. The OASIS process has multiple regulatory requirements to ensure accuracy. Our regulations at § 484.55 require that (1) the assessment must be a comprehensive, accurate assessment of the patient's status and (2) the assessment must accurately reflect the patient's status. Because these requirements are CoPs, failure to comply could result in termination from the Medicare program.

Comment: A commenter requested CMS provide more clarity on its imputation approach to recoding, specifically contrasting it with a Rasch analysis used in the unified PAC PPS prototype, to ensure transparency and clinical significance.

Response: The Rasch analysis in the unified PAC PPS prototype produces a single value to which every single ANA is recoded for a given item across all patients and settings. By contrast, under the imputation approach for the DC Function measure, we estimate a different imputed value for each patient, based on their clinical comorbidities, their score on all other GG items, and setting. We believe our approach accounts for several likely effects: setting-specific coding guidance and practice differences; function scores being correlated with clinical comorbidities; and functional scores for a given GG item being correlated with functional codes on other GG items, particularly on ''adjacent'' (similar) items. Therefore, we believe recoding ANAs based on each patient's specific clinical risk and using all available GG item scores/codes is a more valid approach. For more detailed measure specifications, we direct readers to the document titled Discharge Function Score for Home Health Agencies (HHAs) Technical Report.[70]

[67] Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report (July 2021 TEP). *https://mms-test.battelle.org/sites/default/files/TEP-Summary-Report-PAC-Function.pdf.*

[68] Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report (January 2022 TEP). *https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf.*

[69] *https://www.cms.gov/files/document/hh-discharge-function-score-measure-technical-report.pdf.*

[70] *https://www.cms.gov/files/document/hh-discharge-function-score-measure-technical-report.pdf.*

Comment: Eight commenters expressed concern that providers have not had enough time using the measure prior to use in a performance-based program like HH VBP.

Response: We thank the commenters for their feedback. As stated in section III.D.1 of this final rule, the HH QRP is adopting this measure in CY 2025 HH QRP year with data collection for public reporting beginning with April 1, 2024 discharges. We are finalizing the adoption of this measure for the HH VBP Program beginning with the CY 2027 payment year, with data collection beginning with January 1, 2025 discharges. This timeline will enable HHAs to report the data for a nine months in the HH QRP before they are required to report data for the HH VBP Program. We believe that reporting this measure in the HH QRP for this time is sufficient time for providers to gain familiarity with the measure.

We also note that many of the same commenters did not support the inclusion of this measure in both the HH QRP and HH VBP Program. We responded to those more general comments in section III.D.1. of this final rule. CMS anticipates baseline performance for CY 2023 will be shared in July 2024 as part of the HH VBP Model.

Comment: A commenter supported the DC Function measure, which includes components for both self-care and mobility, but recommended CMS explore separating the measure into individual self-care and mobility function measures so that providers can better identify treatment goals.

Response: The HH QRP currently utilizes several ''improvement in function'' measures that address individual functional activities in both the self-care and mobility domains. As evidenced in the Discharge Function Score for Home Health Agencies (HHAs) Technical Report,[71] the Spearman rank correlation between the DC Function and these measures range from 0.23 to 0.31, indicating a modest positive correlation and suggesting that the measures address different aspects of quality related to function. These differences are by design. Unlike the ''improvement in function'' measures, which evaluate functional improvement, DC Function quantifies whether the patient met or exceeded functional expectations at end of care. Additionally, an HHA can improve DC Function, as a composite measure, by improving individual activities while maintaining other activities, while it can only improve the individual ''improvement in function'' measures by improving the specific activity being measured. In future years, CMS may consider developing new measures that quantify whether the patient met or exceeded expectations at the end of care for individual functions.

Comment: A few other commenters expressed concern regarding the guidance for the GG items will be confused with those for the M1800 item set, which could lead to data fidelity concerns.

Response: As with all other measures, we will routinely monitor this measure's performance, including the statistical imputation approach, to ensure that the measure remains valid and reliable. Finally, we would like to clarify that the adoption of this measure does not change how HHAs should complete the GG items. As stated in the OASIS–E Manual, the ANA codes should only be used after determining that the activity is not completed, and the performance code cannot be determined based on patient/caregiver report, collaboration with other agency staff, or assessment of similar activities. However, we acknowledge that there will be instances where an ANA code is the most appropriate response. We regularly review and update the manual as indicated. Additionally, if HHAs have questions related to the completion of these items, they can submit questions to the HH QRP Help Desk at *HomeHealthQualityQuestions@cms.hhs.gov.*

Comment: A commenter requested that CMS redesign DC Function so that is more equitable.

Response: We recognize that social determinants of health may have an impact on functional outcomes. Testing indicates that adding social determinants of health, such as dual eligibility and race/ethnicity, does not substantively affect provider scores for this measure. However, we will continue to monitor the impact of the previous factors, as is feasible, on the measures and incorporate them in measure calculations, as needed, to ensure the measure remains valid and reliable.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the DC Function measure as an assessment-based outcome measure beginning with the CY 2025 HH QRP as proposed.

2. Removal of the ''Application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function'' Beginning With the CY 2025 HH QRP

We are finalizing the removal of the ''Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function'' (Application of Functional Assessment/Care Plan) measure from the HH QRP beginning with the CY 2025 HH QRP. Section 42 CFR 484.245(b)(3) of our regulations specifies eight factors we consider for measure removal from the HH QRP, and we believe this measure should be removed because it satisfies two of these factors.

First, the Application of Functional Assessment/Care Plan measure meets the conditions for measure removal factor one: measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.[72] Second, this measure meets the conditions for measure removal factor six: there is an available measure that is more strongly associated with desired patient functional outcomes. We believe the DC function measure discussed previously better measures functional outcomes than the current Application of Functional Assessment/Care Plan measure.

In regards to removal factor one, the Application of Functional Assessment/Care Plan measure has become topped out, with average performance rates reaching nearly 100 percent over the past 3 years (ranging from 96–98 percent during calendar years (CYs) 2019–2021).[73] For the 12-month period of third quarter of CY 2021, HHAs had an average score for this measure of 98 percent, with nearly 75 percent of HHAs scoring 100 percent. The proximity of these mean rates to the maximum score of 100 percent suggests a ceiling effect and a lack of variation that restricts distinction among HHAs.

In regards to measure removal factor six, the DC Function measure is more strongly associated with desired patient functional outcomes than the current

[71] *https://www.cms.gov/files/document/hh-discharge-function-score-measure-technical-report.pdf.*

[72] For more information on the factors the Centers for Medicare & Medicaid Services (CMS) uses to base decisions for measure removal, we refer readers to the Code of Federal Regulations, § 484.245(b)(3) *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484/subpart-E/section-484.245.*

[73] CMS. Home Health Agency Data Archive, 2019–2021, Annual Files National Data. PDC, *https://data.cms.gov/provider-data/archived-data/home-health-services.*

process measure, the Application of Functional Assessment/Care Plan measure. As described in section IIII.D.1.e of this final rule, the DC Function measure has the predictive ability to distinguish patients with low expected functional capabilities from those with high expected functional capabilities.[74] We have been collecting standardized functional assessment elements across PAC settings since 2016 which has allowed for the development of the DC Function measure and meets the statutory requirements to submit standardized patient assessment data and other necessary data with respect to the domain of functional status, cognitive function, and changes in function and cognitive function. In light of this development, this process measure, the Application of Functional Assessment/Care Plan measure which measures only whether a functional assessment is completed and a functional goal is included in the care plan, is no longer necessary, and can be replaced with a measure that evaluates the HHA's outcome of care on a patient's function.

Because the Application of Functional Assessment/Care Plan measure meets measure removal factors one and six, we are finalizing to remove it from the HH QRP beginning with the CY 2025 HH QRP. We also proposed that public reporting of the Application of Functional Assessment/Care Plan measure will end by January 2025 or as soon as technically feasible when public reporting of the DC Function measure will begin (see section III.F.2. of this final rule).

HHAs will no longer be required to report a Self-Care Discharge Goal (that is, GG0130, Column 2) or a Mobility Discharge Goals (that is, GG0170, Column 2) on the OASIS beginning with patients with SOC/ROC on January 1, 2025. We will remove the items for Self-Care Discharge Goals (that is, GG0130, Column 2) and Mobility Discharge Goals (that is, GG0170, Column 2) with the next release of the OASIS. Under our proposal, these items will not be required to meet HH QRP requirements beginning with the CY 2025 HH QRP.

We solicited public comment on our proposal to remove the Application of Functional Assessment/Care Plan measure from the HH QRP beginning with the CY 2025 HH QRP. The following is a summary and responses to comments received for the removal of the Application of Functional Assessment/Care Plan measure.

Comment: All commenters supported the removal of the measure Application of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. Some commenters noted that the measure no longer offers meaningful distinction between home health providers since performance is high and unvarying.

Response: We thank commenters for their support of the removal of the Application of Functional Assessment/Care Plan measure.

After careful consideration of the public comments we received, we are finalizing our proposal to remove the Application of Functional Assessment/Care Plan measure from the HH QRP beginning with the CY 2025 HH QRP.

3. COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date, Beginning With the CY 2025 HH QRP

a. Background

COVID–19 has been and continues to be a major challenge for PAC facilities, including HHAs. The Secretary first declared COVID–19 a PHE on January 31, 2020. As of March 15, 2023, the U.S. has reported 103,801,821 cumulative cases of COVID–19, and 1,121,512 total deaths due to COVID–19.[75] Although all age groups are at risk of contracting COVID–19, older persons are at a significantly higher risk of mortality and severe disease following infection, with those over age 80 dying at five times the average rate.[76] Older adults, in general, are prone to both acute and chronic infections owing to reduced immunity, and are a high-risk population.[77] Adults age 65 and older comprise over 75% of total COVID–19 deaths despite representing 13.4% of reported cases.[78] Restrictions on freedom of movement and physical distancing can lead to a disruption of essential care and support for older persons. Physical distancing measures that restrict visitors and group activities can negatively affect the physical and mental health and well-being of older persons, particularly those with cognitive decline or dementia, and who are highly care-dependent.[79]

Since the development of the vaccines to combat COVID–19, studies have shown that being up to date on these vaccines continues to provide strong protection against severe disease, hospitalization, and death in adults, including during the predominance of Omicron BA.4 and BA.5 variants.[80] Initial studies showed the efficacy of FDA-approved COVID–19 vaccines in reducing the risk of severe outcomes caused by COVID–19. Further, residents at skilled nursing facilities (SNF) with high rates of staff testing for COVID–19 were less likely to be hospitalized or die due to COVID–19 than their counterparts in SNFs with low rates of staff testing. Prior to the emergence of the Delta variant of the virus, vaccine effectiveness against COVID–19-associated hospitalization among adults age 65 and older was 91% for those receiving a full mRNA vaccination (Pfizer-BioNTech or Moderna), and 84% for those receiving a viral vector vaccination (Janssen). Adults age 65 and older who were fully vaccinated with an mRNA COVID–19 vaccine had a 94% reduction in risk of COVID–19 hospitalization; those who were partially vaccinated had a 64% reduction in risk.[81] Further, after the emergence of the Delta variant, vaccine effectiveness against COVID–19-associated hospitalization for adults who received the primary series of the vaccine was 76% among adults age 75 and older.[82]

More recently, since the emergence of the Omicron variants and availability of

[74] ''Expected functional capabilities'' is defined as the predicted discharge function score.

[75] Centers for Disease Control and Prevention. COVID Data Tracker. 2023, January 20. Last accessed March 23, 2023. *https://covid.cdc.gov/covid-data-tracker/#cases_totalcases.*

[76] United Nations. Policy Brief: The impact of COVID–19 on older persons. May 2020. *https://unsdg.un.org/sites/default/files/2020-05/Policy-Brief-The-Impact-of-COVID-19-on-Older-Persons.pdf.*

[77] Lekamwasam R, Lekamwasam S. Effects of COVID–19 pandemic on health and wellbeing of older people: a comprehensive review. *Ann Geriatr Med Res.* 2020;24(3):166–172. *http://dx.doi.org/10.4235/agmr.20.0027. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7533189/.*

[78] Centers for Disease Control and Prevention. Demographic trends of COVID–19 cases and deaths in the US reported to CDC. COVID Data Tracker. 2023, March 15. Last accessed March 23, 2023. *https://covid.cdc.gov/covid-data-tracker/#demographics.*

[79] United Nations. Policy Brief: The impact of COVID–19 on older persons. May 2020. *https://unsdg.un.org/sites/default/files/2020-05/Policy-Brief-The-Impact-of-COVID-19-on-Older-Persons.pdf.*

[80] Chalkias S, Harper C, Vrbicky K, et al. A bivalent omicron-containing booster vaccine against COVID–19. *N Engl J Med.* 2022;387(14):1279–1291. doi: 10.0156/NEJMoa2208343. *https://www.nejm.org/doi/full/10.1056/NEJMoa2208343.*

[81] Centers for Disease Control and Prevention. Press Release, April 28, 2021. Fully Vaccinated Adults 65 and Older are 94% Less Likely to Be Hospitalized with COVID–19. *https://www.cdc.gov/media/releases/2021/p0428-vaccinated-adults-less-hospitalized.html.*

[82] Vaccine effectiveness after the emergence of the Delta variant is based on data from CDC's VISION Network, which examined 32,867 medical encounters from 187 hospitals and 221 emergency departments and urgent care clinics across nine states during June–August 2021, beginning on the date the Delta variant accounted for over 50% of sequenced isolates in each medical facility's state (Grannis SJ, et al. *MMWR Morb Mortal Wkly Rep.* 2021;70(37):1291–1293. doi: *http://dx.doi.org/10.15585/mmwr.mm7037e2*).

booster doses, multiple studies have shown that while vaccine effectiveness against infection has waned, protection is higher among those receiving booster doses than among those only receiving the primary series.[83] [84] [85] CDC data show that, among people age 50 and older, those who have received both a primary vaccination series and booster shots have a lower risk of hospitalization and dying from COVID–19 than their non-vaccinated counterparts.[86] Additionally, a second vaccine booster has been shown to be effective against severe outcomes related to COVID–19, such as hospitalization or death.[87] Furthermore, more recent vaccination and booster doses can decrease the rate of COVID–19 transmission between individuals in close contact.[88] Early evidence also demonstrates that the bivalent booster, specifically aimed to combat the prevalent BA.4/BA.5 Omicron subvariants, provokes a superior antibody response against Omicron than the initial COVID–19 vaccines, underscoring, the role of up-to-date vaccination protocols in effectively countering the spread of COVID–19.[89]

(1) Measure Importance

Despite the availability and demonstrated effectiveness of COVID–19 vaccinations, significant gaps continue to exist in vaccination rates.[90] As of March 15, 2023, vaccination rates among people age 65 and older are generally high for the primary vaccination series (94.3%) but lower for the first booster (73.6%) among those who received a primary series) and even lower for the second booster (59.9%) among those who received a first booster).[91] Additionally, though the uptake in boosters among people age 65 and older has been much higher than among people of other ages, booster uptake still remains relatively low compared to primary vaccination among older adults.[92] Variations are also present when examining vaccination rates by race, gender, and geographic location.[93] For example, 66.2% of the Asian, non-Hispanic population have completed the primary series and 21.2% have received the bivalent booster dose, whereas 44.9% of the Black, non-Hispanic population have completed the primary series and only 8.9% have received the bivalent booster dose. Among Hispanic populations, 57.1% of the population have completed the primary series, with 8.5% receiving the bivalent booster dose, while in White, non-Hispanic populations, 51.9% have completed the primary series and 16.2% have received the bivalent booster dose.[94] Disparities have been found in vaccination rates between rural and urban areas, with lower vaccination rates found in rural areas.[95] [96] Data show that 55.1% of the population in rural areas have completed the primary vaccination series, as compared to 66.2% of the population in urban areas.[97] Receipt of first booster doses was similar between urban (50.4%) and rural (49.7%) counties.[98] Receipt of bivalent booster doses has been lower, with 16.9% of urban population having received the booster dose, and 10.9% of the rural population having received the booster dose.[99]

We proposed to adopt the COVID–19 Vaccine: Percent of Patients/Residents who are Up to Date (Patient/Resident COVID–19 Vaccine) measure for the HH QRP beginning with the CY 2025 HH QRP. This final measure has the potential to increase COVID–19 vaccination coverage of patients in HHAs. This final measure also has the potential to prevent the spread of the virus within the HHA patient population. Although this population receives services within their own homes, they can transfer the virus to their caretakers and home healthcare workers, who could then potentially infect other home health patients. The COVID–19 Vaccine measure will also support the goal of the CMS Meaningful Measure Initiative 2.0 to ''Empower consumers to make good health care choices through patient-directed quality measures and public transparency objectives.'' The Patient/Resident COVID–19 Vaccine measure will be reported on Care Compare an interactive web tool that assists individuals by providing information on quality of care. For more information on Care Compare, we refer readers to our website at: *https://www.medicare.gov/care-compare/.* This will provide patients, including those who are at high risk for developing serious complications from COVID–19, and their caregivers, with valuable information they can consider when choosing a HHA. The Patient/Resident

[83] Surie D, Bonnell L, Adams K, et al. Effectiveness of monovalent mRNA vaccines against COVID–19–associated hospitalization among immunocompetent adults during BA.1/BA.2 and BA.4/BA.5 predominant periods of SARS–CoV–2 Omicron variant in the United States—IVY Network, 18 states, December 26, 2021–August 31, 2022. *MMWR Morb Mortal Wkly Rep.* 2022;71(42):1327–1334. *http://dx.doi.org/10.15585/mmwr.mm7142a3.*

[84] Andrews N, Stowe J, Kirsebom F, et al. Covid–19 vaccine effectiveness against the Omicron (B.1.1.529) variant. *N Engl J Med.* 2022;386(16):1532–1546. *https://www.nejm.org/doi/full/10.1056/NEJMoa2119451.*

[85] Buchan SA, Chung H, Brown KA, et al. Estimated effectiveness of COVID–19 vaccines against Omicron or Delta symptomatic infection and severe outcomes. *JAMA Netw Open.* 2022;5(9):e2232760. *http://dx.doi.org/10.1001/jamanetworkopen.2022.32760. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796615.*

[86] Centers for Disease Control and Prevention. Daily update for the United States. COVID Data Tracker. 2023, January 20. Last accessed January 17, 2023. *https://covid.cdc.gov/covid-data-tracker.*

[87] Centers for Disease Control and Prevention. COVID–19 vaccine effectiveness monthly update. COVID Data Tracker. March 23, 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness.*

[88] Tan ST., Kwan AT, Rodriguez-Barraquer I, et al. Infectiousness of SARS–CoV–2 breakthrough infections and reinfections during the Omicron wave. Preprint at medRxiv:

[89] Chalkias S, Harper C, Vrbicky K, et al. A bivalent Omicron-containing booster vaccine against COVID–19. *N Engl J Med* 2022;387(14):1279–1291. doi: 10.0156/NEJMoa2208343. *https://www.nejm.org/doi/full/10.1056/NEJMoa2208343.*

[90] Centers for Disease Control and Prevention. COVID–19 vaccinations in the United States. COVID Data Tracker. March 23, 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-pop5.*

[91] Centers for Disease Control and Prevention. COVID–19 vaccination age and sex trends in the United States, national and jurisdictional. Last accessed March 24, 2023. Vaccination Trends.

[92] Freed M, Neuman T, Kates J, Cubanski J. Deaths among older adults due to COVID–19 jumped during the summer of 2022 before falling somewhat in September. Kaiser Family Foundation. October 6, 2022. *https://www.kff.org/coronavirus-covid-19/issue-brief/deaths-among-older-adults-due-to-covid-19-jumped-during-the-summer-of-2022-before-falling-somewhat-in-september/.*

[93] Saelee R, Zell E, Murthy BP, et al. Disparities in COVID–19 vaccination coverage between urban and rural counties—United States, December 14, 2020–January 31, 2022. *MMWR Morb Mortal Wkly Rep.* 2022;71:335–340. *http://dx.doi.org/10.15585/mmwr.mm7109a2.*

[94] Centers for Disease Control and Prevention. Trends in Demographic Characteristics of People Receiving COVID–19 Vaccinations in the United States. COVID Data Tracker. 2023, January 20. Last accessed March 23, 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends.*

[95] Saelee R, Zell E, Murthy BP, et al. Disparities in COVID–19 vaccination coverage between urban and rural counties—United States, December 14, 2020–January 31, 2022. *MMWR Morb Mortal Wkly Rep.* 2022;71:335–340. DOI: *http://dx.doi.org/10.15585/mmwr.mm7109a2.*

[96] Sun Y, Monnat SM. Rural-urban and within-rural differences in COVID–19 vaccination rates. *J Rural Health.* 2022;38(4):916–922. *http://dx.doi.org/10.1111/jrh.12625. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8661570/.*

[97] Centers for Disease Control and Prevention. Vaccination Equity. COVID Data Tracker; 2023, January 20. Last accessed January 17, 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-equity.*

[98] Saelee R, Zell E, Murthy BP, et al. Disparities in COVID–19 vaccination coverage between urban and rural counties—United States, December 14, 2020–January 31, 2022. *MMWR Morb Mortal Wkly Rep.* 2022;71:335–340. *http://dx.doi.org/10.15585/mmwr.mm7109a2.*

[99] Centers for Disease Control and Prevention. Vaccination Equity. COVID Data Tracker; 2023, January 20. Last accessed January 17, 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-equity.*

COVID–19 vaccine measure will also facilitate patient care and care coordination during the hospital discharge planning process. For example, a discharging hospital, in collaboration with the patient and family, could use this measure to coordinate care and ensure patient preferences are considered in the discharge plan. Additionally, the Patient/Resident COVID–19 Vaccine measure will be an indirect measure of HHA action. Since the patient's COVID–19 vaccination status will be reported at discharge from the HHA, if a patient is not up to date with their COVID–19 vaccination per applicable CDC guidance at the time they are admitted, the HHA has the opportunity to educate the patient and provide information on why they should become up to date with their COVID–19 vaccination. HHAs may also choose to administer the vaccine to the patient prior to their discharge from the HHA or coordinate a follow up visit for the patient to obtain the vaccine at their physician's office or local pharmacy.

(2) Item Testing

Item testing was conducted for the Patient/Resident COVID–19 Vaccine measure using patient scenarios and cognitive interviews to assess HHA providers' comprehension of the item and the associated guidance. The patient scenarios were developed in collaboration with a team of clinical experts and represented the most common scenarios HHA staff encounter. The results of the item testing supported its reliability, and provided information to improve the item itself, as well as the accompanying guidance.

b. Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, each measure specified under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The Patient/Resident COVID–19 Vaccine measure is not consensus-based entity (CBE) endorsed. After review of other CBE endorsed measures, we were unable to identify any CBE endorsed measures for HHAs focused on capturing COVID–19 vaccination coverage of HHA patients and found no related measures in the HH QRP addressing COVID–19 vaccination. There have been COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measures adopted by the Skilled Nursing Facility (SNF) QRP, the Inpatient Rehabilitation Facility (QRP) and the Long-term Care Hospital (LTCH) QRP that captures the percentage of HCPs who receive a complete COVID–19 vaccination course. HHAs do not currently report patient/resident or HCP COVID–19 vaccination data.

Therefore, after consideration of other available measures that assess COVID–19 vaccination rates, we believe the exception under section 1899B(e)(2)(B) of the Act applies. We intend to submit the measure for CBE endorsement when feasible.

c. Interested Parties and Technical Expert Panel (TEP) Input

In the development and specification of this measure, a transparent process was employed to seek input from interested parties and national experts and engage in a process that allows for pre-rulemaking input in accordance with section 1890A of the Act. First, the measure development contractor convened a focus group of patient and family/caregiver advocates (PFAs) to solicit input. The PFAs believe a measure capturing raw vaccination rate, irrespective of HHA action, will be most helpful in patient and family/caregiver decision-making. Next, TEP meetings were held on November 19, 2021 and December 15, 2021 to solicit feedback on the development of Patient/Resident COVID–19 vaccination measures and assessment items for the PAC settings. The TEP panelists voiced their support for PAC Patient/Resident COVID–19 vaccination measures and agreed that developing a measure to report the rate of vaccination in an HHA setting without denominator exclusions was an important goal. All recommendations from the TEP were taken into consideration and applied appropriately where technically feasible and appropriate. A summary of the TEP proceedings titled *Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID–19 Vaccination-Related Items and Measures Summary Report* is available on the CMS Measures Management System (MMS) Hub. at *https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf.*

d. Measures Applications Partnership Review

The pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List that the Secretary is considering adopting, through Federal rulemaking process, for use in Medicare programs. This allows interested parties to provide recommendations to the Secretary on the measures included on the list. The Patient/Resident COVID–19 Vaccine measure was included on the publicly available 2022 MUC List for the HH QRP.[100] Shortly after, several CBE-convened MAP workgroups met virtually to provide input on the measure. First, the MAP Health Equity advisory group convened on December 6, 2022. One MAP member noted that the percentage of true contraindications for the COVID–19 vaccine is low, and the lack of exclusions on the measure makes sense to avoid varying interpretations of valid contraindications.[101] Similarly, the MAP Rural Health advisory group met on December 8, 2022 and publicly stated that the measure is important for rural communities.[102]

Prior to convening the MAP PAC/LTC workgroup, the CBE received seven comments by industry interested parties during the measure's MAP pre-rulemaking process. Interested parties were mostly supportive of the measure and recognized that it is important that patients be vaccinated against COVID–19, and that measurement and reporting is one important method to help healthcare organizations assess their performance in achieving high rates of ''up-to-date'' vaccination. One interested party noted that patient engagement is critical at this stage of the pandemic because best available information indicates COVID–19 variants will continue to require additional boosters to avert case surges. Another interested party noted the benefit of less-specific criteria for

[100] CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and MAP reports. Last accessed March 23, 2023 *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[101] National Quality Forum MAP Health Equity Advisory Group Materials. Meeting Summary—MUC Review Meeting. Last accessed March 23, 2023. *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=97943.*

[102] National Quality Forum MAP Rural Health Advisory Group Materials. Meeting Summary—MUC Review Meeting. Last accessed March 23, 2023. *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=97964.*

inclusion in the numerator and denominator of the Patient/Resident COVID–19 Vaccine measure, which will provide flexibility for the measure to remain relevant to current circumstances. Other interested parties raised concerns about the measure not including measuring the HHA's action in the numerator and excluding patient refusals from the denominator, and noted that there could be unintended consequences to patient access to care should the measure be adopted.

Subsequently, the MAP Post-Acute Care/Long-Term Care (PAC/LTC) workgroup met on December 12, 2022. The voting workgroup members noted the importance of reporting patients' vaccination status but raised concerns that (1) the proposed Patient/Resident COVID–19 Vaccine measure does not account for patient refusals or those who are unable to respond, and (2) the difficulty of implementing ''up to date.'' CMS clarified during the MAP PAC/LTC workgroup meeting that the proposed Patient/Resident COVID–19 Vaccine measure does not have exclusions for patient refusals because the proposed measure was intended to report raw rates of vaccination and this information is important for consumer choice. Additionally, CMS believes that PAC providers, including HHAs, are in a unique position to leverage their care processes to increase vaccination coverage in their settings to protect patients and prevent negative outcomes. CMS also clarified that the measure defines ''up to date'' in a manner that provides flexibility to reflect future changes in CDC guidance. However, the MAP PAC/LTC workgroup reached a 60 percent majority on the vote of ''Do not support for rulemaking'' for this measure.[103]

The MAP received 10 comments by interested parties in response to the MAP PAC/LTC workgroup recommendations. Interested parties generally understood the importance of COVID–19 vaccinations in preventing the spread of COVID–19 infections. However, a majority of commenters did not recommend the inclusion of this measure for the HH QRP and raised several concerns. Specifically, several commenters were concerned about vaccine hesitancy, HHAs' inability to influence measure results based on factors outside of their control. Commenters also noted that the proposed Patient/Resident COVID–19 Vaccine measure has not been fully tested, and encouraged CMS to monitor the measure for unintended consequences and ensure that the measure has meaningful results. A commenter was in support of the proposed Patient/Resident COVID–19 Vaccine measure and provided recommendations for CMS to consider. Including an exclusion for medical contraindications and submitting the measure for CBE endorsement.

Finally, the MAP Coordinating Committee convened on January 24, 2023, and raised concerns which were previously discussed in the PAC/LTC workgroup, such as potential for selection bias based on the patient's vaccination status. CMS noted that this measure does not have exclusions for patient refusals, since this is a process measure intended to report raw rates of vaccination, and is not intended to be an HHA action measure. CMS acknowledged that a measure accounting for variables (such as HHA actions to vaccinate patients) could be important, but CMS is focused on a measure which will provide and publicly report vaccination rates for consumers given the importance of this information to patients and their caregivers.

The MAP Coordinating Committee recommended three changes to make the Patient/Resident COVID–19 Vaccine measure acceptable to the Committee: (i) reconsider exclusions for medical contraindications, (ii) complete reliability and validity measure testing, and (iii) seek CBE endorsement. The MAP Coordinating Committee ultimately reached majority on its voted recommendation of 'Do not support with potential for mitigation.' We refer readers to the final MAP recommendations, titled *2022–2023 MAP Final Recommendations* [104] and the *MAP Final Report.*[105] Despite the Coordinating Committee's vote, we believe it is still important to propose the Patient/Resident COVID–19 Vaccine measure for the HH QRP. As we stated in section III.C.3.e of this final rule, we did not include exclusions for medical contraindications because the PFAs we met with told us that a measure capturing raw vaccination rate, irrespective of any medical contraindications, will be most helpful in patient and family/caregiver decision-making. We do plan to conduct reliability and validity measure testing once we have collected enough data and intend to submit the measure to the CBE for consideration of endorsement when feasible.

e. Quality Measure Calculation

The proposed Patient/Resident COVID–19 Vaccine measure is an assessment-based process measure that reports the percent of home health patients that are up to date on their COVID–19 vaccinations per CDC's latest guidance.[106] This measure has no exclusions and is not risk adjusted.

The numerator for this measure will be the total number of home health patients that are up to date with the COVID–19 vaccine during the reporting period. The denominator for the measure will be the total number of home health quality episodes with an End of Care OASIS (Discharge, Transfer or Death at Home) during the reporting period.

The data source for the final Patient/Resident COVID–19 Vaccine measure is the OASIS assessment instrument for home health patients. For more information about the final data submission requirements, we refer readers to section III.E.2 of this final rule. For additional technical information about this proposed measure, we refer readers to the draft measure specifications document titled *Patient-Resident-COVID-Vaccine-Draft-Specs.pdf* available at: *https://www.cms.gov/files/document/patient-covid-vaccine-measure-hh-qrp-specifications.pdf.*

We solicited public comments on our proposal to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the CY 2025 HH QRP. The following is a summary of the comments we received on our proposal to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure and responses to comments.

Comment: Commenters who supported the Patient/Resident COVID–19 vaccine QM noted the continued risk of infection, particularly among older adults, and demonstrated effectiveness of the vaccine were cited as the main reasons for supporting this CMS proposal. Additionally, respondents stated that public reporting of this data will be beneficial to patients and caregivers when making decisions about choosing an HHA since this would help to incentivize agencies to provide

[103] National Quality Forum MAP Post-Acute Care/Long Term Care Workgroup Materials. Meeting Summary—MUC Review Meeting. Last accessed March 23, 2023. *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=97960.*

[104] *2022–2023 MAP Final Recommendations,* can be found at *https://www.qualityforum.org/map/.*

[105] The Final MAP Report is available at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=98102.*

[106] The definition of ''up to date'' may change based on CDC's latest guidelines and can be found on the CDC web page, ''Stay Up to Date with COVID–19 Vaccines Including Boosters,'' at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html* (updated March 2, 2023).

quality education on vaccination to beneficiaries.

Response: We thank the commenters for their support and agree that the Patient/Resident COVID–19 Vaccine measure would provide patients and caregivers, including those who are at high risk for developing serious complications from COVID–19, with valuable information they can consider when choosing an HHA.

Comment: Some commenters opposed the COVID–19 resident/patient measure because it does not have exclusions, specifically for those who have religious exemptions, for medical contraindications, and for refusals.

Response: As we stated in section III.3.e of this CY 2024 HH PPS final rule, we did not include exclusions for medical contraindications because feedback from a patient and family focus group that provided feedback on the measure emphasized that a measure capturing raw vaccination rate, irrespective of any medical contraindications, would be most helpful in patient and family/caregiver decision-making. Based on this feedback, we believe excluding patients/residents with contraindications from the measure would distort the intent of the measure of providing raw COVID–19 patient vaccination rates, while making the information more difficult for residents/caregivers to interpret, and hence did not include any exclusions.

Comment: Some commenters opposed the measure because of burden concerns. The inclusion of another data element in OASIS and documentation of compliance with the continually changing definition of ''up to date'' were described as likely to cause undue burden to agencies.

Response: CMS believes HHAs should be assessing whether patients are up to date with COVID–19 vaccination as a part of their routine care and infection control processes, and during our item testing, we heard from HHAs that they are routinely inquiring about COVID–19 vaccination status at start of care. To ensure appropriate coding of the assessment item, HHAs would be able to use a range of sources of information to obtain a patient's vaccination status, such as patient interviews, medical records, proxy response, and vaccination cards provided by the patient or their caregivers. As with any assessment item in the OASIS, we will also publish coding guidance and instructions to further support HHAs in collection of these data.

Comment: Some commenters raised the issue that the measure has not been tested for validity and reliability, nor was it supported by a consensus-based entity was also frequently cited as a reason for opposing its inclusion.

Response: CMS acknowledges that we have not yet tested the measure for reliability and validity, we have tested the item proposed for the OASIS to capture data for this measure and its feasibility and appropriateness. Since a COVID–19 vaccination item does not yet exist within the OASIS, we developed clinical vignettes to test item-level reliability of a draft Patient/Resident COVID–19 Vaccine measure. The clinical vignettes were a proxy for patient records with the most common and challenging cases HHAs would encounter, similar to the approach that we use to train HHAs on all new assessment items, and the results demonstrated strong agreement. We have not completed validity testing for this QM since the data element is not yet on OASIS. However, this QM is modeled after other vaccination items and quality measures used in PAC settings. We intend to complete reliability and validity testing for this specific Patient/Resident COVID–19 Vaccine measure once the COVID–19 vaccination item has been added to the OASIS and we have collected sufficient data. Additionally, we solicited feedback from our TEP on the proposed assessment item and its feasibility. No concerns were raised by the TEP regarding obtaining the information that would be required to complete the new COVID–19 vaccination item.

Comment: Some commenters did not support adoption of this measure in light of the Administration's announcement of the end of the COVID–19 PHE on May 11, 2023. Tracking vaccination status was described by some commenters as no longer relevant based on the end of the PHE and the vaccine mandate.

Response: Despite the announcement of the end of the COVID–19 PHE, many people continue to be affected by COVID–19, particularly seniors, the immunocompromised, and people with disabilities. As mentioned in the End of COVID–19 Public Health Emergency Fact Sheet,[107] our response to the spread of SARS–CoV–2, the virus that causes COVID–19, remains a public health priority. Even beyond the end of the COVID–19 PHE, we will continue to work to protect Americans from the virus and its worst impacts by supporting access to COVID–19 vaccines, treatments, and tests, including for people without health insurance. Given the continued impacts of COVID–19, we believe it is important to promote resident vaccination and education, which this measure aims to achieve. Accordingly, we are aligning our approach with those for other infectious diseases, such as influenza, by encouraging ongoing COVID–19 vaccination.[108] Further, published coding guidance will indicate how to code the item taking into account CDC guidelines, and HHAs could access the CDC website at any time to find the definition of up to date. Lastly, this measure as proposed for the HH QRP is not associated with the PHE declaration, or the Conditions of Participation. This measure is being proposed to address our priority to empower consumers to make informed health care choices through resident-directed quality measures and public transparency, as with previous vaccination measures.

Comment: Commenters also suggested that information on COVID–19 vaccination status was already tracked by other healthcare agencies, and believe this measure and item constituted an unnecessary duplication of effort.

Response: We believe that COVID–19 vaccination for high-risk populations, such as those receiving HH care, is of paramount importance. This is particularly important for HH patients, who tend to be older and thus more vulnerable to serious complications from COVID–19. Therefore, if a patient is not vaccinated at start of care, the HHA has the opportunity to continue to educate the patient and provide information on why they should receive the vaccine, irrespective of whether the patient has received prior education.

Comment: A few commenters argued that the measure itself is not actually a reflection of an agency's quality, and that just asking a person if they are up to date on their vaccination does not improve vaccination uptake, infection control, nor does it provide context for their answers or meaningful data for quality of care or outcomes.

Response: We believe the COVID–19 vaccination is a beneficial addition to the other vaccination measure in the HH QRP. We believe it is an indirect measure of provider action since HHAs have the opportunity to encourage, as

[107] Fact Sheet: End of the COVID–19 Public Health Emergency. U.S. Department of Health and Human Services. May 9, 2023. *https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html.*

[108] 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 Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs–IID) To Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID–19 Testing Requirements.

well as coordinate, vaccinations among patients. This is particularly important for HH patients, who tend to be older and thus more vulnerable to serious complications from COVID–19. CDC data show that, among people age 50 and older, those who have received both a primary vaccination series and booster doses have a lower risk of hospitalization and dying from COVID–19 than their non-vaccinated counterparts.[109] Additionally, a second vaccine booster dose has been shown to reduce risk of severe outcomes related to COVID–19, such as hospitalization or death, for older patients. The number of patients who have been vaccinated in a HHA does not impact a HHA's ability to successfully report the measure to comply with the requirements of the HH QRP. Finally, we appreciate the commitment of HHAs and HHA efforts at ensuring patients are educated and encouraged to become and remain up to date with their COVID–19 vaccinations.

Comment: Multiple commenters described that despite efforts to educate and encourage patients to stay up to date on their vaccines, many still decline to take them. Therefore, home health agencies cannot control patient decisions around vaccination and many PAC settings cannot deliver the vaccines themselves even if patients wanted them. Therefore, the ability to affect the measure was perceived as being out of a HH agency's control and more appropriate for primary care.

Response: We acknowledge that individual residents have a choice regarding whether to receive a COVID–19 vaccine or booster dose(s), but patients and their caregivers also have choices about selecting PAC providers, and it is our role to empower them with the information they need to make an informed decision by publicly reporting the data we receive from HHAs on this measure. We understand that despite a HHA's best efforts, there may be instances where a patient may choose not to receive a primary or booster dose of the COVID–19 vaccine. However, we want to remind HHAs that this measure does not mandate patients be up to date with their COVID–19 vaccine. We are unaware of any access issues to COVID–19 vaccines or vaccine production delays. This measure does not require HHAs to administer the vaccine themselves. They could arrange for the patient to obtain the vaccine via a primary care provider or work with community pharmacies.

Comment: Some commenters suggested that in order to make the measure more appropriate for the home health environment, CMS should focus on promotion of the vaccine rather than whether or not patients were up to date. This could include a count of the number of documented encounters agency staff had with a patient and/or their family concerning the COVID–19 vaccine or promoting and/or offering the COVID–19 vaccine as the metric.

Response: We thank commenters for alternate measure suggestions. We believe the measure as currently specified provides the most appropriate information for the public.

Comment: Some commenters also asked CMS to consider how the measure may lead to bias. Commenters suggested that home health agencies serving patient populations that have demonstrated higher vaccine uptake would have an advantage over home health providers who serve populations with vaccine hesitancy, and this could also potentially lead to providers avoiding the care of patients who are not up to date or do not want the COVID vaccine.

Response: We do not anticipate issues with patient access to HH care if this measure is adopted. Use or adoption of other vaccination measures in PAC settings have not previously impacted access to care. We believe HHAs consider patient care of paramount importance and will not refuse care to patients based on their vaccination status. We also believe HHAs should use clinical judgement to determine if a patient is eligible to receive the vaccination. We intend to monitor closely whether any proposed change to the HH QRP has unintended consequences on access to care. Should we find any unintended consequences, we will take appropriate steps to address these issues in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Patient/Resident COVID–19 Vaccine measure as an assessment-based measure beginning with the CY 2025 HH QRP as proposed.

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

1. Final Schedule for Data Submission of the Discharge Function Score Measure Beginning With the CY 2025 HH QRP

As discussed in section III.C.1. of the final rule, we proposed to adopt the Discharge Function Score quality measure beginning with the CY 2025 HH QRP. The measure first public reported in January 2025 will be based on data reported on the OASIS assessment beginning with patients discharged between April 1, 2024 and March 31, 2024 for the CY 2025 HH QRP. Because the Discharge Function Score quality measure is calculated based on data that are currently submitted to the Medicare program, there will be no additional information collection required from HHAs.

We solicited public comments on this proposal to utilize OASIS assessment data for the Discharge Function Score quality measure beginning with assessment data from patients discharged between April 1, 2024 and March 31, 2024 for the CY 2025 HH QRP. We received no comments addressing this proposal. Therefore, after consideration of the public comments we received, we are finalizing our proposal to utilize already collected data to report the Discharge Function measure beginning in CY 2025.

2. Final Schedule for Data Submission of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Beginning With the CY 2026 HH QRP

As discussed in section III.C.3 of the final rule, we are proposed to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date quality measure beginning with the CY 2025HH QRP. If finalized as proposed, HHAs will be required to report these OASIS assessment data beginning with patients discharged between January 1, 2025 and March 31, 2025 for the CY 2025 HH QRP.

If finalized as proposed, we will revise the OASIS in order for HHAs to submit data pursuant to this finalized policy. A new item will be added to the current item set to collect information on whether a patient is up to date with their COVID–19 vaccine at the time of discharge from the HHA. A draft of the new item is available in the *COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date* Draft Measure Specifications at *https://www.cms.gov/files/document/patient-covid-vaccine-measure-hh-qrp-specifications.pdf*.

We solicited public comments on this proposal to require HHAs to report OASIS assessment data for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date quality measure. HHAs will be required to submit data beginning with patients discharged between January 1, 2025 and March 31, 2025 for public reporting of this QM in the CY 2026 HH QRP. The

[109] Centers for Disease Control and Prevention. Rates of laboratory-confirmed COVID–19 hospitalizations by vaccination status. COVID Data Tracker. 2023, February 9. Last accessed March 22, 2023. *https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination.*

following is a summary of the comments we received on our proposal to report OASIS assessment data for the COVID–19 Vaccine for Patients measure and our response to the comments.

Comment: Some commenters raised burden concerns related to the COVID–19 vaccine for patients data element. The inclusion of another data element in OASIS and documentation of compliance with the continually changing definition of ''up to date'' were described as likely to cause undue burden to agencies.

Response: CMS believes HHAs should be assessing whether patients are up to date with COVID–19 vaccination as a part of their routine care and infection control processes, and during our item testing, we heard from HHAs that they are routinely inquiring about COVID–19 vaccination status at start of care. To ensure appropriate coding of the assessment item, HHAs would be able to use a range of sources of information to obtain a patient's vaccination status, such as patient interviews, medical records, proxy response, and vaccination cards provided by the resident or their caregivers. As with any assessment item in the OASIS, we will also publish coding guidance and instructions to further support HHAs in collection of these data.

After consideration of the public comments we received, we are finalizing our proposal to require HHAs to report OASIS assessment data for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date quality measure.

3. Data Elements Finalized for Removal From OASIS–E

CMS plans to remove two OASIS items, the M0110—Episode Timing and M2200—Therapy Need effective January 1, 2025. These items are no longer used in the calculation of quality measures already adopted in the HH QRP, nor are they being used currently for previously established purposes unrelated to the HH QRP, including payment, survey, the HH VBP Model or care planning.

CMS finalizes the removal of items from OASIS–E from the specific time points during a home health episode as outlined in Table C3.

TABLE C3– FINAL DATA ELEMENTS TO BE REMOVED FROM OASIS-E ON JANUARY 1, 2025

OASIS-E item	Data Elements at Each Time Point					
	Start of care	Resumption of care	Follow-up	Transfer to an inpatient facility	Death at home	Discharge – not to an inpatient facility
M0110 Episode Timing	1	1	1			
M2200 Therapy Need	1	1				
Total	2	2	1			

Note: A list of the proposed two OASIS items and their data elements are outlined in the Downloads Section of the CMS OASIS Data Sets page located at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html*

For a discussion in the reduction in burden associated with the removal of these items, see section IX of this final rule.

We requested public comment on our proposal to remove the M0110—Episode Timing and M2200—Therapy Need items from OASIS–E, effective January 1, 2025. The following summarizes comments received on this proposal and our response.

Comment: Commenters unanimously supported the removal of the M0110—Episode Timing data element.

Response: CMS appreciates support for the removal of this data element.

Comment: Most commenters supported the removal of the M2200—Therapy Need data element.

Response: CMS appreciates support for the removal of this data element.

Comment: Some commenters opposed removal of the M2200—Therapy Needs data element out of concern that it would limit CMS' ability to evaluate a patient's therapy need.

Response: CMS appreciates the concern from commenters regarding CMS's ability to evaluate patient's therapy needs. With a broad set of new and current data elements on the OASIS–E assessment tool, CMS has improved the ability of providers to assess functional status and therapy needs that allows for the removal of the M2200-Therapy Need data element.

After consideration of the public comments we received, we are finalizing our proposal to remove the M0110—Episode Timing and M2200—Therapy Need items from OASIS–E, effective January 1, 2025 as proposed.

F. Policies Regarding Public Display of Measure Data for the HH QRP

1. Background

Section 1899B(g)(1) of the Act requires, in part, that the Secretary provide for public reporting of PAC provider performance, including HHAs, on quality measures under section 1899B(c)(1) of the Act, including by establishing procedures for making available to the public information regarding the performance of individual PAC providers with respect to such measures. Section 1899B(g)(2) requires, in part, that CMS give HHAs opportunity to review and submit corrections to the data and information to be made public under section 1899B(g)(1) prior to such data being made public. Section 1899B(g)(3) of the Act requires that such procedures provide that the data and information with respect to a measure and PAC provider is made publicly available beginning not later than 2 years after the applicable specified application date applicable to such measure and provider. Measure data are currently publicly displayed on the Care Compare website, an interactive web tool that assists individuals by providing information on quality of care. For more information on Care Compare, we refer readers to our website at: *https://www.medicare.gov/care-compare/*.

2. Public Reporting of the Cross-Setting Functional Discharge Measure Beginning With the CY 2025 HH QRP

We are finalizing our policy to begin publicly displaying data for the DC Function measure beginning with the January 2025 refresh of Care Compare,

or as soon as technically feasible in a subsequent refresh, using data collected from April 1, 2023 through March 31, 2024 (Quarter 2 2023 through Quarter 1 2024). If finalized as proposed, an HHAs DC Function score will be displayed based on four quarters of data. Provider preview reports will be distributed in October 2024, or as soon as technically feasible. Thereafter, an HHA's DC Function score will be publicly displayed based on four quarters of data and updated quarterly. To ensure the statistical reliability of the data, we are finalizing that we will not publicly report an HHAs performance on the measure if the HHA had fewer than 20 eligible cases in any quarter. HHAs that have fewer than 20 eligible cases will be distinguished with a footnote that notes that the number of cases/patient stays is too small to report.

We solicited public comments on this proposal to publicly report the Discharge Function Score quality measure beginning with CY 2025 HH QRP. The following is a summary of the comments we received on our proposal to publicly report the Discharge Function measure and our responses to the comments.

Comment: Many commenters supported public reporting of the DC Function measure.

Response: We thank the commenters for their support to publicly report the proposed measure.

Comment: Some commenters supported public reporting of the DC Function measure but suggested a longer delay in reporting than the timeframe discussed in the proposed rule.

Response: CMS appreciates the feedback received related to the time frame for public reporting. Since this measure will be derived from assessment data already available on the OASIS, results will be available to providers in 2024 and the Discharge Function measure will be able to be reported in CY2025. This will afford providers the time to review their measure results, CMS sufficient time to provide additional provider education, and replacement of the Application of Functional Assessment/Care Plan with the Discharge Function measure in addressing quality of care related to functional status more comprehensively.

After consideration of the public comments we received, we are finalizing our proposal to publicly report the Discharge Function measure beginning in CY2025.

3. Public Reporting of the Transfer of Health Information to the Patient Post-Acute Care and Transfer of Health Information to the Provider Post-Acute Care Measures Beginning With the CY 2025 HH QRP

We are finalizing our decision to begin publicly displaying data for the measures: (1) Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider); and (2) Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure (TOH-Patient). We will begin displaying data with the January 2025 Care Compare refresh or as soon as technically feasible. We adopted these measures in the calendar year (CY) 2020 HH Prospective Payment System (PPS) final rule (84 FR 60478). In response to the COVID–19 public health emergency (PHE), we released an interim final rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the TOH-Provider and TOH-Patient measures. The compliance date for the collection and reporting of the TOH-Provider and TOH-Patient measures was revised to January 1, 2023 in the calendar year (CY) 2022 Home Health PPS Rate Update final rule (86 FR 62386 through 62390). Data collection for these two assessment-based measures began with patients with SOC/ROCs and discharged on or after January 1, 2023.

We proposed to publicly display data for these two assessment-based measures based on four rolling quarters, initially using discharges from April 1, 2023 through March 31, 2024 (Quarter 2 2023 through Quarter 1 2024), and to begin publicly reporting these measures with the January 2025 refresh of Care Compare, or as soon as technically feasible in a subsequent refresh. To ensure the statistical reliability of the data, we proposed that we will not publicly report an HHA's performance on the measure if the HHA had fewer than 20 eligible cases in any quarter. HHAs that have fewer than 20 eligible cases will be distinguished with a footnote that notes that the number of quality episodes is too small to report.

We invited public comment on our proposal for the public display of the (1) Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider) and (2) Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure (TOH-Patient) assessment-based measures. The following is a summary of the comments received:

Comment: Most commenters support the public reporting of the Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider) and Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure (TOH-Patient) assessment-based measures.

Response: CMS thanks commenters for the support of this proposal.

Comment: A few commenters suggested delaying by a few years the public reporting of the TOH measures to afford more time for review of data output or to incorporate further changes to the measures.

Response: Providers will have the opportunity to review their TOH scores via provider reports in 2023 in advance of public reporting. Consistent with the implementation of these measures in other PAC settings, we began providing provider education in 2022. Additionally, our helpdesks have been responding to provider questions about these measures since data collection began for TOH data elements in January 2023. We believe the TOH measures have addressed substantive public feedback that resulted in the creation of separate patient and provider measures.

After consideration of the public comments we received, we are finalizing our proposal to publicly report the Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider) and Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure (TOH-Patient) assessment-based measures, as proposed beginning with the January 2025 Care Compare refresh or as soon as technically feasible after.

4. Public Quarterly Reporting of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Beginning With the CY 2026 HH QRP

We are finalizing our policy to begin publicly displaying quarterly data for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the January 2026 refresh of Care Compare or as soon as technically feasible after using data collected for Q1 2025 (January 1, 2025 through March 31, 2025). As noted previously, we are displaying the measure, ''Patient/Resident level COVID–19 Vaccine percent of patients who are up to date'' based on one quarter of data. Provider preview reports will be distributed in October 2025, or as soon as technically feasible. Thereafter, the percent of HHA patients who are up to date with their COVID–19 vaccinations will be publicly displayed based on one quarter of data per report and updated with new data quarterly. To ensure the statistical

reliability of the data, we proposed that we will not publicly report an HHAs performance on the measure if the HHA had fewer than 20 eligible cases in any quarter. HHAs that have fewer than 20 eligible cases will be distinguished with a footnote that notes that the number of quality episodes is too small to report.

We sought public comment on the proposal for the public display of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the January 2026 refresh of Care Compare, or as soon as technically feasible after. The following summarizes comments received on this proposal and our response.

Comment: Some commenters supported publicly reporting the COVID–19 measure for the benefit the measure information would provide to the public.

Response: CMS thanks the commenters for their support of this proposal.

Comment: Some commenters suggested that without CBE endorsement and measure testing, public reporting should be delayed. Others suggested reporting the results of patient COVID–19 vaccination status without characterizing the result as a quality measure.

Response: CMS has a long history of reporting vaccination measures to support improvement of care and outcomes in healthcare settings. CMS believe the public reporting of the COVID–19 patient vaccination measure will be consistent with prior vaccination QMs and addresses an important, ongoing health concern.

After consideration of the public comments we received, we are finalizing our proposal to publicly report the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure as proposed beginning with the January 2026 refresh of Care Compare, or as soon as technically feasible after.

G. Health Equity Update

1. Background

In the CY 2023 Home Health Payment Rate Update final rule (87 FR 66866), we included a Request for Information (RFI) on several questions related to a proposed health equity measure concept. CMS defines health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [110] 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 and models, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive. CMS's goals outlined in the *CMS Framework for Health Equity 2022–2023* [111] are in line with Executive Order 13985, on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 25, 2021).[112] The goals included in the CMS Framework for Health Equity include: strengthening CMS's infrastructure for assessment, creating synergies across the health care system to drive structural change, and identifying and working to eliminate barriers to CMS-supported benefits, services, and coverage. These goals also support suggested policies outlined in the Executive Order 14095, on Increasing Access to High-Quality Care and Supporting Caregivers (April 18, 2023), that seeks to address improvement in the provision of long-term care and support the caregivers who support patient care.[113]

In addition to the CMS Framework for Health Equity, CMS seeks to ''advance health equity and whole-person care'' as one of eight goals comprising the CMS National Quality Strategy (NQS).[114] The NQS identifies a wide range of potential quality levers that can support our advancement of equity, including: (1) establishing a standardized approach for patient-reported data and stratification; (2) employing quality and value-based programs to publicly report and incentivize the closing of equity gaps; and, (3) developing equity-focused performance metrics, regulations, oversight strategies, and quality improvement initiatives. The NQS also acknowledges the contribution of structural racism and other systemic injustices to the persistent disparities that underlie our healthcare system.

Racial disparities in health, in particular, are estimated to cost the U.S. an estimated $93 billion in excess medical costs and $42 billion in lost productivity per year, in addition to economic losses due to premature deaths.[115] Racial and ethnic diversity has increased over recent decades in the United States and territories. An increase in the percentage of people who self-identify as two or more races in US Census Bureau data accounts for most of the increase in diversity, rising from 2.9 percent to 10.2 percent between 2010 and 2020.[116] Social determinants of health, including social, economic, environmental, and community conditions, may have a stronger influence on the population's health and well-being than services delivered by practitioners and healthcare delivery organizations.[117]

Measure stratification helps identify disparities by calculating quality measure outcomes separately for different beneficiary subpopulations. By looking at measure results for different populations separately, CMS and providers can see how care outcomes may differ between certain patient populations in a way that will not be apparent from an overall score (that is, a score averaged over all beneficiaries). This helps CMS to better fulfill their health equity goals. For example, certain quality measures related to oral healthcare outcomes for children, when stratified by race, ethnicity, and income, show how important health disparities have been narrowed, because outcomes for children in the lowest income households and for Black and Hispanic children improved faster than outcomes for children in the highest income households or for White children.[118]

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[110] Centers for Medicare and Medicaid Services. Available at *https://www.cms.gov/pillar/health-equity.* Accessed February 1, 2023.

[111] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[112] Executive Order 13985, on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' can be found at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[113] The Executive Order14095 on Increasing Access to High-Quality Care and Supporting Caregivers can be found at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/18/executive-order-on-increasing-access-to-high-quality-care-and-supporting-caregivers/.*

[114] Centers for Medicare & Medicaid Services. What is the CMS Quality Strategy? Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[115] Ani Turner, The Business Case for Racial Equity, A Strategy for Growth, W.K. Kellogg Foundation and Altarum, April 2018.

[116] 2022 National Healthcare Quality and Disparities Report, page 15. Content last reviewed November 2022. Agency for Healthcare Research and Quality, Rockville, MD. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.*

[117] 2022 National Healthcare Quality and Disparities Report. Content last reviewed November 2022, page 2. Agency for Healthcare Research and Quality, Rockville, MD. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.*

[118] 2022 National Healthcare Quality and Disparities Report, page 6. Content last reviewed November 2022. Agency for Healthcare Research and Quality, Rockville, MD. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.*

These differences in outcomes will not be apparent without stratification.

Additionally, the RFI solicited public comments on a potential health equity structural composite measure. We refer readers to the CY 2023 Home Health Payment Rate Update final rule (87 FR 66866) for a summary of the public comments and suggestions received in response to the health equity RFI.

We took these comments into account, and we continue to work to develop policies, quality measures, and measurement strategies on this important topic. After considering public comments, CMS decided to convene a health equity technical expert panel to provide additional input to inform the development of health equity quality measures. The work of this technical expert panel is described in detail in the following section.

2. Home Health and Hospice Health Equity Technical Expert Panel

To support new health equity measure development, the Home Health and Hospice Health Equity Technical Expert Panel (Home Health & Hospice HE TEP) was convened by a CMS contractor in Fall 2022. The Home Health & Hospice HE TEP comprised health equity experts from hospice and home health settings, specializing in quality assurance, patient advocacy, clinical work, and measure development. The TEP was charged with providing input on a potential cross-setting health equity structural composite measure concept as set forth in the CY 2023 Home Health Payment Rate Update final rule noted previously as part of an RFI related to the HH QRP Health Equity Initiative. In specific, the TEP assessed the face validity and feasibility of the potential structural measure. The TEP also provided input on possible confidential feedback report options to be used for monitoring health equity. TEP members also had the opportunity to provide ideas for additional health equity measure concepts or approaches to addressing health equity in hospice and home health settings. A summary of the Home Health and Hospice HE TEP meetings and proposed TEP recommendations are available at *https://mmshub.cms.gov/sites/default/files/HomeHealth-Hospice-Health-Equity-TEP-Report-508c.pdf* .

3. Anticipated Future Health Equity Activities

CMS is committed to developing approaches to meaningfully incorporate the advancement of health equity into the HH QRP. We are considering health equity measures used in other settings like those in acute care that further health equity in post-acute care. We realize that the social determinants of health data items in post-acute care under the IMPACT Act of 2014 differ from the SDOH data items in the acute care health equity quality measures. We could consider a future health equity measure like screening for social needs and intervention. With 30 to 55 percent of health outcomes attributed to SDOH,[119] a measure capturing and addressing SDOH could encourage providers to identify specific needs and connect patients with the community resources necessary to overcome social barriers to their wellness. We could specify it using the SDOH data items that we currently collect as standardized patient assessment data on the OASIS. These SDOH data items assess health literacy, social isolation, transportation problems, preferred language (including need or want of an interpreter), race, and ethnicity. These SDOH data items differ from data elements considered as screening items in the acute care settings, which are housing instability, food instability, transportation needs, utility difficulties, and interpersonal safety. This means that we might consider in the future adding the SDOH data items used by acute care providers into the HH QRP as we develop future health equity quality measures under our HH QRP statutory authority. This supports our desire to align quality measures across CMS consistent with the CMS path forward for advancing health equity solutions.[120] Consistent with ''The Path Forward: Improving Data to Advance Health Equity Solutions'' (CMS OMH, November 2022) we also see value in aligning SDOH data items across all care settings and to the United States Core Data for Interoperability (USCDI) where applicable and appropriate. The USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange, including data elements and associated vocabulary standards to support computerized, interoperable use of SDOH data.[121]

As we move this important work forward, we will continue to take input from interested parties. As of this publication, the Initial Proposals for Updating OMB's Race and Ethnicity Statistical Standards, (88 FR 5375), has collected public comment. Additionally, the Office of the National Coordinator for Health IT (ONC) welcomes submissions proposing additional data classes and data elements via the USCDI ONC New Data Element and Class (ONDEC) submission system for future versions of the USCDI.[122] In addition, while some of the anticipated health equity efforts will proceed through the rulemaking process, other activities may be pursued through subregulatory channels, such as Open-Door Forums (ODF), Medicare Learning Network (MLN), and public summary reports such as TEP reports or information gathering reports (IGR).

Although we did not directly solicit feedback to our update, we did receive some public comments, which we summarize as follows.

Comment: Commenters supported evaluating the potential for future health equity measures. A commenter encouraged CMS to utilize nurses to their fullest extent in terms of drawing from their experience and expertise. Another suggested that CMS capture information about family caregiver status, support offered to the caregiver(s), and caregiver experience of care provided to the patient as part of the health equity initiative. Lastly, another commenter suggested that CMS require health equity strategies in the Conditions of Participation for Home Health Agencies and other Medicare and Medicaid participating providers, particularly health equity accreditation to encourage greater adoption of health equity strategies.

Response: We thank all the commenters for responding to our update on this important CMS priority. We will continue to prioritize our efforts to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all people served by our programs.

H. Finalizing Codification of the HH QRP Data Completion Thresholds

1. Compliance

Section 1895(b)(3)(B)(v)(I) of the Act requires that, for the CY 2007 payment determination and subsequent years, each HHA submit to the Secretary quality data specified by the Secretary in a form and manner, and at a time, specified by the Secretary. As required in accordance with subclause (II) for such a year, for any HHA that does not submit data in accordance with section 1895(b)(3)(B)(v)(I) of the Act with respect to a given calendar year will result in the reduction of the annual

[119] World Health Organization (WHO). (n.d.). Social Determinants of Health. *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1*, accessed February 1, 2023.

[120] *https://www.nejm.org/doi/full/10.1056/NEJMp2215539,* February 1, 2023.

[121] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[122] *https://www.healthit.gov/isa/ONDEC.*

home health market basket percentage increase otherwise applicable to an HHA for that calendar year by 2 percentage points. In the CY 2016 HH PPS final rule (80 FR 68703 through 68705), we finalized a proposal to define the quantity of OASIS assessments each HHA must submit to meet the pay-for reporting requirement. We finalized a proposal that increased the reporting threshold for HHAs over three years, starting with the CY 2017 reporting period. HHAs were required to score at least 70 percent on the Quality Assessment Only (QAO) metric of pay-for-reporting performance requirement for CY 2017 (reporting period July 1, 2015 to June 30, 2016), 80 percent for CY 2018 (reporting period July 1, 2016 to June 30, 2017) and 90 percent for CY 2019 (reporting period July 1, 2017 to June 30, 2018) or be subject to a 2 percentage point reduction to the home health market basket update for that reporting period. In the 2018 HH PPS final rule (82 FR 51737 through 51738), we finalized a policy to apply the 90 percent threshold requirements established in the CY 2016 HH PPS rule to the submission of standardized patient assessment data beginning with the CY 2019 HH QRP.

2. Proposal To Codify HH QRP Data Completion Thresholds

In the CY 2024 proposed rule (88 FR 43654), we proposed to codify these already-finalized data completeness thresholds at § 484.245(b)(2)(ii)(A) for measures data collected using the OASIS (88 FR 43737–38). Under this section, we proposed to codify our requirement that HHAs must meet or exceed a data submission threshold set at 90 percent of all required OASIS and submit the data through the CMS designated data submission systems. This threshold would apply to required quality measures data and standardized patient assessment data adopted into the HH QRP. We also proposed to codify our policy at § 484.245(b)(2)(ii)(B) that a HHA must meet or exceed this threshold to avoid receiving a 2-percentage point reduction to its annual payment update for a given CY as codified at § 484.225(b).

We sought public comment on our proposal to codify in regulations text the HH QRP data completion thresholds at § 484.245(b)(2)(ii)(A) for measures and standardized patient assessment elements collected using the OASIS and compliance threshold to avoid receiving 2 percentage point reduction as described under § 484.245(b)(2)(ii)(B). A summary of comments received and CMS response to public comments is as follows.

Comment: Most commenters who addressed this proposal supported codification of this regulatory text.

Response: We thank commenters for their support of this important policy.

Comment: Some commenters supported the goal of codifying the proposed regulatory text with some suggested changes. These commenters suggested the removal of language ''. . . within 30-days of the beneficiary's admission or discharge . . .'' since there are more factors than a strict 30-day deadline in the application of submission requirements during the calculation of quality assessments only (QAO) compliance.

Response: CMS reviewed the comments that suggest a revision to the proposed regulatory text and is in agreement with suggested change. We believe that this change will be beneficial to our data collection activities because it addresses the overall submission requirements for OASIS data collection that assesses overall HHA compliance for each submission year, irrespective of the kinds of assessments submitted for that given year. CMS is concerned with not only the SOC/ROC and discharge assessments, but assessments collected at other timepoints.

After consideration of the public comments we received, we are finalizing our proposal to codify in regulations text the HH QRP data completion thresholds with the suggested replacement of text. CMS supports the suggested replacement of the timeframe language while codifying the following language: ''A home health agency must meet or exceed the data submission threshold for each submission year (July 1–June 30) set at 90 percent of all required OASIS or successor instrument records and submitted through the CMS designated data submission systems''.

I. Principles for Selecting and Prioritizing HH QRP Quality Measures and Concepts Under Consideration for Future Years: Request for Information (RFI)

1. Background

CMS has established a National Quality Strategy [123] for its quality programs which support a resilient, high-value health care system promoting quality outcomes, safety, equity and accessibility for all individuals. The CMS National Quality Strategy is foundational for contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. To advance these goals, CMS leaders from across the Agency have come together to move towards a building-block approach to streamline quality measures across CMS quality programs for the adult and pediatric populations. This ''Universal Foundation'' [124] of quality measures will focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. The development and implementation of the Preliminary Adult and Pediatric Universal Foundation Measures will promote the best, safest, and most equitable care for individuals as we all come together on these critical quality areas.

In alignment with the CMS National Quality Strategy, the HH QRP endeavors to move towards a more parsimonious set of measures while continually improving the quality of health care for beneficiaries. In the CY 2024 proposed rule, we requested information on existing gaps in HH QRP measures and solicited public comment on either fully developed HH measures, fully developed measures in other programs that may be appropriate for the HH QRP, and measurement concepts that could be developed into HH QRP measures, to fill these measurement gaps (88 FR 43738–40). While we will not be responding to specific comments submitted in response to this RFI in the CY2024 HH PPS final rule, we have summarized the comments received, and intend to use this input to inform future policies.

This RFI consisted of four sections. The first section was a background. The second section discussed a general framework or set of principles that CMS utilizes to identify future HH QRP measures. The third section drew from an environmental scan conducted to identify HH QRP measurement gaps, and measures or measure concepts that could be used to fill these gaps. This section solicited public comment on (a) the set of principles for selecting measures for the HH QRP, (b) identified measurement gaps, and (c) measures that are available for immediate use, or that may be adapted or developed for use in the HH QRP. For a detailed

[123] Schreiber M, Richards A, Moody-Williams J, Fleisher L. The CMS National Quality Strategy: a person-centered approach to improving quality. Centers for Medicare and Medicaid Services. June 6, 2022. Available at: *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality.* Opens in new tab.

[124] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. *N Engl J Med* 2023; 338:776–779. DOI: 10.1056/NEJMp2215539.

presentation of the RFI, see the CY2024 NPRM (88 FR 43738–40). CMS sought input on data available to develop measures, approaches for data collection, perceived challenges, or barriers, and approaches for addressing challenges. We received several comments in response to this RFI, which are summarized later in this section.

2. Comments on Principles for Selecting and Prioritizing QRP Measures

In general, commenters supported the CMS principles and criteria for selecting and prioritizing measures. A commenter shared a concern that the proposed principle of ''provider responses to payment'' raises concerns due to the ambiguity of the term ''unwanted responses.'' Many commenters advocated for the addition of stakeholder engagement (for example, technical expert panels, and review and analysis of beneficiary and family input) as a guiding principle. A suggestion was made to include a guiding principle related to discontinuing metrics without continually adding more metrics given the burden the constant addition of metrics places on agencies. Another suggestion was to add the principle of Timeliness and Clarity of CMS data, described as promoting increased availability and frequency of data with lesser time lag, and clarity around the reportability and feedback of data to and from CMS and in compliance with QRP. A respondent advocated for incorporating ''objectivity'' as a principle, described as prioritizing claims-based measures over provider reported measures in order to mitigate measure manipulation and another respondent advocated incorporation of a guiding principle that only measures for which data elements are clearly defined, valid, and well standardized be prioritized for the HH QRP measure set.

3. Comments on HH QRP Measurement Gaps

a. Cognitive Function and Behavioral and Mental Health

While commenters agreed that there may be gaps related to cognitive function and behavioral and mental health, most were opposed to these being an area of further exploration in measure development in home health. They did not see the benefit or feasibility of developing performance measures around cognition or behavioral and mental health due to the limited ability to affect these disorders in the home health setting. Some suggested that if CMS would like to examine how to better align the behavioral health clinical grouping with the needs of patients, this could be an area for future consideration for CMMI or another entity looking at how to better serve older adults with cognitive and/or behavioral or mental health needs. One gap that was identified and recommended for future exploration in relation to cognitive function was the need for HHAs to better identify mild cognitive impairment. Although the OASIS requires a combination of the BIMS, CAM, and PHQ–9 to identify cognitive status, one respondent noted that these assessments are not sufficient to identify mild and mild to moderate cognitive impairment which were described as being crucial to intervening in functional decline for home health patients.

Overall there was significant opposition to the implementation of a measure related to cognitive function and/or behavioral health. Commenters stated that such measures would not make sense as performance measure domains in home health care due to limited time, resources, and expertise to provide interventions that would directly impact a patient's cognition, behavioral and/or mental health. They suggested that the focus in HH is to stabilize cognitive function and/or behavioral health—especially during the limited period the beneficiary is receiving home health services. While some commenters stated that the Brief Interview for Mental Status (BIMS) and Confusion Assessment Method (CAM©) measures already collected were sufficient, others objected to their use for quality measurement noting that a patient's BIMS score is not expected to improve with treatment. Respondents also suggested that CMS pause adding additional metrics until there are more data to determine whether they are effective. They noted that if CMS has decided that BIMS and/or CAM are not effective, they should be exchanged with new metrics, as opposed to adding additional metrics on top of CAM and BIMS.

b. Chronic Conditions

Commenters expressed overall support for exploring gaps and performance measures related to chronic illness in the home health setting, but emphasized these should focus on maintenance or stabilization of chronic conditions rather than improvement. Performance measures aimed at stabilizing chronic conditions and measuring appropriate interventions for those patients that are expected to decline were suggested to be a better reflection of quality home health care than focusing solely on improvement in conditions and activities, and hospitalization rates. There was also support for continuing to include these more comprehensively within the case mix weight, rather than adding additional metrics and further exploration of measures that assess quality of life for the beneficiary and the family caregiver in relation to chronic illness.

Commenters supported CMS's effort to align quality measures across care settings through the Universal Foundation and strongly support CMS focusing efforts on developing performance measures around chronic conditions. Commenters stated that although current measures are directed at managing chronic illnesses, many are physician focused. The commenters suggested CMS needs to develop performance measures that address chronic illness in the home health setting. They suggested that CMS needs to develop performance measures that recognize progressive chronic conditions for which measures of maintenance and/or stabilization are a more accurate reflection of quality home health care. Commenters also suggested that CMS should measure the effect of appropriate interventions for those patients that are expected to decline. There was also support for a stratification approach for quality measurement for patients with chronic illnesses and complex needs.

c. Pain Management

Commenters supported further exploration of gaps in measurement related to pain management in home health, particularly the assessment of pain and its effect on sleep, therapy activities, and day-to-day activities and function. Pain assessment and management were described as critically important in the home health environment, and there was a call to explore how to better incorporate therapy services in pain assessment, intervention, and quality measurement in the home health setting. While commenters expressed support for further exploration of gaps related to pain, they also described confusion based on the prior CMS decision to remove this domain as a performance measure in home health due to the opioid crisis, and the need for CMS to send a consistent message to providers if new measurements were developed. For pain, standardized assessments were recommended as the best metric to evaluate, including the standardized pain scale 0–10, Wong-Baker, and PAINAD. Commenters emphasized the need to have options, as not every patient fits into one specific scale. They

also encouraged CMS to recognize that some patients, even those with substance use disorder, may be appropriately taking opioids or other pain medications and that should be factored into their plan of care. They also encouraged CMS to identify tools that can address the inequities in pain assessment and treatment, specifically among African Americans.

d. Other Measure Gaps

Additional gaps for further exploration identified by respondents included identifying and addressing social risk for patients, support for caregivers and caregiver status, and assessment, treatment and referral for patients with chronic obstructive pulmonary disease. A commenter also identified the need to better explore improvement of delivery and responses to patient satisfaction surveys in home health in order to improve understanding of patient experiences. Commenters supported adding measures to the HH QRP that would identify social risk factors and specifically incorporating financial needs into social risk factor assessment. One suggestion for measuring this in the home health setting was adding ''needs navigation'' services as a requirement to the HH QRP with a measure that confirms whether these services have been offered or delivered. The Social Need Screening and Intervention HEDIS measure was also recommended for home health because it is designed to collect social needs data from multiple sources in addition to the EMR. There was also support for aligning social risk factor/social needs measures with the Gravity Project's work to standardize interoperable social needs data. Commenters also suggested a number of existing measures to consider for incorporation into the HHQRP program. A commenter recommended the addition of Caregiver Status to the list of standardized patient assessment data required for reporting by HHAs and other PAC providers. Another identified three measurements that if added to the HH QRP would improve the care of COPD patients in the home health setting and after discharge: Referral to Smoking Cessation Counseling or Program, Referral to Pulmonary Rehabilitation Clinic, and COPD GOLD Strategy treatment for HH patients. Additional suggested measures for CMS consideration included Advance care planning (ACP), the Depression Screening and Follow-Up for Adolescents and Adults (DSF), and person-centered care outcome (PCO) measures. Commenters also suggested incorporating measures more appropriate for patients at the end of life in home health: the new patient-reported quality measure ''Felt Heard and Understood'' (already endorsed by the CBE), a measure on referral or access to palliative care and a measurement of timely and appropriate referral to hospice.

e. Data Available To Develop Measures

Related to equity, commenters suggested that CMS minimize additional administrative burdens while striving to gather meaningful equity-related information. This could entail leveraging data that CMS already collects from claims. Commenters suggested that health outcome measures may need to include some form of adjustment for the relative amount and quality of resources available in different localities to care for different patient populations. Additional suggestions for addressing equity included: providing clarity around the definition of health equity; identifying validated measures of equity and determining feasibility for assessment at the HH level; incorporating equity as a case mix indicator and provider resources for management of health equity challenges with reimbursement; providing cost appropriate interventions from HH clinicians to achieve outcomes in a HH length of stay; and providing evidence-based data about interventions that can affect equity and outcomes.

f. Challenges With Current HH QRP Measures

Overall, commenters focused on voicing their opposition to the CMS' emphasis on reducing hospitalizations and keeping patients in the community as the gold standard for quality performance in the home health setting. This was described as a longstanding frustration for HHAs and a disincentive to care for patients with complex health needs, contributing to some HHAs avoiding servicing patients with complex needs. Opposition was justified by highlighting the growing number of medically complex patients coming from community rather than post-acute care referrals, and recognition that home health agencies have limited ability to prevent hospitalizations with many complex patient populations/patient conditions. For patients with complex and/or chronic care needs, measures that address delays in transfers to higher levels of care may be a better reflection of quality home health care and transfers to the hospital or a skilled nursing facility may ultimately be an appropriate discharge disposition. A stratification approach for quality measurement for patients with chronic illnesses and complex needs was also described as an appropriate alternative.

Response: We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this input to inform our future measure development efforts.

IV. Changes to the Expanded Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and proposed 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.[125] 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 and the CMS Chief Actuary certified that expansion of the HHVBP Model will produce Medicare savings if expanded to all states.[126]

On January 8, 2021, CMS announced the certification of the HHVBP Model for expansion nationwide, as well as the

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

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

intent to expand the Model through notice and comment rulemaking.[127]

In the CY 2022 HH PPS final rule (86 FR 62292 through 62336) and codified at 42 CFR part 484 subpart F, we proposed 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. During CY 2022, CMS provided HHAs with resources and training, to allow HHAs time to prepare and learn about the expectations and requirements of the expanded HHVBP Model without risk to payments. We proposed that the expanded Model will generally use benchmarks, achievement thresholds, and improvement thresholds based on CY 2019 data to assess achievement or improvement of HHA performance on applicable quality measures and that HHAs will compete nationally in their applicable size cohort, smaller-volume HHAs or larger-volume HHAs, as defined by the number of complete unique beneficiary episodes for each HHA in the year prior to the performance year. All HHAs certified to participate in the Medicare program prior to January 1, 2022, will be required to participate and will be eligible to receive an annual Total Performance Score based on their CY 2023 performance.

We proposed the quality measure set for the expanded Model, as well as policies related to the removal, modification, and suspension of applicable measures, and the addition of new measures and the form, manner, and timing of the OASIS-based, Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey-based, and claims-based measures submission in the applicable measure set beginning in CY 2022 and subsequent years. We also proposed an appeals process, an extraordinary circumstances exception policy, and public reporting of annual performance data under the expanded Model.

Additionally, in the CY 2022 HH PPS final rule (86 FR 62312), we summarized and responded to comments received on the challenges unique to value-based purchasing frameworks in terms of health equity and ways in which we could incorporate health equity goals into the expanded HHVBP Model. Comments received were related to the use of stabilization measures to promote access to care for individuals with chronic illness or limited ability to improve; collection of patient level demographic information for existing measures; and stratification of outcome measures by various patient populations to determine how they are affected by social determinants of health (SDOH).

In the CY 2023 HH PPS final rule (87 FR 66869 through 66876), we proposed our policy to replace the term *baseline year* with the terms *HHA baseline year* and *Model baseline year,* and to change the calendar years associated with each of those baseline years. Specifically, we changed the HHA baseline year for the CY 2023 performance year from 2021 to 2022 for ''new'' HHAs with CMS certification numbers (CCNs) with effective dates prior 2022, and the Model baseline year from CY 2019 to CY 2022 starting in CY 2023. Additionally, we summarized the comments received on future approaches to health equity (HE) in the expanded HHVBP Model. Comments received were related to the support of addressing health equity, potential unintended consequences, thorough consideration and testing of potential HE measures, data collection and, applying HE data to the expanded Model's cohorts and risk adjustment models.

In the CY 2024 HH PPS proposed rule (87 FR 43740 through 43752), we proposed codification of the HHVBP measure removal factors at § 484.380; to remove five and add three quality measures to the applicable measure set, revise weights of the individual measures within the OASIS-based measure category and within the claims-based measure category and, an updated Model baseline year (from CY 2022 to CY 2023) starting in the CY 2025; and, an amendment to the appeals process such that reconsideration decisions may be reviewed by the Administrator with conforming regulation text changes at § 484.375(b)(5). We included an update to the RFI, *Future Approaches to Health Equity in the Expanded HHVBP Model,* that was published in the CY 2023 HH PPS rule. We also included a reminder that we will begin public reporting HHVBP performance data on or after December 1, 2024.

We received public comments related to these provisions from 50 commenters. Commenters included groups representing HHAs, home health and hospice associations, hospital associations, professional associations, hospitals, and medical centers. The remaining comments were from individual practitioners and private citizens. A summary of the major issues and our responses follow:

B. Proposed Changes to the Applicable Measure Set

We proposed to make changes to the applicable measure set. First, we proposed to codify the HHVBP measure removal factors effective in CY 2024. Second, we proposed to remove five measures from the current applicable measure set and add three measures starting in CY 2025. Third, due to the net change in the number of measures proposed, we proposed to adjust the weights for the measures in the OASIS-based and claims-based measure categories starting in CY 2025. Lastly, we proposed to update the Model baseline year for all measures starting in CY 2025.

Comment: Some comments agreed with all proposed updates to the expanded Model. Some commenters requested that we not make any updates to the expanded Model at this time stating it was too soon, and that we should wait to make proposals after HHAs have seen data on the proposed measures. A commenter suggested that before any measure replacement is adopted, CMS conduct a detailed comparison of the measure that would be removed and the measure that would be adopted as a replacement to ensure the replacement measure provides at least the scope and granularity of information as the measure being replaced, especially in the case where the measure domain of the proposal would be affected (such as when a claims-based measure is proposed to replace an OASIS-based measure).

Response: For the Expanded HHVBP Model, CMS refines the measure set and selects quality measures with consideration to the domains of the CMS Quality Strategy that map to the six National Quality Strategy (NQS) priority areas: (1) Clinical quality of care; (2) Care coordination; (3) Population/community health; (4) Efficiency and cost reduction; (5) Safety; and (6) Patient and caregiver-centered experience. CMS also prioritizes alignment of the measure set with the HH QRP. Additionally, CMS considers feedback from a Technical Expert Panel (TEP) and stakeholders when considering refinements to the measure set. There are eight specific factors that CMS considers for measure removal, which were detailed in the CY 2022 HH PPS final rule and are being codified through this final rule. Further, prior to removing a measure and adopting a replacement, CMS compares the measures to ensure that the replacement measure is an improvement as compared to the measure being replaced. CMS assesses the type of

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

information covered by the measure as well as the level of detail. This involves review of the specifications and analysis of the measure performance and trends. As finalized in the CY 2022 HH PPS rule (86 FR 62315), CMS exercised its waiver authority under section 1115A of the Act to waive certain requirements of the pre-rulemaking process for the selection of quality and efficiency measures as necessary to test the expanded HHVBP Model. In particular, CMS waived the requirements outlined in section 1890A(a)(1) and (3) through (6) of the Act. Per section 1890(a)(2) of the Act, which is not waived, CMS makes information on the measures considered for selection publicly available. Specifically, this means that, through notice and comment rulemaking we propose any measures considered for selection, receive public comments in response, and then finalize the measures in a final rule. The names of any measures added to the expanded HHVBP Model are posted on the CMS website by December 1.

Additionally, the adjustments to the applicable measure set included in this rule are in response to requests from the HHA industry through public comments on the CY 2022 HH PPS proposed rule and questions submitted during HHVBP-specific learning events. The comments applicable to individual proposals are summarized and responded in the relevant sections as follows.

1. Codification of the HHVBP Measure Removal Factors

In the CY 2022 HH PPS final rule (86 FR 62312), we stated that removal of an expanded HHVBP Model measure will take place through notice and comment rulemaking. In that same final rule (86 FR 62311 through 62312), we adopted eight measure removal factors that we consider when determining whether to remove measures from the expanded HHVBP Model's applicable measure set:

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

To be consistent with the HH QRP and other quality reporting programs (that is SNF QRP, IRF QRP, and LTCH QRP) we will finalize to codify the eight HHVBP measure removal factors for the expanded Model at § 484.380.

We invited public comments on this proposal. We did not receive comments specific to the codification of the Measure Removal Factors. Therefore, we are finalizing this provision without modification.

2. Changes to the Applicable Measure Set

a. Background

In the CY 2022 HH PPS final rule (86 FR 66308 through 66310), we proposed the applicable measure set effective in the CY 2022 pre-implementation year and subsequent years, which includes five OASIS-based measures, two claims-based measures, and five HHCAHPS Survey-based measures (see Table D1). Details of these measures were included in Tables 26 and 27 of the CY 2022 HH PPS proposed rule (86 FR 35923 through 35926).

TABLE D1: CURRENT MEASURE SET FOR THE EXPANDED HHVBP MODEL

Measure Category	Measure Full Title/Short Form Name (if applicable)
OASIS-based	Improvement in Dyspnea/Dyspnea
OASIS-based	Discharged to Community
OASIS-based	Improvement in Management of Oral Medications/Oral Medication
OASIS-based	Total Normalized Composite Change in Mobility/TNC Mobility
OASIS-based	Total Normalized Composite Change in Self- Care/TNC Self-Care
Claims-based	Acute Care Hospitalization During the First 60 Days of Home Health Use/ACH
Claims-based	Emergency Department Use without Hospitalization During the First 60 Days of Home Health/ED Use
HHCAHPS Survey-based	Care of Patients/Professional Care
HHCAHPS Survey-based	Communications Between Providers and Patients/Communication
HHCAHPS Survey-based	Specific Care Issues/Team Discussion
HHCAHPS Survey-based	Overall Rating of Home Health Care/Overall Rating
HHCAHPS Survey-based	Willingness to Recommend the Agency/Willing to Recommend

In that same final rule (86 FR 62310 through 62313), we stated that, during the expanded Model, we will address any needed adjustments or modifications to the applicable measure set. This process involves notice and comment rulemaking for removing or adding measures and for adopting changes to measures that we consider to substantially change the nature of the measure. We also post the names of any measures added to the expanded Model proposed through the rulemaking process on the CMS website by the December 1 after publication of the applicable final rule. Examples of changes that we might consider to be substantive will be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent, such as changes in acceptable timing of medication, procedure/process, test administration, or expansion of the measure to a new setting. If an update to a measure is necessary in a manner that we consider to not substantially change the nature of the measure, we will use a sub-regulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically,

we will revise the information that is posted on the CMS website so that it clearly identifies the updates and provides links to where additional information on where the updates can be found.

We have determined that five of the measures proposed in the CY 2022 HH PPS final rule require further consideration. Specifically, we proposed to remove the following measures from the applicable measure set: (1) OASIS-based Discharged to Community (DTC); (2) OASIS-based Total Normalized Composite Change in Self-Care (TNC Self-Care); (3) OASIS-based Total Normalized Composite Change in Mobility (TNC Mobility); (4) claims-based Acute Care Hospitalization During the First 60 Days of Home Health Use (ACH); and (5) claims-based Emergency Department Use without Hospitalization During the First 60 Days of Home Health (ED Use).

We proposed to replace these five measures with three measures (see Table D2). Specifically, we proposed to add the following measures: (1) the claims-based Discharge to Community-Post Acute Care (DTC–PAC) Measure for Home Health Agencies; (2) the OASIS-based Discharge Function Score (DC Function) measure; and (3) the claims-based Home Health Within-Stay Potentially Preventable Hospitalization (PPH) measure. The claims-based DTC–PAC measure will replace the OASIS-based DTC measure. The OASIS-based DC Function measure will replace the two OASIS-based TNC measures (Self-Care and Mobility). The claims-based PPH measure will replace the claims-based ACH and ED Use measures.

We proposed to make these changes to the applicable measure set beginning with the CY 2025 performance year and subsequent performance years. The proposed changes will align the measures used in the expanded HHVBP Model with the measures in the HH QRP and publicly reported on the Care Compare website. This alignment will support comparisons of provider quality and streamline home health providers' data capture and reporting processes. Table D2 summarizes the proposed applicable measure set that will be effective for the CY 2025 performance year (CY 2027 payment year).

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TABLE D2: PROPOSED MEASURE SET FOR THE EXPANDED HHVBP MODEL

Measure Full Title/Short Form Name (if applicable)	Measure Type	Data Source	Numerator	Denominator	Current	Proposed
Improvement in Dyspnea/Dyspnea[1]	Outcome	OASIS (M1400) (M2420) (M0100)	Number of home health quality episodes where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health quality episodes ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions (see note 1).	X	
Improvement in Management of Oral Medications/Oral Medication[1]	Outcome	OASIS (M2020) (M1700) (M1710) (M1720) (M2420) (M0100)	Number of home health quality episodes where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health quality episodes ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions (see note 1).	X	
Discharge Function Score/DC Function[2]	Outcome	OASIS (GG Item Set)	Number of home health episodes with an observed discharge function score that is equal to or higher than the calculated expected discharge function score.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure- specific exclusions.		X
Home Health Within-Stay Potentially Preventable Hospitalization/PPH[3]	Outcome	CCW (Claims)	Number of patients with at least one potentially preventable hospitalization (that is, in an ACH/LTCH) or observation stay during the HH stay. For the Potentially Preventable Hospitalization measure, a stay is a sequence of HH payment episodes by at least two days. episodes separated from other HH payment episodes by at least 2 days.	All Medicare Fee-for-Service patients in the HH setting that do not meet the exclusion criteria.		X
Discharge to Community/DTC-PAC[4]	Outcome	CCW (Claims)	Number of home health stays for patients who have a Medicare FFS claim with Patient Discharge Status codes 01 and 81, do not have an unplanned admission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window.	Number of home health stays that begin during the 2-year observation period.		X
Care of Patients/Professional Care[5]	Outcome	Home Health Consumer Assessment Healthcare Providers and Systems (HHCAHPS) Survey; the component questions for this measure are Q9, Q16, Q19, and Q24	Numerator details are included in the link provided in note 5.	Denominator details are included in the link provided in note 5.	X	
Communications Between Providers and Patients/Communication[5]	Outcome	HHCAHPS Survey; the component questions for this measure are Q2, Q15, Q17, Q18, Q22, and Q23.	Numerator details are included in the link provided in note 5.	Denominator details are included in the link provided in note 5.	X	
Specific Care Issues/Team Discussion[5]	Outcome	HHCAHPS Survey; the component questions for this measure are Q3, Q4, Q5, Q10, Q12, Q13, and Q14	Numerator details are included in the link provided in note 5.	Denominator details are included in the link provided in note 5.	X	
Overall Rating of Home Health Care/Overall Rating[5]	Outcome	HHCAHPS Survey; the component question for this measure is Q20	Numerator details are included in the link provided in note 5.	Denominator details are included in the link provided in note 5.	X	

Measure Full Title/Short Form Name (if applicable)	Measure Type	Data Source	Numerator	Denominator	Current	Proposed
Willingness to Recommend the Agency/Willingness to Recommend[5]	Outcome	HHCAHPS Survey; the component question for this measure is Q25	Numerator details are included in the link provided in note 5.	Denominator details are included in the link provided in note 5.	X	

Notes:

[1] https://www.cms.gov/files/document/home-health-outcome-measures-table-oasis-e2023.pdf

[2] https://www.cms.gov/files/document/hh-discharge-function-score-measure-technical-report.pdf

[3] https://www.cms.gov/files/document/hh-qrp-specificationspotentiallypreventablehospitalizations.pdf

[4] https://www.cms.gov/files/document/home-health-outcome-measures-table-oasis-e2023.pdf

[5]https://homehealthcahps.org/Portals/0/HHCAHPS_steps_calculate_composites.pdf?ver=7PCs8ovwE7U9VewwEbtXVg%3d%3d

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b. Changes to the Applicable Measure Set

We proposed to make all changes to the applicable measure set discussed in this rule beginning with the CY 2025 performance year, thus all changes will affect the same payment year beginning with the CY 2027 payment year.

(1) Proposal To Replace the OASIS-based DTC Measure With the Claims-Based DTC–PAC Measure Beginning CY 2025

We proposed to replace the current OASIS-based DTC measure with the claims-based DTC–PAC measure. The claims-based DTC–PAC measure assesses successful discharge to the community from an HHA, with successful discharge to the community including no unplanned re-hospitalizations and no death in the 31 days following discharge. This measure was adopted as part of the Home Health Quality Reporting Program (HH QRP) in the CY 2017 HH PPS final rule (81 FR 76765 through 76770). Details about the measure can be found in the CY 2017 HH PPS final rule (81 FR 76765 through 76770) and the CY 2018 HH PPS final rule (84 FR 60564 through 60566). One difference between the current OASIS-based DTC measure and the proposed claims-based DTC–PAC measure is the time period of the measure. The proposed claims-based DTC–PAC measure uses two years of claims data, whereas the current OASIS-based DTC measure uses one year of OASIS data. Furthermore, the claims-based DTC–PAC measure is aligned across PAC settings in terms of risk-adjustment, exclusions, numerator, and measure intent, whereas the OASIS-based DTC measure is not aligned. Therefore, making the replacement is in accordance with Measure Removal Factor 4: A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

Additionally, the replacement will further align the expanded HHVBP Model applicable measure set with the HH QRP measures. The HH QRP added the claims-based DTC measure in 2017 and stopped publicly reporting the OASIS-based DTC measure in 2017. The proposed use of the claims-based DTC–PAC measure has additional benefits as compared to the current OASIS-based DTC measure in that it assesses broader outcomes by assessing post-discharge hospitalization and mortality. Specifically, it first examines whether a patient was discharged to the community from the PAC setting. For patients discharged to the community, this measure examines whether they remained alive in the community without an unplanned admission to an acute care hospital or LTCH in the 31-day post- discharge observation window following discharge to the community.

(2) Proposal To Jointly Replace the OASIS-Based TNC Self-Care and TNC Mobility Measures With the OASIS-Based Discharge Function Score Measure Beginning CY 2025

We proposed to jointly replace the TNC Self-Care and TNC Mobility measures with the DC Function measure. We adopted the TNC Self-Care and TNC Mobility measures in the CY 2019 HH PPS final rule (83 FR 56529 through 56535) for use in the original Model beginning with performance year 4 (CY 2019). The TNC measures, which are composite measures, replaced three individual measures (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion). For these composite measures, HHA performance on the three mobility OASIS-items are included in the TNC measures. The TNC measures also include six additional activities of daily living (ADL) measures to create a more comprehensive assessment of HHA performance across a broader range of patient ADL outcomes. The TNC measures report the magnitude of patient change (either improvement, no change, or decline) across six self-care and three mobility patient functional activities. This methodology accounts for changes to the scores on individual OASIS items while also considering that not all patients are able to improve on all aspects of each composite measure. The DC Function measure determines how successful each HHA is at achieving an expected level of functional ability for its patients at discharge. An expectation for discharge function score is built for each HHA episode by accounting for patient characteristics that impact their functional status. The final DC Function measure for a given HHA is the proportion of that HHA's episodes where a patient's observed discharge score meets or exceeds their expected discharge score. Functional status is measured through Section GG of OASIS assessments, which are cross-setting items. Section GG evaluates a patient's capacity to perform daily activities related to three self-care (GG0130) activities and eight mobility (GG0170) activities.

The DC Function measure has been proposed for adoption in all PAC settings. We included the proposed DC Function measure on the 2022 Measure Under Consideration (MUC) list for the Inpatient Rehabilitation Facility QRP, Home Health QRP, Long Term Care Hospital QRP, SNF QRP, and SNF VBP.[128] It is proposed for the Skilled Nursing Facility (SNF) Value-Based Purchasing program in the FY 2024 SNF PPS proposed rule and in this CY 2024 HH PPS proposed rule for adoption in the HH QRP beginning CY 2025; details about the measure can be found in section III.D. of the proposed rule. We proposed adopting the measure for the expanded HHVBP Model on the same timeline as the HH QRP (CY 2025) given that the GG items used in the measure have gone through extensive testing, and the measure has received conditional support for rulemaking as part of the most recent Measure Applications Partnership (MAP) process. While the DC Function measure is not yet implemented in the HH QRP or other PAC programs, the OASIS data elements used to calculate this measure have been collected since 2019. As such, we believe HHAs have had sufficient time to ensure successful reporting of the data elements needed for this measure.

Replacement of the TNC measures with the DC Function measure will further align the expanded HHVBP Model measure set with the HH QRP measures, as well as with other PAC settings. For these reasons, this replacement is in accordance with Measure Removal Factor 4. Additionally, the DC Function measure addresses self-care and mobility through a single measure rather than two measures, thereby streamlining the calculation and reporting of measure results.

(3) Proposal To Jointly Replace the Acute Care Hospitalization During the First 60 Days of Home Health Measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health Measure With the Home Health Within Stay Potentially Preventable Hospitalization (PPH) Measure Beginning CY 2025

We proposed to jointly replace the Acute Care Hospitalization During the First 60 Days of Home Health Measure (''ACH'' measure) and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health Measure (''ED Use'' measure) with the Home Health Within Stay Potentially Preventable

[128] *See* CMS, Measures Under Consideration List for 2022 (Dec. 1, 2022), available at *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

Hospitalization (PPH) Measure. The current specifications for the PPH measure are available on the CMS website at *https://www.cms.gov/files/document/hh-qrp-specifications potentiallypreventable hospitalizations.pdf.*

The CY 2022 HH PPS final rule (86 FR 62340 through 62345) proposed the joint replacement of the ACH measure and ED Use measure with the PPH measure in the HH QRP beginning CY 2023. This replacement under the HH QRP was made under Measure Removal Factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available. Additional details of the reason for replacement are found in the CY 2022 HH PPS final rule (86 FR 62340 through 62345). Because these measures have been proposed to be jointly replaced with the PPH measure in the HH QRP beginning CY 2023, we are proposing to remove them from the expanded HHVBP Model.

In the CY 2022 HH PPS proposed rule (86 FR 35929), we requested comments on whether we should align the expanded HHVBP Model with the proposed changes for the HH QRP by proposing to remove the same two measures (''ACH'' and ''ED Use'' measures) from the expanded Model in a future year. As summarized in the CY 2022 HH PPS final rule (86 FR 62312), the feedback was generally supportive, recommending that the expanded HHVBP Model's applicable measure set align with the HH QRP measures. Replacing ACH and ED Use with PPH will further align the expanded Model's applicable measure set with the HH QRP measures.

We proposed no changes to the five HHCAHPS Survey-based measures used for the expanded HHVBP Model.

We invited public comments on these proposals.

Comment: Several commenters supported the changes to the applicable measure set, some stating their belief that measures should be harmonized with those in HH QRP and other VBP programs as well as other CMS initiatives creating efficiencies for HHAs' performance improvement strategies. A commenter expressed their support for reducing the total number of measures in the Model. Another commenter stated that the Discharge Function measure (when viewed in combination with the DTC–PAC measure) shows a more balanced reflection of a patient's return to function in the home setting and successful care transitions from Post Acute Services to independence in the home environment.

Response: We appreciate this supportive feedback.

Comment: A few commentors commented that it was too soon to make changes to the applicable measure set, given that HHAs have invested a significant amount of effort to improve their performance on the original set of measures and are not prepared to begin shifting to accommodate a new set of applicable measures, and that changes will require software updates that are costly and time-consuming.

Response: The policy updates included in this rule are effective in CY 2025. This means HHAs new to the expanded Model will have had three years to improve performance on the applicable measures proposed in the CY 2022 HH PPS final rule. And, those HHAs located in the nine states that competed in the original Model have had five years to improve performance on those same measures. By including the new measure set in the 2024 rulemaking cycle, HHAs have more than a year to prepare. And, we believe we have given sufficient notice so that software updates can be made timely.

Comment: Most commenters were supportive of the replacement of the OASIS-based DTC measure with the claims-based DTC–PAC measure. A commenter stated their belief that the claims-based version is a better measure of their patients' discharge to community rates.

Response: We appreciate these commenters' understanding of the value of the DTC–PAC measure and the supportive feedback.

Comment: A commenter expressed their concern that the DTC–PAC measure will penalize HHAs for patients with progressive disease states and for outcomes that are beyond the control of the HHA.

Response: Since the introduction of this measure into the HH QRP, we have not seen evidence to corroborate these concerns.

Comment: Most comments related to concerns about adoption of the DC Function measure in the expanded HHVBP Model were also submitted regarding the HH QRP. Mutual concerns are related to the imputation approach and methodology, validity of measure testing, lack of Consensus-Based Entity (CBE) endorsement, timing and broad approach for implementation, and applicability for maintenance patients. As stated in the proposed rule, final achievement thresholds and benchmarks will be provided in the July 2024 Interim Performance Report (IPR). To help provide feedback to HHAs on the applicable measure set effective in CY 2025, we plan to make the most current HHA-specific performance data for the applicable measures available to each HHA in iQIES. We intend for this to include current performance relative to other HHAs nationally as soon as administratively possible and before the start of the CY 2025 performance year and again before the IPR scheduled for July 2025.

Comment: The majority of commenters were supportive of replacing the ACH and ED Use measures with the PPH measure stating their belief that this measure reflects that not all hospitalizations or ED visits that occur while a patient is receiving home health services can be mitigated or prevented; the measure more accurately reflects the efforts that HHAs undertake to prevent hospitalizations without penalizing them for taking on more acutely ill patients; and is more likely to reflect whether HHAs are providing proper management and care as well as clear discharge instructions and referrals, allowing CMS to better assess quality of care for the purposes of the expanded HHVBP Model.

Response: We appreciate these commenters' understanding of the value of the PPH measure and the supportive feedback.

Comment: A commenter expressed concern that the PPH measure does not effectively gauge readmissions and does not truly mirror the quality of care of an HHA without providing reasons for their concern. Another commenter recommended a delay in the inclusion of this measure into the expanded Model until CMS can provide additional transparency with data around coding practices of inpatient providers.

Response: Since the introduction of this measure into the HH QRP, we have not seen evidence to corroborate these concerns. Additionally, as indicated in the CY 2022 HH PPS final rule (86 FR 62343), the process of developing the measure specifications included performing analyses on Medicare claims data to identify the most frequent diagnoses associated with admissions among home health beneficiaries.

After consideration of the public comments received, we are finalizing these provisions without modification.

3. Measure Categories

As shown in Table D3, the expanded Model utilizes established measure categories that represent the data sources including OASIS-based, claims-based, and HHCAHPS Survey-based. Although measures in the original Model have been added, removed, or substituted in the past, the measure category weights have remained constant, maintaining the weighting

proportions of 35 percent, 35 percent, and 30 percent for OASIS-based, claims-based and HHCAHPS Survey-based measures for the larger-volume cohort, respectively. For HHAs in the smaller-volume cohort, the weighting proportions of the OASIS-based and claims-based measures are 50 percent and 50 percent, respectively. Weights for individual measures within these categories have changed in the past due to changes to the applicable measure set (for example, replacing three individual OASIS-based measures with the two TNC measures) and to encourage improvement in the claims-based measures. With the proposed changes to the applicable measures in the proposed rule, the number of measures within the OASIS-based measure category will change. Table D3 illustrates the change in the measure set including the removal of the OASIS-based DTC measure, the replacement of the two OASIS-based TNC change measures to the OASIS-based DC Function measure, and the replacement of the claims-based Acute Hospitalization Measure and claims-based ED Use Measure for the claims-based PPH measure. Despite the changes to the applicable measure set, we intend to maintain the existing measure categories and their relative weights. For example, for the larger-volume cohort, the claims-based measures will continue to have a total weight of 35 percent. The relatively higher weight given to the claims-based measures reflects our belief in the importance of those measures relative to OASIS-based measures, which use self-reported data and that the incentive to reduce hospital utilization is maintained. We continually monitor the effects of weighting and will propose changes if we determine there is a need through future rulemaking.

TABLE D3. CURRENT AND PROPOSED MEASURE CATEGORY WEIGHTS BY QUALITY MEASURE IN THE EXPANDED HHVBP MODEL

Measure	Measure Weights			
	Larger-Volume Cohort		Smaller-Volume Cohort	
	Current	Proposed	Current	Proposed
OASIS-based Measures				
Discharged to Community (OASIS-based)	X	-	X	-
Improvement in Dyspnea	X	X	X	X
Improvement in Management of Oral Medications	X	X	X	X
Total Normalized Composite (TNC) Change in Mobility	X	-	X	-
Total Normalized Composite (TNC) Change in Self-Care	X	-	X	-
DC Function	-	X	-	X
Sum of OASIS-based Measures	**35.000**	**35.000**	**50.000**	**50.000**
Claims-based Measures				
Acute Care Hospitalizations	X	-	X	-
Emergency Department Use Without Hospitalization	X	-	X	-
Potentially Preventable Hospitalization	-	X	-	X
Discharged to Community (Claims-based)	-	X	-	X
Sum of Claims-based Measures	**35.000**	**35.000**	**50.000**	**50.000**
HHCAHPS Survey-based Measures				
Care of Patients	X	X	-	-
Communications Between Providers and Patients	X	X	-	-
Specific Care Issues	X	X	-	-
Overall Rating of Home Health Care	X	X	-	-
Willingness to Recommend the Agency	X	X	-	-
Sum of HHCAHPS Survey-based Measures	**30.00**	**30.000**	**-**	**-**
Sum of All Measures	**100.000**	**100.000**	**100.000**	**100.000**

4. Weighting and Redistribution of Weights Within the Measure Categories

a. Background

As proposed in the CY 2022 HH PPS final rule (86 FR 62240), the expanded HHVBP Model uses the same policies regarding the weighting of measures and the redistribution of weights when measures or measure categories are missing as under the original Model (83 FR 56536).

As previously discussed in section IV.B.2.b of the proposed rule, to align with quality measures used in the HH QRP, CMS proposed to replace the OASIS-based DTC measure with the claims-based DTC measure, jointly replace the claims-based ACH and ED Use measures with the claims-based PPH measure, and jointly replace the OASIS-based TNC Change in Mobility and TNC Change in Self-Care measures with the OASIS-based DC Function measure in CY 2025 and subsequent performance years. Due to these changes to the applicable measure set and the data sources, CMS proposed changes in weights and redistribution of weights within the measure categories accordingly.

b. Quality Measure Weights Within Measure Categories

Along with the proposed revisions to the current measure set, we proposed to revise the weights of the individual measures within the OASIS-based measure category and within the claims-based measure category. Currently, the OASIS-based, claims-based, and HHCAHPS Survey-based measures

contribute 35 percent, 35 percent, and 30 percent, respectively, to the Total Performance Score (TPS) for HHAs in the larger-volume cohort. For HHAs in the smaller-volume cohort, the OASIS-based and claims-based measures both contribute 50 percent to the TPS. The weights of the measure categories, when one category is missing, are based on the relative weight of each category for which measures are available. For example, if an HHA is missing the HHCAHPS Survey-based measure category, the remaining two measure categories (OASIS-based and claims-based) each have a weight of 50 percent. Table 28 in the CY 2022 HH PPS final rule (86 FR 62323 through 62324) presents the current weights for measures and measure categories under various reporting scenarios.

Table D4 shows the measure weights by quality measure in the expanded HHVBP Model currently in place and proposed for CY 2025 and subsequent performance years for HHAs in the larger-volume and smaller-volume cohort, respectively.

As discussed in section IV.B.3 of the proposed rule, for HHAs in the larger-volume cohort, we are keeping the measure category weights unchanged at 35 percent, 35 percent, and 30 percent for OASIS-based, claims-based, and HHCAHPS Survey-based measure categories, respectively. Similarly, for HHAs in the smaller-volume cohort, we are keeping the measure category weights unchanged at 50 percent and 50 percent for OASIS-based and claims-based measure categories, respectively. By keeping these measure category weights unchanged, the number of individual measures in each measure category will affect the magnitude of the individual measure weights. As proposed, changes to the applicable measure set will decrease the OASIS-based measures from five measures to three, while the number of individual measures for the claims-based measures and HHCAHPS Survey-based measures will remain unchanged. Given these proposals, the individual measure weights within the OASIS-based measure category will be higher than those under the current applicable OASIS-based measure category. The subsequent sections discuss in more detail the proposed measure weight redistributions for each measure category.

(1) Proposal To Redistribute Weights Within the OASIS-Based Measure Category

Because we proposed to replace the two TNC measures jointly with the DC Function measure, we proposed that the sum of the TNC measure weights be given to the DC Function measure. This will maintain the same relative weight for functional measures. Due to the proposed removal of the OASIS-based DTC measure, we also proposed to distribute the weight for that measure across the remaining three OASIS-based measures. In addition, we proposed to maintain a relatively small weight for Improvement in Dyspnea compared to the other measures in the applicable measure set. Under the current measure set, Improvement in Dyspnea is weighted at 5.833 for larger-volume HHAs and 8.333 for smaller-volume HHAs. Similarly, under the proposed applicable measure set, Improvement in Dyspnea will be weighted at 6.000 for the larger-volume cohort and 8.571 for the smaller-volume cohort. This approach aims to encourage improvement in quality of care, while reducing its importance relative to other quality measures that encourage both improvement and maintenance of quality care for all home health patients. These proposed changes will be effective in CY 2025. Table D4 describes the proposed measure weight redistributions for all measure categories by larger-volume and smaller-volume cohort, respectively. In addition to increasing the individual measure weight for Improvement in Dyspnea to 6.000, CMS proposed to increase the individual measure weight for Improvement in Management of Oral Medications to 9.000 and to assign the individual measure weight for DC Function to 20.000 for HHAs in the larger-volume cohort. These changes maintain the overall weight of the OASIS-based measures at 35 percent for the larger-volume cohort and 50 percent for the smaller-volume cohort.

TABLE D4. PROPOSED MEASURE WEIGHT REDISTRIBUTIONS FOR HHAS IN THE LARGER-VOLUME AND SMALLER-VOLUME COHORT

	Proposed Redistributions			
	Current Measure Weights		Proposed Measure Weights	
Measure	Larger-Volume Cohort	Smaller-Volume Cohort	Larger-Volume Cohort	Smaller-Volume Cohort
OASIS-Based Measures				
Discharged to Community	5.833	8.333	-	-
Improvement in Dyspnea	5.833	8.333	6.000	8.571
Improvement in Management of Oral Medications	5.833	8.333	9.000	12.857
Total Normalized Composite (TNC) Change in Mobility	8.750	12.500	-	-
Total Normalized Composite (TNC) Change in Self-Care	8.750	12.500	-	-
DC Function	-	-	20.000	28.571
Sum of OASIS-based Measures	**35.000**	**50.000**	**35.000**	**50.000**
Claims-based Measures				
Acute-Care Hospitalizations (ACH)	26.250	37.500	-	-
Emergency Department Use Without Hospitalization (ED)	8.750	12.500	-	-
Potentially Preventable Hospitalization	-	-	26.000	37.143
Discharge to Community (DTC-PAC)	-	-	9.000	12.857
Sum of Claims-based Measures	**35.000**	**50.000**	**35.000**	**50.000**
HHCAHPS Survey-based Measures				
Care of Patients	6.000	0.000	6.000	0.000
Communications Between Providers and Patients	6.000	0.000	6.000	0.000
Specific Care Issues	6.000	0.000	6.000	0.000
Overall Rating of Home Health Care	6.000	0.000	6.000	0.000
Willingness to Recommend the Agency	6.000	0.000	6.000	0.000
Sum of HHCAHPS Survey-based Measures	**30.000**	**0.000**	**30.000**	0.000
Sum of All Measures	**100.000**	**100.000**	**100.000**	**100.000**

Note: The weights of the measure categories, when one category is missing, are based on the relative weight of each category when all measures are used. For example, if an HHA is missing the HHCAHPS category, the remaining two measure categories (OASIS-based and claims-based) represent 50 percent.

(2) Proposal To Redistribute Weights Within the Claims-Based Measure Category

Because we proposed to remove the ACH and ED Use measures, we proposed to allot an individual measure weight of 26.000 to the final PPH measure. The redistribution to the PPH measure is intended to give this measure approximately the same combined weight as the ACH and ED Use measures had previously. In addition, CMS proposed to allot an individual measure weight of 9.000 to the claims-based DTC–PAC measure for the larger-volume cohort. The slight increase in weight for the claims-based DTC–PAC measure maintains the same overall weight of 35.000 for claims-based measures for the larger-volume cohort. Table D4 lists the corresponding individual claims-based measure weight redistributions applicable to HHAs in the smaller-volume cohort.

(3) Weights Within the HHCAHPS-Based Measure Category

Given there were no changes proposed to the measures within the HHCAHPS Survey-based measure category, we proposed to keep the individual measure weights for measures in this measure category unchanged. Specifically, each HHCAHPS Survey-based measure will continue to have an individual measure weight of 6.000 for HHAs in the larger-volume cohort. Given that HHAs in the smaller-volume cohort are not assessed based on their HHCAHPS Survey-based measure performance, the individual measure weight is set to zero (0.000) for the smaller-volume cohort (see Table D4).

We invited public comments on these proposals.

Comment: A few commenters provided feedback related to the redistribution of weights for individual measures within the OASIS-based measure category. A commenter stated that the weight of the DC Function measure was too high. Another commenter expressed concern that the weight of the DC Function measure is more than the combined weight of the two TNC measures it is replacing.

Response: With the reduction in the number of total measures in the program and in the OASIS category, and the decision to maintain the weights of each category, it was necessary to increase weight in either some or all the measures in the OASIS category. When redistributing the weights among the remaining measures in the OASIS category, we selected a weight for the DC Function measure that is slightly higher than the current combined weight of the TNC measures. We selected this weight because of our belief that function is critical for beneficiaries to safely remain in their home. Further, the measure's robust risk adjustment methodology that captures the different functional potential of all home health patients and the imputation methodology that mitigates missing data challenges and limits gaming makes it an important quality measure that should have the weight that it has in the expanded Model. As with all our measures, we will monitor and evaluate the impact of the weighting of the DC Function measure.

Comment: A few commenters stated that the redistribution of weights for the DTC–PAC and PPH measures are too heavy and will promote ''cherry-picking.'' They believe the PPH measure targets patients with at least one potentially preventable hospitalization observation stay during a home health episode, and is challenging for patients with complex needs, who have chronic

conditions that are subject to exacerbation. Another commenter suggests that the weight of the DTC–PAC measure seems extreme for patients that are often at a stage in disease progress but are not ready to elect the Medicare Hospice Benefit.

Response: Although the total number of measures have been reduced overall, there has not been any reduction in the weight or the number of measures in the claims category. The PPH measure may be considered as an improvement of the ACH measure because it includes those conditions that are preventable, and we kept its weight very close to the original Model. Evaluation of the ACH readmission measure showed better quality results and did not identify any access issues. We decided to maintain the weight of the PPH measure to encourage further improvement in reducing hospitalizations that are potentially preventable. We believe our proposed weighting will encourage increased focus on quality of care and on accountability for areas of significant Medicare spending, which includes hospitalizations. The DTC–PAC measure excludes patients discharged to home or facility-based hospice care. Thus, discharges to hospice are not considered discharges to community, but rather are excluded from the measure calculation. We wish to also note that including 31-day post-discharge mortality outcomes is intended to identify successful discharges to community, and to avoid the potential unintended consequence of inappropriate community discharges that bypass hospice care. As with all our measures, we will monitor and evaluate the impact of the weighting of the PPH measure.

Comment: Another commenter believes that the weighting of the PPH measure (26%) is disproportionately weighted higher than other important measures and devalues the patient's functional improvement and ability to remain at home long term; and the next-highest measure weighting is the new DC Function measure (20%). A commenter recommend that CMS change the weighting of PPH measure to 20% and the weighting of the DTC–PAC measure to 15%. While the PPH measure looks at a single outcome, the DC Function measure (when considered in combination with the DTC–PAC measure) provides a more balanced reflection of a patient's return to function in the home setting and successful care transitions from PAC services to independence in the home environment. Accordingly, this commenter recommends that CMS reduce the weighting of the claims-based PPH measure to 20% and the increase the weighting of the DTC–PAC measure to 15%.

Response: We agree that the DC Function and DTC–PAC measures are important measures. As discussed in this section, while we proposed to weight these two measures lower than the PPH measure, as the commenter noted, the DC Function measure is the next heaviest weighted measure, followed by DTC–PAC measure (which has the same weighting as Improvement in Management of Oral Medications). As previously noted, we selected the weight for PPH to encourage further improvement in reducing hospitalizations that are potentially preventable and place increased focus on accountability for areas of significant Medicare spending. We believe the proposed reweighting balances our interest in encouraging focus on reducing hospitalizations as well as on other quality improvement efforts, such as achieving an expected level of functional ability for patients at discharge and successful discharge to the community from an HHA. As with all our measures, we will monitor and evaluate the impact of the weighting of the DC Function measure. Regarding the commenter's suggestion to reweight the PPH measure to 20 percent and the DTC–PAC measure to 15 percent, for introduction of these measures into HHVBP, we are proposing weights for these two measures that are close to the weights for the current claims-based measures. We will continue to evaluate these measures and will be convening a TEP and will solicit their input on weighting.

Comment: Some commenters believed that the proposed reweighting may disincentivize some HHAs from serving vulnerable populations that are at risk for hospitalizations. A commenter stated that the proposed reweighting may incentivize hospital stays.

Response: Although the total number of measures have been reduced overall, requiring some reweighting of measures to occur, there has not been any reduction in the weight of the claims-based measure category or the number of measures in the claims-based measure category and only a minute change to the PPH measure. We believe that the selected weighting will encourage HHAs to further enhance their service structures to appropriately address the needs of Medicare beneficiaries of all types by using quality improvement processes that support the expanded Model's quality measures, including processes intended to reduce hospitalizations. We do not believe that the proposed weighting of the measures will discourage HHAs from serving vulnerable populations or incentivize further hospital stays. Rather, we believe that weighting the measures to increase the emphasis on the PPH measure will encourage HHAs to increase the coordination with other providers and suppliers such as physicians and inpatient facilities (hospitals and post-acute care (PAC) facilities) in order to reduce ED visits and hospital admissions as was determined in the evaluation of the HHVBP model. We note that the claims-based PPH measure is included in the HH QRP and reflects goals consistent with other CMS initiatives that focus on reducing avoidable hospital admissions, such as the Hospital Readmissions Reduction Program. We expect the proposed increase in the weight of the PPH measure to incentivize avoiding hospital stays, not additional hospitalizations. We also do not expect that the weighting will cause HHAs to implement policies that do not serve vulnerable populations at risk of hospitalization, but will instead encourage care coordination between HHAs and other health care providers to avoid hospitalizations, which may result in improved care for all beneficiaries, including vulnerable populations.

Comment: Although we did not propose changes to the weights for the measure categories, a few comments expressed concerns about the weights of the measure categories as described previously. MedPAC believes the weights for the OASIS-based measure category are too heavy given their concerns about the accuracy of OASIS data. One national association stated that some of their members believe the weight assigned to HHCAHPS measure category is too high claiming that the types of beneficiaries their members serve—lower socioeconomic status, more complex, often dual eligible status—are less likely to complete the HHCAHPS survey. They request that CMS look at how to account for discrepancies in HHCAHPS response rates based on the population served in the expanded HHVBP Model.

Response: We will add the weighting of measure categories to the agenda for the TEP planned for November of this year and share these comments with the HHVBP Technical Expert Panel (TEP) and we will monitor to determine if the measures will impact beneficiaries of lower socioeconomic status.

We received no comments concerning individual measure weights for the HHCAHPS-based measure category.

After consideration of the public comments received, we are finalizing these provisions without modification.

(4) Alternatives Considered

Several measure weighting alternatives were considered prior to choosing the previously discussed proposals. Tables D5 describes these alternative options for HHAs in the larger-volume cohort, including weights proportional to the weights for the initial measure set (Option 1), maintaining measure category weights consistent with current measure set weights and equal within-category weights (Option 2), using equal measure category weights and maintaining within-category weight proportions (Option 3), using equal measure category weights and equal within-category weights (Option 4), and having equal weights for all measures (Option 5). We also considered these options for the smaller-volume cohort and came to the same conclusions. Therefore, we only provided a table with measure weighting alternatives for the larger-volume cohort.

TABLE D5. MEASURE WEIGHTING ALTERNATIVES CONSIDERED FOR HHAs IN THE LARGER-VOLUME COHORT

Measure	Option 1 Proportional	Option 2 Maintain Category Weights; Equal Within Proportion	Option 3 Equal Category Weights; Maintain Within Proportion	Option 4 Equal Category Weights; Equal Within Proportion	Option 5 Equal Weights
OASIS-based Measures					
Improvement in Dyspnea	8.750	11.667	8.333	11.111	10.000
Improvement in Management of Oral Medications	8.750	11.667	8.333	11.111	10.000
DC Function	17.500	11.667	16.667	11.111	10.000
Sum of OASIS-based Measures	**35.000**	**35.000**	**33.333**	**33.333**	**30.000**
Claims-based Measures					
Potentially Preventable Hospitalization	26.250	17.500	25.000	16.667	10.000
Discharged to Community-PAC	8.750	17.500	8.333	16.667	10.000
Sum of Claims-based Measures	**35.000**	**35.000**	**33.333**	**33.333**	**20.000**
HHCAHPS Survey-based Measures					
Care of Patients	6.000	6.000	6.667	6.667	10.000
Communications Between Providers and Patients	6.000	6.000	6.667	6.667	10.000
Specific Care Issues	6.000	6.000	6.667	6.667	10.000
Overall Rating of Home Health Care	6.000	6.000	6.667	6.667	10.000
Willingness to Recommend the Agency	6.000	6.000	6.667	6.667	10.000
Sum of HHCAHPS Survey-based Measures	**30.000**	**30.000**	**33.333**	**33.333**	**50.000**
Sum of All Measures	**100.000**	**100.000**	**100.000**	**100.000**	**100.000**

Note: The weights of the measure categories, when one category is missing, are based on the relative weight of each category. For example, for HHAs that do not have data for the HHCAHPS measures, the remaining two measure categories (OASIS-based and claims-based) are both 50.000.

Of these alternatives, Option 1 is most consistent with the final weights and most consistent with the weights used for the current measure set; however, it fails to apply the minimal weight possible for Improvement in Dyspnea. Similarly, Options 2–4 do not reduce the weight for Improvement in Dyspnea and deviate more substantially than Option 1 from the current weighting scheme. By attributing equal weight to all measures in the proposed measure set, Option 5 satisfies the minimal weight criterion for Improvement in Dyspnea; however, it does so at the expense of applying the same weight, which is inconsistent with previous decisions about apply differential weighting to measures to incentivize HHAs to act on improving measures with higher weights in the applicable measure set as outlined in the CY 2022 HH PPS final rule (86 FR 62322).

5. Updates to the Model Baseline Year

a. Background

In the CY 2022 HH PPS final rule, we proposed that the first Model baseline year for the expanded HHVBP Model will be CY 2019 (January 1, 2019 through December 31, 2019), the first performance year will be CY 2023, and the first payment year will be CY 2025 (86 FR 62294 through 62300). We decided on CY 2019 as the Model baseline year, as opposed to CY 2020 or CY 2021, due to the potentially de-stabilizing effects of the public health emergency (PHE) on the CY 2020 data and because it was the most recent full year of data available prior to CY 2020. The performance year and payment year were proposed after originally proposing CY 2022 to be the first performance year and CY 2024 to be the first payment year. We decided to delay implementation by 1 year to allow additional time for HHAs to prepare and learn about the expanded Model, thus CY 2022 was defined as the pre-implementation year. In the CY 2023 HH PPS final rule, we changed the Model baseline year to CY 2022 (87 FR 66869 through 66874). We decided to use more recent data from the CY 2022 time period because it is more likely to be aligned with performance years' data under the expanded Model, and provide a more appropriate baseline for assessing HHA improvement for all measures under the expanded Model as compared to both the pre-PHE CY 2019 data, as previously proposed for existing HHAs, and the CY 2021 data, as previously proposed for new HHAs certified between January 1, 2019 and December 31, 2020.

Additionally, in the CY 2022 HH PPS final rule (86 FR 62308 through 62309),

we proposed the current measure set, as indicated in Table 25 of that final rule. The removal and replacement of measures from the current measure set necessitates an updated implementation and data reporting timeline, which will be applied to all applicable measures so that the Model baseline year is consistent across measures.

b. Proposal To Update the Model Baseline Year

Beginning with performance year CY 2025, we proposed to update the Model baseline year to CY 2023 for all applicable measures in the proposed measure set, including those measures included in the current measure set. The one exception is the new claims-based DTC–PAC measure, which uses two years of data. As such, the Model baseline year for the claims-based DTC–PAC measure will be CY 2022 and CY 2023 for the 2-year performance year spanning CY 2024 and CY 2025. For performance years CY 2023 and CY 2024, the Model baseline year will continue to be CY 2022. Table D6 lists the data periods for each measure and respective Model baseline, performance year, and payment years.

TABLE D6: DATA PERIODS USED UNDER THE PROPOSED MEASURE SET FOR PERFORMANCE YEAR CY 2025 AND PAYMENT YEAR CY 2027

Measure	Data Period	Data Period Used for Model Baseline Year*	Data Period Used for Performance Year	Payment Year
OASIS-based Measures				
Improvement in Dyspnea	1-year	CY 2023	CY 2025	CY 2027
Improvement in Management of Oral Medications	1-year	CY 2023	CY 2025	CY 2027
DC Function	1-year	CY 2023	CY 2025	CY 2027
Claims-based Measures				
Potentially Preventable Hospitalizations	1-year	CY 2023	CY 2025	CY 2027
Discharge to Community-Post Acute Care	2-year	CY 2022/2023	CY 2024/2025	CY 2027
HHCAHPS Survey-based Measures				
Care of Patients	1-year	CY 2023	CY 2025	CY 2027
Communications Between Providers and Patients	1-year	CY 2023	CY 2025	CY 2027
Specific Care Issues	1-year	CY 2023	CY 2025	CY 2027
Overall Rating of Home Health Care	1-year	CY 2023	CY 2025	CY 2027
Willingness to Recommend the Agency	1-year	CY 2023	CY 2025	CY 2027

*Beginning with performance year CY 2025, the baseline year and AT/BMs will be updated to CY 2023 for all remaining measures from the initial measure set.

If we finalize our proposal to use CY 2023 for the Model baseline year, we will provide HHAs with the final achievement thresholds and benchmarks in the July 2024 Interim Performance Report (IPR). For all measures but the claims-based DTC–PAC measure, this timeline allows for one year of performance between the first performance year and the proposed updated Model baseline year. Because the claims-based DTC–PAC measure is a two-year measure, there will be no gap between the proposed updated Model baseline year and the first performance year, which will be consistent with the rollout of the original HHVBP Model, in which benchmarks and achievement thresholds using CY 2015 data were made available to HHAs during the summer of the first performance year (CY 2016).

Furthermore, because the claims-based DTC–PAC measure is a 2-year measure, there will be an overlap in how discharge to community is measured for the expanded Model. Specifically, CY 2024 performance will be based on the current measure set, which includes the OASIS-based DTC measure. For the OASIS-based DTC measure, CY 2024 performance will be compared to baseline year CY 2022. CY 2025 performance will be based on the proposed measure set, which includes the claims-based DTC–PAC measure and thus replaces the OASIS-based DTC measure. Because the DTC–PAC measure is a two-year measure, CY 2025 performance for the claims-based DTC–PAC measure will be calculated based on two years of performance data (CY 2024/2025) and compared to two years of baseline year data (CY 2022/2023). Thus, for both the OASIS-based DTC measure and the claims-based DTC–PAC measure, CY 2022 data will be used to calculate performance in a Model baseline year, and CY 2024 data will be used to calculate performance in a performance year. Beyond CY 2025, data for calculating DTC–PAC performance will continue to overlap. For example, CY 2026 DTC–PAC (claims-based) performance will be based on data from CY 2025/2026, which overlaps by one year with the CY 2025 DTC–PAC (claims-based) performance year data. See Table D7. The DTC–PAC measure was designed as a 2-year measure to optimize reliability. In addition, each performance year will consist of 1 year of performance data that does not overlap with the prior performance year data, which provides sufficient opportunity to capture quality improvement over time. Finally, the DTC–PAC (claims-based) will provide a smoother performance trend over time compared to 1-year measures by reflecting performance across a longer reporting period.

TABLE D7. MODEL BASELINE YEARS AND PERFORMANCE YEAR DATA PERIODS FOR THE DTC MEASURES IN PERFORMANCE YEARS CY 2024-2026

			Data Periods				
Performance Year	OASIS-based DTC	Claims-based DTC-PAC	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026
PY 2024	X		Baseline		Performance*		
PY 2025		X	Baseline	Baseline	Performance*	Performance**	
PY 2026		X	Baseline	Baseline		Performance**	Performance

* Indicates the overlap in CY 2024 performance year data used for the OASIS-based DTC measure and claims-based DTC-PAC measure.
** Indicates the overlap in performance year data used for the claims-based DTC-PAC measure starting in performance year CY 2025.

c. Alternatives Considered

We considered several alternative timelines for updating the Model baseline year. First, we considered leaving the baseline year at CY 2022 for those measures on the previously proposed measure set. We opted against this alternative because it uses less recent data and makes it more difficult for HHAs to track which achievement thresholds and benchmarks are based on which years of baseline data.

Second, because of the time between the Model baseline year and the performance year, we considered delaying the implementation of the claims-based DTC–PAC measure by one year. Under this scenario, the measure's baseline year will remain CY 2022/2023, but the measure's first performance year will be CY 2025/2026. The first payment year that uses the claims-based DTC–PAC measure will then be CY 2028. As such, CY 2025 will be a transition year in between the current applicable measure set and the proposed applicable measure set. During this transition year, the OASIS-based DTC measure could be retained through CY 2025 or removed. Retaining the OASIS-based DTC measure during the transition year will ensure that the concept of being discharged to the community will be reflected in all performance and payment years, while removing it before the transition year will better align with the removal of the other measures as proposed. Because we view the concept of being discharged to the community as an important aspect of home health quality, we favor retaining the OASIS-based DTC measure during the transition year over removing it, assuming we delay implementation of the claims-based DTC measure. We rejected delayed implementation, however, because it temporarily increases the complexity of the expanded Model and requires that the Model uses the legacy OASIS-based DTC measure for another year, despite its removal from the HH QRP.

Third, we considered delaying implementation of the OASIS-based DC Function measure, which is proposed for CY 2025 implementation in the HH QRP as indicated in section III.D.1. of the proposed rule. Although a delay will allow more time to evaluate the measure's performance prior to HHVBP implementation, data utilized in this measure have been a part of the HH QRP's OASIS assessment tool since CY 2019. We prefer the proposed timeline for the OASIS-based DC Function measure because it expedites alignment with the HH QRP, SNF VBP, and the other PAC programs and the timing corresponds with the proposed removal and replacement of other measures in the Model.

Lastly, we considered delaying implementation for all replacement measures, such that their Model baseline years will end on December 31, 2023, and their first performance years will end on December 31, 2026 (CY 2026 for the OASIS-based DC Function and claims-based PPH measures and CY 2025/2026 for the claims-based DTC–PAC measure). Under this alternative, the first payment year to use the proposed applicable measure set will be CY 2028. We favor the proposed timeline because we prefer aligning more closely with the HH QRP measure set as early as possible.

We invited public comments on this proposal.

Comment: Many commenters requested that we not change the Model baseline year, claiming it ''moves the goal post'' negating the quality improvement efforts they have made in preparation for the expanded Model. Another commenter believe that moving the baseline penalizes HHAs that took the initiative to improve quality and rewards those HHAs that have not started improving performance since the start of the expanded HHVBP Model. A couple of commenters expressed concern that baseline data will not be available until October 2024.

Response: We believe that updating the Model baseline in 2025 serves several purposes: (1) it measures an HHA's improvement based on recent changes in performance using the most current data available, (2) it establishes a baseline year that it is the same for the existing measures as for the newly adopted measures, and (3) it supports continuous quality improvement. We appreciate the comments regarding the consideration of HHAs' efforts to improve quality. However, to add new measures to HHVBP, we must establish a Model baseline year for these measures. We believe that it is beneficial to align the Model baseline year for the existing measures with the new measures, particularly given that the new measures contribute heavily to the HHA performance scores. Maintaining different Model baseline years could cause more burden and confusion, compared to updating the Model baseline year for all measures at the same time. The expanded HHVBP Model performance scoring methodology rewards progress in raising quality scores not only through improvement points, but also through achievement points. Under the expanded Model, achievement is prioritized relative to improvement. As we stated in the CY 2023 HH PPS final rule (87 FR 66874), quality improvement efforts undertaken by HHAs that show impact on performance year quality scores may be recognized through achievement points, regardless of when those efforts were initiated. For example, an HHA that has improved their overall quality will potentially get more achievement points attributed to their TPS than from improvement points and would potentially result in the same payment adjustment if we had not changed the baseline. As stated in the proposed rule, final achievement thresholds and benchmarks will be provided in the July 2024 Interim Performance Report (IPR). To help provide feedback to HHAs on the applicable measure set effective in CY 2025, we plan to make the most current HHA-specific performance data for the applicable measures available to each HHA in iQIES. We intend for this to include current performance relative to other HHAs nationally as soon as

administratively possible and before the start of the CY 2025 performance year and again before the first IPR scheduled for July 2025.

After consideration of the public comments received, we are finalizing the provisions without modification.

6. Future Topics for Measure Considerations

We will take into consideration opportunities for further alignment with measures in the HH QRP and publicly reported on Home Health Care Compare because alignment will facilitate comparative assessments of provider quality and streamline home health providers' data capture and reporting processes. If we consider adding new measures that require data that is not already collected through existing quality measure data reporting systems, we will propose that option in future rulemaking while being mindful of provider burden.

To further the goals of the CMS National Quality Strategy, CMS leaders from across the Agency have come together to move towards a building-block approach to streamline quality measures across CMS quality programs for the adult and pediatric populations. This ''Universal Foundation'' [129] of quality measures will focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. The development and implementation of the Preliminary Adult and Pediatric Universal Foundation Measures will promote the best, safest, and most equitable care for individuals as we all come together on these critical quality areas. As CMS moves forward with the Universal Foundation, we will be working to identify foundational measures in other specific settings and populations to support further measure alignment across CMS programs as applicable.

In recognition of persistent health disparities and the importance of closing the health equity gap, we will consider future modifications that promote health equity and ways in which we could incorporate health equity goals into the Model. Any changes will be proposed in future notice and comment rulemaking.

[129] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the universal foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

While we did not make any specific proposals here, we invited interested parties to suggest future measures and the value they may provide to the expanded HHVBP Model.

Comment: We received one suggestion for a measure to be included in the Model, the Medicare Spending Per Beneficiary measure.

Response: We appreciate this suggestion and will share it with the HHVBP TEP as future measures for consideration is an agenda item for the TEP planned for November of this year.

C. Proposed Changes to the Appeals Process

1. Background

As codified at § 484.375, the appeals process under the expanded HHVBP Model allows HHAs to submit recalculation requests for the interim performance reports and the Annual Total Performance Score (TPS) and Payment Adjustment Report (Annual Performance Report or APR). Under this process, an HHA may also make a reconsideration request if it disagrees with the results of a recalculation request for the APR. We refer the reader to the CY 2022 HH PPS final rule (86 FR 62331 through 62332) for details of the appeals process. We also proposed (86 FR 62329) that we will make available the Final APR after all reconsideration requests are processed and no later than 30 calendar days before the payment adjustment takes effect annually, both for those HHAs that requested a reconsideration and all other competing HHAs.

2. Proposed Revisions

We proposed revisions to the policy at § 484.375(b)(5) to acknowledge the ability of the CMS Administrator to review reconsideration decisions, and to change the time for filing a request for reconsideration. In particular, we proposed to amend § 484.375(b)(5) to specify that an HHA may request Administrator review of a reconsideration decision within 7 days from CMS' notification to the HHA contact of the outcome of the reconsideration request. We proposed to amend § 484.375(b)(5) to state that the CMS reconsideration official issues a written decision that is final and binding 7 calendar days after the decision unless the CMS Administrator renders a final determination reversing or modifying the reconsideration decision. And, that an HHA may request within 7 calendar days of the decision that the CMS Administrator review the reconsideration decision. The CMS Administrator may decline to review the reconsideration decision, render a final determination, or choose to take no action on the request for administrative review. Reconsideration decisions are considered final if the CMS Administrator declines an HHA's request for review or if the CMS Administrator does not take any action on the HHA's request for review within 14 days.

This proposed change will ensure that accountability for the decisions of CMS is vested in a principal officer and brings the reconsideration review process to a more similar posture as other CMS appeals entities that provide Administrator review. This revision also ensures that HHAs are aware that administrative review is available to those HHAs who wish to seek additional review of a reconsideration decision.

We invited public comment on this proposal.

Comment: In addition to support of the added step to the HHVBP appeals process, a commenter asked that we give HHAs more time to make the final request. Another commenter suggested that we notify them why an appeal is not moving forward.

Response: To accommodate the time needed to process all reconsideration requests, issue final reports, notify HHAs of their payment adjustment percentages for the upcoming calendar year 30 days before the start of that year, and submit payment adjustment percentages to the MACs, we cannot extend the period of time to make a final request. We thank you and appreciate the suggestion to notify an HHA of why an appeal is not moving forward. We believe that providing the Administrator's rationale for declining review would be burdensome. However, we will monitor the issue and consider it for future rulemaking if appropriate.

After consideration of the public comments received, we are finalizing the proposed provisions without modification.

D. Public Reporting Reminder

In the CY 2022 HH PPS final rule (86 FR 62332 through 62333), we proposed that we will publicly report the following information for the expanded HHVBP Model:

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

- The HHA's TPS Percentile Ranking; and
- The HHA's payment adjustment for a given year.

In that same rule, we stated that we anticipate this information will be made available to the public on a CMS website on or after December 1, 2024, the date by which we will intend to complete the CY 2023 Annual Report appeals process and issuance of the Final Annual Report to each competing HHA. For each year thereafter, we anticipate following the same approximate timeline for publicly reporting the payment adjustment for the upcoming calendar year. This policy is codified at § 484.355(c). We did not propose any changes to this policy. This simply serves as a reminder of our existing policy.

We did not receive comments on this reminder.

E. Health Equity Update

1. Background

In the Calendar Year 2023 Home Health Prospective Payment System Proposed Rule (CMS–1766–P), we included a Request for Information (RFI) on a future approach to health equity in the expanded HHVBP Model. We define health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [130] We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs and models, 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. Our goals outlined in the *CMS Framework for Health Equity 2022–2032* [131] are in line with Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.'' [132] The goals included in the CMS Framework for Health Equity serve to further advance health equity, expand coverage, and improve health outcomes for the more than 170 million individuals supported by our programs, and sets a foundation and priorities for our work including: strengthening our infrastructure for assessment, creating synergies across the health care system to drive structural change, and identifying and working to eliminate barriers to CMS-supported benefits, services, and coverage.

In addition to the CMS Framework for Health Equity, CMS seeks to ''advance health equity and whole-person care'' as one of eight goals comprising the CMS National Quality Strategy (NQS).[133] The NQS identifies a wide range of potential quality levers that can support our advancement of equity, including: (1) establishing a standardized approach for patient-reported data and stratification; (2) employing quality and value-based programs to address closing equity gaps; and, (3) developing equity-focused data collection, analysis, regulations, and quality improvement initiatives.

A goal of this NQS is to address persistent disparities that underly our healthcare system. Racial disparities, in particular, are estimated to cost the U.S. $93 billion in excess medical costs and $42 billion in lost productivity per year, in addition to economic losses due to premature deaths.[134] At the same time, racial and ethnic diversity has increased in recent years, with an increase in the percentage of people who identify as two or more races accounting for most of the change, rising from 2.9 percent to 10.2 percent between 2010 and 2020.[135] Therefore, we need to consider ways to reduce disparities, achieve equity, and support our diverse beneficiary population through the way we measure quality and display the data.

We solicited public comments via the previously discussed RFI on policy changes that we should consider on the topic of health equity. We specifically requested input on whether we should explore incorporating adjustments into the expanded HHVBP Model to reflect the varied patient populations that HHAs serve around the country and tie equity-focused outcomes to the payment adjustments we make based on HHA performance under the Model. We refer readers to the CY 2023 HH PPS final rule (87 FR 66876), for a summary of the public comments and suggestions we received in response to the health equity RFI. We will take these comments into account as we continue to work to develop policies and quality measures on this important topic.

2. Anticipated Future State

We are committed to developing approaches to meaningfully incorporate the advancement of health equity into the expanded HHVBP Model. As we move this important work forward, we will continue to take input from interested parties. We also note that there are proposals being made to implement a health equity adjustment in the Hospital Inpatient Quality Reporting Program and the SNF Value-Based Purchasing Program. At this time, however, we will give HHAs time to learn the requirements of the expanded Model, gather at least two 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.

Comment: Several commenters expressed their support of the approach described in this update, particularly the plan to gather two years of performance data prior to adding a HE adjustment. However, a commenter strongly encouraged CMS to continue to pursue ways to incentivize the achievement of health equity in the expanded HHVBP Model without delay as they believe that the learning process related to the Model can occur simultaneously with CMS actively continuing efforts to further health equity. A commenter encouraged CMS to create a standardization of social determinants for health data collection and analysis. Another commenter expressed concerns that those HHAs that accept complex patients that have significant issues associated with SDH may have poorer outcomes and may exclude patients that will negatively impact their payments. This same commenter asked that we consider a more efficient way to gather information related to health equity.

Response: We appreciate these comments and will share them with the HHVBP TEP as the incorporation of health equity is an agenda item for the TEP planned for November of this year.

[130] Centers for Medicare and Medicaid Services. Available at *https://www.cms.gov/pillar/health-equity.* Accessed February 1, 2023.

[131] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[132] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[133] Centers for Medicare & Medicaid Services. What is the CMS Quality Strategy? Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[134] Ani Turner, The Business Case for Racial Equity, A Strategy for Growth, W.K. Kellogg Foundation and Altarum, April 2018.

[135] 2022 National Healthcare Quality and Disparities Report. Content last reviewed November 2022. Agency for Healthcare Research and Quality, Rockville, MD, *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.*

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

A. General Background

1. Statutory Background

Division FF, section 4134(a) 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, by amending the existing IVIG benefit category at section 1861(s)(2)(Z) of the Act. 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, made to a supplier for all items and services related to administration of IVIG furnished in the home during a calendar day separate from the payment for the IVIG product.

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.[136] The goal of Ig therapy is to use Ig obtained from normal donor plasma to maintain a sufficient level of antibodies in the blood of individuals with PIDD to fight off bacteria and viruses. Ig is formulated for both intravenous and subcutaneous administration (SCIg). Clinicians can prescribe either product to the beneficiary with PIDD according to clinical need and preference, and beneficiaries can switch between intravenous and subcutaneous administration of Ig.

3. Legislative Summary

Section 642 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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 would improve access to home IVIG therapy for patients with PIDD. The Medicare IVIG Access Act mandated that Medicare would establish a per visit payment amount for the items and services necessary for the home administration of IVIG therapy for beneficiaries with specific PIDD diagnoses. The Demonstration did not include Medicare payment for the IVIG product which continues to be paid under Part B in accordance with section 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.[137]

On September 28, 2017, Congress passed the Disaster Tax Relief and Airport and Airway Extension Act of 2017 (Pub. L. 115–63). Section 302 of Public Law 115–63 extended the Demonstration through December 31, 2020.

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

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

4. Demonstration Overview

Under the Demonstration, which will end on December 31, 2023, Medicare provides 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 applies to situations where the beneficiary requires IVIG for the treatment of certain PIDD diagnoses or was receiving SCIg to treat PIDD and wishes to switch to IVIG.

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

In order to participate in the Demonstration, beneficiaries must meet 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 items and services).
- Must receive the service in their home or a setting that is ''home like''.

To participate in the Demonstration, the beneficiary must submit an application, signed by their physician.

DME suppliers billing for the items and services covered under the

[136] 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.

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

Demonstration must meet 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 is subject to coinsurance and deductible.

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

- 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.

The code is used for the IVIG Demonstration only. Suppliers must bill Q2052 as a separate claim line on the same claim for the IVIG drug.

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. Currently, IVIG is covered in the home under Part B if all of 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 would apply for the IVIG administration items and services described in section V.A.4. of this final rule. Subpart B of Part 410 of the regulations set out the medical and other health services requirements under Part B. The regulations at § 410.10 identify the services that are subject to the conditions and limitations specified in this subpart. Section 410.10(y) includes intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases. Section 410.12 outlines general basic conditions and limitations for coverage of medical and other health services under Part B, as identified in section 410.10. Section 410.12(a) includes the conditions that must be met in order 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, we proposed to add the term ''items and services'' to the regulation at § 410.10(y). Furthermore, sub-regulatory guidance documents (that is, IVIG LCD (33610) [138] and IVIG Policy Article (A52509) [139]) provide direction on coding and coverage for the IVIG product at home. Through the Local Coverage Determination (LCD) for Intravenous Immune Globulin (L33610),[140] 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 in order to qualify to receive the items and services covered under section 1861(s)(2)(Z) of the Act. Furthermore, for any item (including IVIG) to be covered by Medicare, it must (1) be eligible for a defined Medicare benefit category, (2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and (3) meet all other applicable Medicare statutory and regulatory requirements. Guidance for the LCD for IVIG [141] 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 E1.

BILLING CODE 4120–01–P

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

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

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

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

TABLE E1: 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

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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 E1 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 guidance is revised as needed by the DME MACs to reflect updated and changed ICD–10–CM codes. And finally, in order 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 will update this guidance pursuant to the CAA, 2023 to reflect the expansion of the benefit to the items and services related to the administration of IVIG at home. Leveraging the existing regulations and sub-regulatory guidance will maintain one set of standards across the entire IVIG benefit (that is, for the product and for the related items and services). This will result in seamless implementation from the existing IVIG Demonstration, thereby ensuring immediate access for beneficiaries requiring such items and services. We solicited comments on our proposal to add ''items and services'' to the regulation at § 410.10(y).

Comment: We received seven comments on the implementation of the home IVIG items and services payment. Overall, commenters were supportive of CMS's proposed regulations to implement the home IVIG items and services payment in a manner that seamlessly carries out the law as enacted. Commenters agreed that ''home infusion offers better access to infused therapies for beneficiaries living in rural areas and with disabilities, while improving clinical outcomes.'' Another commenter reiterated the benefits of home IVIG administration discussed in the 2022 IVIG Demonstration Report to the Congress, stating advantages such as better access to IVIG, decrease in transportation barriers, higher rates of compliance, and reduced risk of infection.

Response: We appreciate commenters support of the proposals in this rule.

Final Decision: We are finalizing the amendment to the regulation at § 410.10(y) to add ''items and services'' as proposed.

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. We stated in the CY 2024 HH PPS proposed rule (88 FR 43754) that we interpret section 4134 of the CAA, 2023 to make permanent coverage of the same items and services under the existing IVIG Demonstration to ensure continuous and comprehensive coverage for beneficiaries who choose to receive home IVIG therapy. Under the Demonstration, the bundled payment for the items and services necessary to administer the drug intravenously in the home includes the infusion set and tubing, and nursing services to complete an infusion of IVIG lasting on average three to five hours.[142] Although ''items

[142] 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.*

and services'' are not explicitly defined under section 4134 of the CAA, 2023, we believe the items and services covered under the Demonstration are inherently the same items and services that would be covered under the payment added to the benefit category at section 1861(s)(2)(Z) of the Act. While we did not enumerate a list of services that must be included in the separate bundled payment, we stated in the proposed rule that we anticipate that the nursing services would include such professional services as IVIG administration, assessment and site care, and education. Moreover, it would be up the provider to determine the services and supplies that would be appropriate and necessary to administer the IVIG for each individual. This may or may not include the use of a pump. Because IVIG does not have to be administered through a pump (although it can be), external infusion pumps are not covered under the DME benefit for the administration of IVIG. An external infusion pump is only covered under the DME benefit if the infusion pump is necessary to safely administer the drug. The Local Coverage Determination (LCD) for External Infusion Pumps identify the drugs and biologicals that the DME Medicare Administrative Contractors (MACs) have determined require the use of such pumps and cannot be administered via a disposable elastomeric pump or the gravity drip method.[143] As such, under the IVIG Demonstration, coverage cannot extend to the DME pump, and therefore would not be covered separately under the home IVIG items and services payment.

We invited comments on any additional interpretations of items and services that may be considered under the scope of the home IVIG benefit. We did not receive any comments suggesting coverage of additional items and services under this payment. Therefore we expect that suppliers will furnish the same items and services under the permanent benefit, as provided under the Demonstration. We remind commenters that the IVIG product is covered under a separate 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, 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. As such, in the case that a beneficiary is receiving home health services under the home health benefit, the home health agency could continue to bill for these items and services under the home health benefit and the drug would be continued to be paid under Part B. A separate payment for the IVIG items and services under the IVIG benefit would be prohibited.

With regard to the home infusion therapy (HIT) services benefit, 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),[144] with the exception of insulin pump systems and certain drugs and biologicals on a self-administered drug exclusion list. In order 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 in the home are covered under the HIT services benefit. While a DME supplier and a HIT supplier (or a DME supplier also enrolled as a HIT supplier) could not furnish services related to the administration of immunoglobulin (either IVIG or SCIg) to the same beneficiary on the same day, a beneficiary could potentially receive services under both benefits for services related to the infusion of different drugs. For example, a DME supplier also accredited and enrolled as a HIT supplier, could furnish HIT services to a beneficiary receiving intravenous acyclovir as well as IVIG, and bill both the IVIG and the HIT services benefits on the same date of service. We also recognize that a beneficiary may, on occasion, switch from receiving immunoglobulin subcutaneously to intravenously and vice versa, and as such, utilize both the HIT services and the IVIG benefits within the same month.

We invited comments on how typical it is for a patient to alternate between receiving IVIG and SCIg and the frequency with which it may occur. The following is a summary of the comments received and our responses.

Comment: Commenters representing people with primary immunodeficiency diseases, provided several reasons why patients may alternate between IVIG and SCIg. They explained that the route of administration affects the types of adverse reactions for patients receiving Ig therapy. They stated that IVIG may have more systemic adverse events such as headaches and nausea, whereas, SCIg may have more local reactions related to self-infusions. Other reasons for switching may be related to age, dexterity, and other physical abilities, as well as comfort level, convenience, or physician recommendation.

Response: We appreciate this explanation and will consider these comments as we move forward with implementation to ensure that the benefit meets the needs of beneficiaries impacted by primary immunodeficiency diseases.

Comment: A few commenters had questions and comments pertaining to the delivery of these services by HHAs. Commenters stated that furnishing IVIG in the home would be overly burdensome on HHAs who may already be challenged by staffing shortages or who may not be ''equipped to infuse the product, for example, being unable to secure experienced infusion nurses.'' Other commenters questioned whether the beneficiary could receive IVIG as an outpatient under Part B (that is, at the physician's office or infusion center), stating the beneficiary would have to switch to another agency or a home infusion therapy supplier if their HHA does not have staff who are able to administer the product.

Response: To clarify: these IVIG administration services can only be

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

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

billed by a DME supplier. If an HHA does not have staff able to furnish these services, they are not required to do so. However, the items and services related to the administration of IVIG in the home, and as identified on the home health plan of care, would be included in the payment for the 30-day home health period payment. As such, 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. Thus, if an HHA is unable to furnish the items and services related to the administration of IVIG (as indicated in the plan of care) in the home, they are responsible for arranging these services (including arranging for services in an outpatient facility) and are required to bill these services as home health services under the HH PPS.

We note that this aligns with current practice as it applies payment under the IVIG demonstration and Medicare home health coverage and payment. Under the IVIG demonstration program, beneficiaries who are receiving care under the Medicare home health benefit are not eligible to have covered services separately paid for under the Demonstration as these services have always been covered under the Medicare home health benefit.

Therefore, we believe concerns about access to care for non-homebound beneficiaries and additional burden on HHAs are misplaced, as this permanent policy is simply an extension of current practice under the Demonstration.

Comment: A few commenters provided feedback related to the home infusion therapy services benefit, specifically regarding changing the definition of ''infusion drug administration calendar day,'' and bundling the Part B disposable supplies with the home infusion therapy services.

Response: We remind commenters that the home infusion therapy services benefit is a separate benefit from the home IVIG items and services benefit, and as such, comments related to payment for home infusion therapy services are out of the scope of this final rule.

C. IVIG Administration Items and Services Payment

As discussed previously, 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. We stated in the CY 2024 HH PPS proposed rule that we believe 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.

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 suppliers of medical equipment and supplies, by adding a new subparagraph (E), clarifying with respect to payment, that items and services related to the administration of intravenous immune globulin furnished on or after January 1, 2024, as described in section 1861(zz) of the Act, are included in the definition of medical equipment and supplies. This means that suppliers that furnish IVIG administration items and services must meet the existing DMEPOS supplier requirement for payment purposes under this benefit. Suppliers of IVIG administration items and services must enroll as a DMEPOS supplier and comply with the Medicare program's DMEPOS supplier standards (found at 42 CFR 424.57(c)) and DMEPOS quality standards to become accredited for furnishing medical equipment and supplies. Further, in order 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 in order 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 arrangements 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. We did not receive any comments on the supplier type who may furnish home IVIG items and services.

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' [145].'' 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, CAH, or SNF as defined in § 410.38(b). We did not receive any comments on our definition of ''home.''

D. Home IVIG Items and Services Payment Rate

1. Payment Amount for Home IVIG Items and Services for CY 2024

Section 1842(o) of the Act provides the authority for the development of a separate bundled payment for Medicare-covered items and services related to the administration of intravenous immune globulin to an individual in the patient's home during a calendar day, in an amount that the Secretary determines to be appropriate. This 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).

In accordance with section 101(d) of the Medicare IVIG Access Act, the Secretary established a per visit payment amount for the items and services needed for the in-home administration of IVIG based on the

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

national per visit low-utilization payment amount (LUPA) under the prospective payment system for home health services established under section 1895 of the Act. Per the Demonstration, the bundled payment amount for services needed for the home administration of IVIG includes infusion services provided by a skilled nurse. Therefore, the bundled payment is 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 is annually updated based on the nursing LUPA rate for such year. The service is subject to coinsurance and deductibles like other Part B services.

As stated in section V.B.1. of the CY 2024 HH PPS proposed rule, we believe that payment under section 1861(s)(2)(Z) of the Act covers the same items and services covered under the IVIG Demonstration. Likewise, we also agreed that the professional services needed to safely administer IVIG in the home would be services furnished by a registered nurse. Therefore, we stated that we believe 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 ($408.23) is appropriate. However, although 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, we stated that we believe it is appropriate to propose to update the CY 2023 IVIG services Demonstration rate by only the CY 2024 home health payment rate update percentage (proposed 2.7%) and 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. Therefore, we proposed that the home IVIG items and services payment rate for CY 2024 would be $408.23 * 1.027 = $419.25.

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 we believe that, as the statute aligns the payment amount with such amount determined under the Demonstration, the best reading of ''calendar day'' is ''per visit.'' Additionally, we stated that we would expect a supplier to furnish only one visit per calendar day.

We proposed to establish 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 proposed at § 414.1700(a), that a single payment amount is made for items and services furnished by a DMEPOS supplier per visit. We proposed at § 414.1700(b), to set 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 proposed CY 2024 home health update percentage of 2.7 percent.[146]

We solicited comments on these payment proposals, including the proposed CY 2024 payment rate. The following is a summary of the comments received and our responses.

Comment: A commenter agreed with the approach CMS has taken to calculate the payment in accordance with the approach taken in the Demonstration. This commenter stated appreciation for recognizing that a registered nurse should be delivering this care.

Response: We thank the commenter for their support of the payment approach.

Comment: Two commenters stated that CMS should reevaluate the LUPA-based rate calculation to ensure reimbursement is commensurate with the extensive services required to provide equitable access to IVIG treatments in the home, including for those beneficiaries residing in rural areas. A commenter stated that the proposed LUPA-based rate calculation may undervalue significant services and resources involved in the provision of home-based IVIG therapy. Another commenter suggested that CMS raise the rate to reflect five hours of the LUPA rate, rather than the initial four hours established under the Medicare IVIG Access Act.

Response: The Demonstration payment rate was initially set in accordance with the national per-visit LUPA amount under the HH PPS, as directed by section 101(d) of the Medicare IVIG Access Act. CMS tied payment to the LUPA amount for skilled nursing because payment is for infusion services furnished by a skilled nurse. As payment under the permanent benefit is for these same services, we believe 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 is appropriate. However, while the demonstration continued to use the LUPA rate to annually update this payment amount, we proposed to update the CY 2023 IVIG services Demonstration rate by only the CY 2024 home health payment rate update percentage and not include the wage index budget neutrality factor, which is included in the LUPA update. The commenter does not state what other services beyond skilled nursing are involved in the provision of home-based IVIG therapy; however, we remind the commenter that this payment is strictly for the items and services needed to administer the IVIG in the patient's home. The IVIG product is covered under separate statutory authority. Regarding the suggestion to raise the payment rate to reflect five hours of the full LUPA rate for skilled nursing, a review of the Updated Interim Report to Congress: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration Project [147] shows that physicians' offices average 3.14 hours of infusion time and hospital outpatient facilities average 3.09 hours infusion time. As such, we continue to believe that the initial calculation methodology established under the Demonstration program is sufficient to continue under the permanent benefit.

Comment: A commenter agreed with our approach to not apply a geographic wage adjustment to the permanent IVIG item and services payment.

Response: We thank the commenter for their support.

Final Decision: We are finalizing our proposal to update the CY 2024 home IVIG items and services payment rate by the CY 2024 home health payment rate update. The final home health update is 3.0 percent. The CY 2024 home IVIG items and services payment rate for CY 2024 is $408.23 * 1.030 = $420.48.

(a) Annual Payment Update

As discussed previously, the IVIG Demonstration used the nursing LUPA rate, which is annually adjusted by the wage index budget neutrality factor, as well as the home health update percentage, as the payment rate for such year of services. In the CY 2024 HH PPS proposed rule we stated that, because the IVIG services payment is not geographically wage adjusted, we believe it is more appropriate to

[146] The final home health update percentage is 3.0.

[147] *https://innovation.cms.gov/data-and-reports/2022/ivig-updatedintrtc.*

annually adjust the IVIG items and services payment rate only by the home health payment update percentage. As such we proposed at § 414.1700(c), beginning in 2025, the per-visit payment amount from the prior year will be annually increased by the home health update percentage for the current calendar year. We solicited comments on the use of the home health update percentage to annually update the IVIG items and services payment beyond CY 2024.

Comment: A commenter supported the proposal to annually update the IVIG items and services payment for CY 2025 and subsequent calendar years by the home health update percentage.

Response: We thank the commenter for their support.

Final Decision: We are finalizing our proposal to update the CY 2025 home IVIG items and services payment rate and subsequent years, by the home health payment rate update for such year.

E. Billing Procedures for Home IVIG Items and Services

In order to ensure a smooth transition for DME suppliers to bill for the items and services related to the home administration of IVIG, we will use the existing Q-code (Q2052) under the Demonstration, with a new descriptor (''Services, Supplies, and Accessories used in the Home for the Administration of Intravenous Immune Globulin (ivig)'') in order to bill for items and services under Medicare FFS. The Q-code will continue to be billed separately from, or on the same claim as, the J-code for the IVIG product and will be processed through the DME MACs. The Q-code should be billed as a separate claim line on the same claim for the same place of service as the J-code for the IVIG. In cases where the IVIG product is mailed or delivered to the patient prior to administration, the date of service for the administration of the IVIG (the Q-code) may be no more than 30 calendar days after the date of service on the IVIG product claim line. No more than one Q-code should be billed per claim line per date of service.

If a provider is billing for multiple administrations of IVIG on a single claim, then the supplier will bill the Q-code for each date of service on a separate claim line, which will be payable per visit (that is, each time the IVIG is administered). There may be situations in which multiple units of IVIG are shipped to the patient and billed on a single ''J'' code claim line followed by more than one Q-code administration claim line, each with the date of service on which the IVIG was administered. However, only one Q-code shall be paid per infusion date of service. To implement the requirements for this separate bundled payment under section 1861(s)(2)(Z) of the Act, we will issue a Change Request (CR) prior to implementation of this payment, including the Q-code needed for billing, outlining the requirements for the claims processing changes needed to implement this payment.

VI. Hospice Informal Dispute Resolution and Special Focus Program

A. Background and Statutory Authority

Division CC, section 407 of the Consolidated Appropriations Act (CAA), 2021, amended Part A of Title XVIII of the Act to add a new section 1822, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements, required public reporting of survey information, and a new hospice hotline.

The provisions in the CAA, 2021, direct the Secretary to create a Special Focus Program (SFP) for poor-performing hospice programs, give authority for imposing enforcement remedies for noncompliant hospice programs, and require the development and implementation of a range of remedies as well as procedures for appealing determinations regarding these remedies. These enforcement remedies can be imposed instead of, or in addition to, termination of the hospice programs' participation in the Medicare program. The remedies include civil money penalties (CMP), directed in-service training, directed plan of correction, suspension of all or part of payments, and appointment of temporary management to oversee operations.

In the CY 2022 HH PPS final rule (86 FR 62240), we addressed provisions related to hospice survey enforcement and other activities described in the rule. A summary of the finalized CAA, 2021 provisions regarding hospice survey and enforcement can be found in the CY 2022 HH PPS final rule (86 FR 62243), available at *https://www.govinfo.gov/content/pkg/FR-2021-11-09/pdf/2021-23993.pdf.* We finalized all the CAA, 2021 provisions related to hospice survey and enforcement in CY 2022 rulemaking except for the SFP. As outlined in the CY 2022 HH PPS final rule, we stated that we will consider public comments we received and seek additional collaboration with stakeholders to further develop a revised proposal and methodology for the SFP.

In the FY 2023 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements final rule (87 FR 4566) (Hospice rule), we affirmed our intention to initiate a hospice Technical Expert Panel (TEP) to provide input on the structure and methodology of the SFP. Public comments received in response to the FY 2023 Hospice rule generally supported CMS's efforts to establish an SFP and to convene a TEP as part of the SFP development. A 30-day call for nominations was held July 14 through August 14, 2022, and nine TEP members were selected, representing a diverse range of experience and expertise related to hospice care and quality. A CMS contractor convened a TEP in October and November 2022, which provided feedback and considerations on the preliminary SFP concepts, including developing a methodology to identify hospice poor-performers, criteria for completing the SFP and for termination from Medicare when a hospice cannot complete the SFP, and public reporting. Details from the TEP meetings, including their recommendations, are available in the TEP summary report [148] on the CMS website at *https://www.cms.gov/medicare/quality-safety-oversight-certification-compliance/hospice-special-focus-program.*

B. Proposed Regulatory Provisions

1. Overview

We proposed in Subpart M—Survey and Certification of Hospice Programs, to add new definitions of ''Hospice Special Focus Program,'' ''IDR,'' ''SFP status,'' and ''SFP survey'' at § 488.1105. We also proposed a hospice informal dispute resolution process at § 488.1130 to provide hospice programs an informal opportunity to resolve disputes related to condition-level survey findings for those hospice programs that are seeking recertification from the State survey agency (SA), CMS, or reaccreditation from the Medicare-approved accrediting organization (AO) for continued participation in Medicare. Informal dispute resolution would also be offered to hospice programs following a complaint or validation survey and those in the SFP. We proposed the specific details on the hospice SFP at § 488.1135, which includes the criteria for selection and completion of the SFP, hospice termination from Medicare, and public reporting of the SFP. We proposed that the hospice SFP would commence as of

[148] 2022 Technical Expert Panel and Stakeholder Listening Sessions: Hospice Special Focus Program Summary Report (April 28, 2023).

the effective date of the rule, and we anticipated selecting SFP hospices in CY 2024. We also proposed to periodically review the effectiveness of the methodology and the algorithm.

We received 58 comments on the Hospice IDR and SFP proposals. Overall, a majority of commenters agreed with the intent and purpose of the IDR process and SFP. However, commenters had concerns about the data sources and individual measures chosen for the SFP algorithm, as well as concerns about various steps of the algorithm. Commenters also inquired about the various aspects of the SFP program, including selection criteria, graduation and termination criteria, technical assistance, and public reporting. Other commenters expressed support for the program as proposed but requested additional details regarding certain aspects of the SFP, such as how the algorithm will be monitored and how hospices will be selected for the SFP.

2. Proposed Definitions (§ 488.1105)

We proposed to add four new definitions to § 488.1105, that would define the hospice SFP, IDR, SFP status, and SFP survey. The proposed definitions are as follows:

- *Hospice Special Focus Program (SFP)* means a program conducted by CMS to identify hospices as poor performers, based on defined quality indicators, in which CMS selects hospices for increased oversight to ensure that they meet Medicare requirements. Selected hospices either successfully complete the SFP program or are terminated from the Medicare program.
- *IDR* stands for informal dispute resolution.
- *SFP status* means the status of a hospice provider in the SFP with respect to the provider's progress in the SFP, which is indicated by one of the following status levels: Level 1—in progress; Level 2—completed successfully; or Level 3—terminated from the Medicare program.
- *SFP survey* refers to a standard survey as defined in this section and is performed after a hospice is selected for the SFP and is conducted every 6 months, up to 3 occurrences.

We did not receive comments on the proposed definitions, and we are finalizing them as proposed. (See 42 CFR 488.1105.)

3. Informal Dispute Resolution (§ 488.1130)

We proposed at new § 488.1130 to make an Informal Dispute Resolution (IDR) process available to hospice programs to address disputes related to condition-level survey findings following a hospice program's receipt of the official survey Statement of Deficiencies and Plan of Correction, Form CMS–2567. The proposed IDR for hospices would be similar to the process already in existence for home health agencies. The IDR process for hospice programs, like that of HHAs, is for condition-level survey findings which may be the impetus for an enforcement action. Standard-level findings alone do not trigger an enforcement action and are not accompanied by appeal and hearing rights. The proposed IDR process would provide hospice programs an informal opportunity to resolve disputes regarding survey findings for those hospice programs seeking recertification from the SA, CMS, or reaccreditation from the AO for continued participation in Medicare. Additionally, the proposed IDR may be initiated for programs under SA monitoring (either through a complaint investigation or validation survey) and those in the proposed SFP. For hospice programs deemed through a CMS-approved AO, the AO would receive the IDR request from their deemed hospice program, following the same process and coordinating with CMS regarding any enforcement actions. In accordance with 42 CFR 488.5(a)(4), AOs must have a comparable survey process to the SAs. For deemed hospice programs, the AO communicates any condition-level findings to the applicable CMS Location. If a deemed hospice fails to meet the Medicare requirements or shows continued condition-level noncompliance, deemed status is generally removed and compliance oversight is placed under the SA. The purpose of the proposed IDR process would be to provide an opportunity to settle disagreements at the earliest stage, prior to a formal hearing, and to conserve time and money resources potentially spent by the hospice, the SA, and CMS. The proposed IDR process may not be used to refute an enforcement action or selection into the SFP. Additionally, we proposed that failure of CMS, or the State or the AO, as appropriate, to complete IDR must not delay the effective date of any enforcement action.

When survey findings indicate a condition-level deficiency (or deficiencies), the hospice program would be notified in writing of its opportunity to request an IDR for those deficiencies. This notice would be provided to the hospice program when the CMS–2567 Statement of Deficiencies and Plan of Correction is issued to the hospice. We proposed that the hospice's request for IDR must be submitted in writing (electronically or hard copy), include the specific survey findings that are disputed, and be submitted within the same 10 calendar days allowable for submitting an acceptable plan of correction.

The proposed IDR provision balances the need for hospice programs to avoid unnecessary disputes and protracted litigation using the most rapid mechanism for correcting deficiencies and aligning with the interests of hospice patients/caregivers. IDR is meant to be an informal process whereby the provider has an opportunity to address the surveyor's findings, either by disputing them or providing additional information.

We proposed that if any survey findings are revised or removed by the State or CMS based on IDR, and if CMS accepts the IDR results, the CMS–2567 would be revised accordingly. If CMS accepts the IDR results and the revised Form CMS–2567, then CMS would adjust any enforcement actions imposed solely due to those cited and revised deficiencies. If the survey findings are upheld by CMS or the state following IDR, the Form CMS–2567 would not be revised based on the IDR and there would not be adjustments to the enforcement actions.

Comment: Many commenters supported the establishment of an IDR process for hospices.

Response: We thank the commenters for their support of the IDR process for hospices.

Comment: A commenter suggested that CMS consider including language that promotes avoidance of the IDR process when findings surpass a certain level of seriousness.

Response: We thank the commenters for their suggestion but are not accepting it. Immediate jeopardy findings are cited at the condition-level on the Form CMS–2567. As with HHAs, hospice providers may dispute condition-level findings during IDR since such findings may be the impetus for an alternative sanction or termination. This would give the hospice provider an opportunity to present evidence in support of its position prior to imposition of a remedy or termination. However, a hospice's initiation of the IDR process will not postpone or otherwise delay the effective date of any enforcement action, especially if there was an immediate jeopardy finding. Additionally, the IDR process does not guarantee a finding will be overturned and may even convince hospices that, because there is ample support for the survey findings,

it would be unwise to pursue litigation. Further, if any findings are revised or removed based on IDR, the official Statement of Deficiencies is revised accordingly and any enforcement actions imposed as a result of those revised or removed deficiencies are adjusted accordingly. CMS will publish guidance on the IDR process and address limitations for the use of IDR for hospices following the rule's finalization.

Comment: A commenter questioned whether a more formal process involving an independent third party may be needed to ensure impartial assessment and resolution of the concerns raised through the IDR process.

Response: We are not aware of any concerns with the HHA IDR process since its inception in 2014. Therefore, we anticipate the IDR process for hospices will also be effective, based on its similarity to the HHA IDR process.

Comment: Several commenters recommended that CMS publish guidance on timeframes in the hospice IDR process. The commenters recommended as a reasonable timeframe for the IDR process to be completed to be 14 days and 30 calendar days from the date the dispute is filed.

Response: Following the rule's finalization, CMS will publish guidance for the hospice IDR process, similar to the guidance established for the HHA IDR. We will include timeframes for the process and for completing the IDR as expeditiously as possible.

Comment: A commenter recommended that CMS develop a process to track providers utilizing the IDR process and the final resolutions, and that CMS ensure the final IDR resolution, if changed from the initial findings in the CMS–2567, is reflected in a revised CMS–2567 and posted to the tracking process.

Response: The national surveyor database (iQIES) tracks the IDR process. If findings are changed due to IDR, a revised CMS–2567 is sent to the provider and updated in the national database.

Comment: Some commenters stated that they believed that the IDR should be available to hospices to refute SFP selection. Also, commenters noted that the first hospices selected for SFP would not have had the benefit of the IDR. Some commenters had concerns on the applicability of the IDR process as it relates to survey and substantiated complaint data used to choose providers for the SFP. Commenters also stated that the IDR outcome should be considered a part of the data used prior to making a final choice on hospice selection into the SFP.

Additionally, commenters encouraged CMS to standardize the survey process, enhance data interpretation accuracy and consistency, and not count condition-level deficiencies that are being disputed in the IDR process in the SFP algorithm. Commenters also noted that if CMS implements the SFP as proposed, the IDR process will not be available for deficiencies already cited until 2024.

Response: The IDR process provides an opportunity for a hospice provider to dispute any active condition-level findings upon receipt of survey findings. The SFP algorithm utilizes survey data from the finalized survey reports (CMS–2567), which are not pending IDR or subject to disputes.

Final Decision: After considering the public comments, CMS is finalizing the hospice IDR as proposed. (See 42 CFR 488.1130.)

4. Special Focus Program (§ 488.1135)

Section 1822(b) of the Act requires the Secretary to conduct a Special Focus Program for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements of the Act. We proposed at § 488.1135 a hospice SFP to address issues that place hospice beneficiaries at risk for poor quality of care through increased oversight. We proposed that specific criteria would be used to determine whether a hospice program participates in the SFP as outlined in the proposed rule. We also proposed the hospice SFP would commence as per the effective date of this final rule when published, and we anticipate selecting SFP hospices starting in CY 2024. We proposed to periodically review the effectiveness of the methodology and the algorithm and make adjustments through rulemaking as necessary.

a. Proposed Hospice Special Focus Program Algorithm

In establishing the proposed Hospice SFP, we examined the Special Focus Facility program for nursing homes and its methodology for facility selection. Although the proposed methodology for the hospice program SFP is similar in certain facets, the proposed SFP methodology is tailored specifically to this setting and to the data that is available to evaluate hospice performance.

We proposed to identify a subset of 10 percent of hospice programs based on the highest aggregate scores determined by the algorithm. The hospices selected for the SFP from the 10 percent would be determined by CMS.

To identify ''poor performance,'' we have identified several indicators, namely, survey reports with Condition-Level Deficiencies (CLDs) and complaints with substantiated allegations, and CMS Medicare data sources from the Hospice Quality Reporting Program (HQRP) (Medicare claims and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey). These indicators, which can be used to identify potential poor performance, have been integrated into the proposed SFP algorithm to assist in identifying potential hospice providers for the SFP.

As discussed previously, we proposed to use multiple data sources to provide a comprehensive view of the quality of care provided at the identified hospices. The compilation of these data sources illustrates areas of concern—validated/identified issues based on in-person/on-site review of a hospice to meet Medicare requirements; caregiver and public complaints about hospices not providing quality of care or not meeting Medicare requirements; and quality measures that inform the public of whether a hospice is providing expected care processes or outcomes. We believe these are indicators of poor quality hospice care. The final SFP algorithm is designed as an initial step in identifying poor quality indicators.

b. Proposed Use of Medicare Data Sources To Identify Poor Performing Hospices

To identify hospices with poor quality indicators, we proposed using the most recent complete Medicare hospice data from two data sources: (1) hospice surveys; and (2) Medicare HQRP. Each source represents distinct dimensions of hospice care that we have identified as related to a hospice's performance or practices. From these data sources, we proposed to use multiple indicators of hospice care delivery to identify poor performing hospices (see Table 1). Hospices would be identified for potential SFP enrollment if they (1) have data from any of the aforementioned data sources; (2) are listed as an active provider (that is, have billed at least one claim to Medicare FFS in the last 12 months); and (3) operate in the United States, including the District of Columbia and U.S. territories. Each data source and the quality indicators are discussed further later in this preamble. Based on these proposed criteria, in CY 2019 through CY 2021 analytic file, 5,943 hospices out of 6,093 active hospice providers (97.5 percent) would be eligible for participation in the SFP.

TABLE F1. PROPOSED PRIMARY MEDICARE DATA SOURCES AND INDICATORS IN THE SPECIAL FOCUS PROGRAM

Data Source	Hospice Surveys	Hospice Quality Reporting Program (HQRP)	
		Claims Data	CAHPS® Hospice Survey Measures
Indicators	Quality-of-Care Condition-Level Deficiencies	Hospice Care Index (HCI)	Help for Pain and Symptoms
			Getting Timely Help
	Substantiated Complaints		Willingness to Recommend this Hospice
			Overall Rating of this Hospice

(1) Hospice Survey Data

(a) Quality-of-Care Condition-Level Deficiencies (CLDs)

Hospices are surveyed for compliance with hospice program requirements prior to becoming certified as a hospice provider in Medicare (initial certification survey) and then at least once every 36 months (standard survey for recertification (§ 418.1110)), with roughly one-third of all hospices being surveyed each year. A post-survey revisit or follow-up survey may also occur to determine if the hospice corrected cited deficiencies and are in substantial compliance with all requirements. Hospice survey data (initial certification, standard recertification, and follow-up) is collected on the Certification And Survey Provider Enhanced Reports (CASPER) system. CMS will be posting publicly available hospice survey finding information to the Quality, Certification and Oversight Report (QCOR) website in CY 2023. For information related to the hospice survey process, we encourage the public to review the CMS State Operations Manual (SOM), Appendix M (Internet-Only Manual, Publication 100–07).

A CLD is cited on a survey when a hospice is found to be noncompliant with all or part of a condition of participation (CoP), which is one of the health and safety requirements all hospices are required to meet to participate in Medicare. As discussed in the QSOG memo (QSO–23–08–Hospice) issued on January 27, 2023, a significant change in the hospice survey protocol was made to provide an enhanced approach to investigating the quality-of-care provided to hospice patients. While each of the 23 CoPs continues to have equal weight in the final certification and enforcement decision, special attention is directed to those CoPs directly impacting patient care for purposes of the proposed SFP. Consistent with this enhanced survey process, we have identified 11 CoPs that directly contribute to the quality of care delivered to patients, their caregivers, and families, and believe that a cited CLD on any one of them may indicate a hospice is providing poor quality-of-care. Therefore, we proposed to include the 11 quality-of-care CLDs (noted in Table F2) as data indicators in the SFP algorithm. The SFP algorithm would focus on quality-of-care CLDs because they are based on observable quality concerns seen and reported by hospice surveyors to identify hospices that provide poor quality-of-care to hospice patients. Additionally, we did not propose to include all 23 hospice CoPs because we did not want to dilute the methodology's ability to identify quality concerns. However, in the proposed rule we noted that we may explore incorporating other CoPs into the methodology, and we solicited comments on an alternative approach that would incorporate other CoPs in the calculation for the SFP algorithm.

TABLE F2. ELEVEN QUALITY OF CARE CLDs (ALGORITHM INDICATORS)

Tag	Condition of Participation
§418.52	Condition of participation: Patient's rights.
§418.54	Condition of participation: Initial and comprehensive assessment of the patient.
§418.56	Condition of participation: Interdisciplinary group, care planning, and coordination of services.
§418.58	Condition of participation: Quality assessment and performance improvement.
§418.60	Condition of participation: Infection control.
§418.64	Condition of participation: Core services.
§418.76	Condition of participation: Hospice aide and homemaker services.
§418.102	Condition of participation: Medical director.
§418.108	Condition of participation: Short-term inpatient care.
§418.110	Condition of participation: Hospices that provide inpatient care directly.
§418.112	Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/IID.

We proposed to count the total number of quality-of-care CLDs from the previous 3 consecutive years of data. Our analysis of data from CY 2019 through 2021 found that very few hospices are not present in the survey data, and that the overwhelming majority of hospices (88.3 percent of all proposed SFP-eligible hospices or 5,248 out of 5,943) had no quality-of-care CLDs cited over these 3 years. Of the 5,943 hospices identified that will be SFP-eligible under the CY 2019–2021 data, 5.7 percent (that is, 341 hospices) are not present in the survey data. This means that each of those 341 hospices has not yet received its standard survey or their survey results had not been

recorded as of the time the data was accessed for analysis from the CASPER system and/or had no recorded substantiated complaint in the iQIES). Considering public comments received on the CY 2022 HH PPS final rule (86 FR 62240) and the SFP TEP feedback, stakeholders expressed concern about inter-surveyor reliability and state-to-state variability in survey policy as potential drawbacks of including survey data as part of the SFP program methodology. However, the TEP also acknowledged the importance and value of survey data that identifies whether a hospice complies with Medicare requirements to support basic care quality. Furthermore, the TEP supported using the total count of quality-of-care CLDs to indicate significant noncompliance with multiple CoPs. To address the inter-surveyor reliability and variability concerns, we have implemented improvements to surveyor training guidelines to increase surveyor standardization between SAs and AOs. Based on our efforts to improve surveyor training, and considering the TEP and stakeholder concerns, we proposed to count the total number of quality-of-care CLDs from the last 3 consecutive years of data.

(b) Substantiated Complaints

In addition to quality-of-care CLDs, we proposed to include the total number of substantiated complaints received against a hospice in the last 3 consecutive years of data before the release of the SFP selection list. Complaints against a hospice may be filed with the SA or Beneficiary and Family Centered Care Quality Improvement Organization at any time by a patient and/or caregiver(s) and hospice staff members (see generally SOM Chapter 5, Complaint Procedures). Once a complaint is filed with the SA, the SA can conduct an unannounced complaint investigation survey to substantiate or refute the allegations. If the allegation is found to be substantiated or confirmed, the SA informs the hospice and submits the findings to iQIES. A post-survey revisit or follow-up survey may also occur to determine if the hospice has made corrections and is in compliance with all requirements. A hospice may have many complaints filed against them, but not all complaints may be substantiated upon SA review. The results of the review of complaints are submitted to the iQIES system, which is not publicly available. Like quality-of-care CLDs, most hospices in our analysis currently have no substantiated complaints in the identified 3-year period. Our CY 2019–2021 survey data analysis found that currently 81.8 percent of hospice programs (that is, 4,860 of the 5,943 SFP-eligible hospices) have had no substantiated complaints over the past 3 years. As noted previously, there are 5.7 percent of eligible hospices that have no survey data, or in other words, there is missingness in the survey data for those hospices. Unlike quality-of-care CLDs, where missingness is likely due to the absence of a recent survey, the absence of substantiated complaints from this data is likely because the hospice program has no substantiated complaints.

(2) Hospice Quality Reporting Program (HQRP) Data

In addition to survey data, we proposed to use quality measures from the HQRP to capture hospice care processes and beneficiary/caregiver care experiences. The HQRP includes data submitted by hospices via the Hospice Item Set (HIS), Medicare hospice claims, and the CAHPS Hospice Surveys. All Medicare-certified hospices must comply with these reporting requirements or face penalties for a failure to report, although some hospices may be exempt from reporting certain measures.[149] This ensures that most hospices have these data available for use in the SFP algorithm. These quality measure data are publicly available in the Provider Data Catalog (PDC) at *https://data.cms.gov/provider-data/topics/hospice-care* and Care Compare at *https://www.medicare.gov/care-compare/?providerType=Hospice.* A description of current HQRP measures and public reporting dates is available online. We proposed to include five publicly reported HQRP measures to identify poor performing hospices. The proposed measures are as follows:

- Medicare claims-based measure:—Hospice Care Index (HCI) Overall Score
- CAHPS Hospice Survey Data measures:
  - ++ Help for Pain and Symptoms
  - ++ Getting Timely Help
  - ++ Willingness to Recommend this Hospice
  - ++ Overall Rating of this Hospice

(a) Hospice Care Index (HCI)

We proposed including the HCI overall score based on eight quarters of Medicare claims data. The HCI captures multiple aspects of care delivery across ten indicators that comprise a composite HCI overall score, with hospices earning a point for each indicator met (range: 0–10 such that a lower score indicates lower quality of care). The proposed HCI overall score indicates hospice care quality between admission and discharge (HCI Technical Report and 86 FR 42528). Moreover, the HCI score is based on Medicare claims data, which provide direct evidence of care delivery decisions at a hospice that is readily available for all hospices. For public reporting, hospices with less than 20 claims over the eight quarters are excluded from reporting the measure. The HCI measure would also be suppressed if any 1 of the 10 indicators is not reported for any reason as each indicator is a key component of the measure and all ten are necessary to derive the HCI score. Additional details of the HCI, such as the quality measure specifications, individual indicator information, data period, and exclusion criteria, are available in the HQRP Quality Measure (QM) User's Manual posted on the HQRP Current Measures web page. The SFP TEP and previous public comments generally supported the inclusion of HCI data in the preliminary methodology because the HCI captures a robust majority of hospices participating in Medicare and covers key aspects of the hospice care continuum. Our analysis of FYs 2019 to 2021 (excluding January through June 2020) HCI data found that 78.3 percent of hospice programs (that is, 4,656 of the 5,943 SFP-eligible hospices) had a publicly reported HCI score. The overwhelming majority of those hospices receive an HCI score of 8 or more out of 10—4,007 (86.1 percent) of the 4,656 SFP eligible hospices with a publicly reported HCI score.

(b) CAHPS Hospice Survey

To represent decedent/caregiver experience of hospice care, and in consideration of TEP and stakeholder perspectives, we proposed using four measures from the CAHPS Hospice Survey: (1) help for pain and symptoms; (2) getting timely help; (3) willingness to recommend the hospice; and (4) overall rating of the hospice. CAHPS Hospice Survey measure scores are calculated across eight rolling quarters for all hospices with at least 30 completed surveys. Some hospices do not participate in CAHPS as new hospices are exempt from reporting CAHPS measures for the calendar year in which they receive their CMS Certification Number (CCN), and hospices can apply for a CAHPS exemption if they serve fewer than 50 survey—eligible decedents/caregivers in a given calendar year. The CAHPS Hospice measures are

[149] Information on the reporting requirements and Annual Payment Update payment penalties for the failure to report can be found on the HQRP Overview website or section 1814*(i)* of the Act.

publicly available from the Provider CAHPS Hospice Survey Data file on the Hospice PDC. Additional details are in the QM User's Manual on the HQRP Current Measures web page and the CAHPS Hospice Survey website at *https://www.hospicecahpssurvey.org/.* These CAHPS Hospice Survey measure scores are also publicly reported on the Care Compare website at *https://www.medicare.gov/care-compare/?providerType=Hospice.* As discussed in the SFP TEP report, TEP and other stakeholders agreed that the algorithm is strengthened by including the four CAHPS Hospice Survey measures as they reflect caregiver-reported experiences in key areas of hospice quality not reflected in claims or inspection surveys.

From the CAHPS Hospice Survey data, we proposed to use adjusted bottom-box scores of the four measures described previously to create a CAHPS Hospice Survey Index. As described in the CMS document, ''Calculating CAHPS® Hospice Survey Top-, Middle-, and Bottom-Box Scores,'' that summarizes the steps we use to calculate CAHPS Hospice Survey measure scores, ''bottom-box'' scores are calculated for each respondent as ''100'' if the respondent selected the least positive response categories for that question and ''0'' if the respondent selected a different response category; survey respondents who do not answer a question are not included in the scoring of that question. In the CAHPS Hospice Survey, different questions have different response scales, so the bottom-box responses vary across the survey. For example, for questions with response options of ''Yes, definitely,'' ''Yes, somewhat,'' and ''No,'' the bottom-box response is ''No''; for questions with response options of ''Never,'' ''Sometimes,'' ''Usually,'' and ''Always,'' where ''Always'' indicates the most positive response, the bottom-box responses are both ''Never'' and ''Sometimes''; Person-level bottom-box scores for each question are then adjusted for mode of survey administration and case-mix to produce hospice-level bottom-box scores. Bottom-box scores for a particular question can be interpreted as the percentage of respondents who selected the least positive response category(ies) after adjusting for mode of survey administration and differences in the mix of decedent/caregiver characteristics across hospices. Composite measure scores, such as those for Help for Pain and Symptoms and Getting Timely Help, are formed by taking the average of fully adjusted hospice-level question scores within the composite. We proposed using bottom-box scores for the SFP, because they quantify reported problematic care experiences. To create the CAHPS Hospice Survey Index, we proposed to calculate a single score for each hospice by taking a weighted sum of the bottom-box scores for the four CAHPS measures, as described later in this section. Specifically, we proposed that the two measures that represent overall assessments of hospice care (that is, Willingness to Recommend this Hospice and Overall Rating of this Hospice) each be given a weight of 0.5 as these measures assess similar concepts. We proposed to weight the other two measures, Help for Pain and Symptoms and Getting Timely Help, at 1.0 each to reflect that these measures assess distinct aspects of care.

To illustrate, not including usually applied adjustments to the data for case mix and mode of survey administration, if Hospice A received a bottom-box score of 100 on the Overall Rating of this Hospice, that means that all the survey respondents responded to the question and gave the hospice an overall rating of zero to six, the least positive possible responses (middle-box options: 7–8; top-box option: 9–10). The hospice could then receive, a bottom-box score of 0 on the Help for Pain and Symptoms measure, meaning none of the survey respondents selected the least positive responses on any of the questions that make up this measure. If Hospice A also received a bottom-box score of 12 on the Willingness to Recommend this Hospice and a bottom-box score of 4.5 on the Getting Timely Help measure, meaning that approximately 12 percent and 4.5 percent of respondents, respectively, selected the bottom-box scores, then Hospice A's total CAHPS Hospice Survey Index will be 60.5, calculated as follows: ((100 + 12) * 0.5) + (0 + 4.5) = 60.5. The maximum value for the CAHPS Hospice Survey Index would be 300 points. For this index, a lower number of points would indicate a higher quality score.

Our analysis of CYs 2019 to 2021 (excluding January through June 2020) CAHPS Hospice Survey data found that 49.3 percent of eligible hospice programs (2,929 of the 5,943 SFP-eligible hospices) report the four CAHPS Hospice Survey measures. Compared to the other three indicators (quality-of-care CLDs, substantiated complaints, and HCI), the scores from the four CAHPS measures are more dispersed around their average value. The average CAHPS Hospice Survey Index value for these four measures combined is 24, with an overall range of 2 to 83 from the SFP-eligible hospices (lower scores indicate better performance; total possible range: 0–300). The distribution of these values is roughly symmetric and centered on an average such that the likelihood of observing a value different from the average value becomes smaller the further away the value is from the average.

c. Final Data Source Preparation

We proposed to compile the data for the algorithm indicators (quality-of-care CLDs, substantiated complaints, HCI, the four CAHPS Hospice measures) and remove hospices not eligible for SFP to create a single score for every hospice. A Medicare-certified hospice program would be included in the algorithm if it—(1) is an active provider that has billed at least one claim to Medicare FFS in the last 12 months as captured in iQIES; and (2) has data for at least one algorithm indicator.

For the HCI and CAHPS data, we proposed to pull the latest HCI and CAHPS data from the Hospice PDC. For example, we would use data from November 2023 to identify the pool of hospices eligible to be in the SFP on or after January 1, 2024.

(1) Survey Data and HCI

For the survey data, we proposed the following steps to prepare data for the algorithm:

- Step One: We would pull 3 consecutive years of survey data preceding the release of the SFP selection list, including data for all relevant hospice survey types (initial certification, standard, complaint, and follow-up surveys). For identifying the pool of hospices eligible to be in the SFP on or after January 1, 2024, we would use 2020–2023 survey data.
- Step Two: From the survey data in Step One, we would count the total number of quality-of-care CLDs for each hospice in the data file. Quality-of-care CLDs can be found in any hospice survey (initial certification, standard, complaint, follow-up). They are denoted within a survey under specific citation codes (Table F2).
- Step Three: From the data file in Step One, we would count the total number of substantiated complaints for each hospice in the data file. Substantiated complaints can be found in complaint and follow-up hospice surveys.

Our initial analysis found that the proposed SFP-eligible hospices may have missing indicators from the survey data (quality-of-care CLDs, substantiated complaints) and/or HCI. To address the algorithm's missing data for these indicators, we proposed standardizing

each indicator for quality-of-care CLDs, substantiated complaints, and HCI. When the data for each indicator is standardized, it is rescaled to have a mean of zero and a standard deviation of one. We proposed that hospices missing any of these three indicators would be assigned a value of zero for that indicator after standardization (see section VI.B.4.d. of this final rule).

(2) CAHPS® Hospice Survey Data

As discussed previously, CAHPS Hospice Survey data are not available for hospices that are exempt from participating due to size or newness, or for hospices for which there are fewer than 30 completed surveys over an eight-quarter reporting period. Since these hospices may differ systematically from hospices that do have publicly reported CAHPS Hospice Survey data, we do not believe it is appropriate to assign hospices the average value of the CAHPS Hospice Survey Index if they are missing these data. After standardizing the CAHPS Hospice Survey measures (using the same process for survey data and HCI in sections VI.B.4. and VI.B.4.d. of this final rule), we proposed addressing missing CAHPS Hospice Survey data by averaging the total number of data indicators used to derive the score. The score for hospices with missing CAHPS Hospice Survey data would be based solely on all other indicators (CLDs, complaints, and HCI), and the score for hospices with available CAHPS Hospice Survey data includes the CAHPS Hospice Survey Index in addition to the other indicators (see section VI.B.4.d.(2) of this final rule).

d. Proposed Data Source Standardization

We proposed standardizing each indicator (that is, quality-of-care CLDs, substantiated complaints, HCI, and the CAHPS Hospice Survey Index) to compare indicators equally despite each data source's different units of measurement. For example, both quality-of-care CLDs and substantiated complaints are continuous variables that have no ceiling to how many quality-of-care CLDs or substantiated complaints a single hospice can receive. In contrast, a hospice can only receive a maximum value of 10 from the HCI quality measure. Therefore, if we do not rescale HCI, we will be deemphasizing the importance of HCI for the SFP as a relevant dimension of care quality because the range of possible values for HCI is much smaller than the range of possible values for quality-of-care CLDs and substantiated complaints. By standardizing the data as proposed, we can understand how different the indicator is for a single hospice compared to the indicator from the average hospice and shift the unit to a magnitude of difference from the average across all indicators to compare the data source indicators under a shared measurement unit.

As a simplified example to illustrate the importance of standardization, Hospice A has one quality-of-care CLD and an HCI score of 3. These two numbers' absolute differences are two (3 HCI − 1 quality-of-care CLD = 2). However, examining the absolute difference in these numbers does not indicate that Hospice A delivers poor care quality. To better explain how these two indicators relate to one another and quality, we look at the likelihood that Hospice A will receive one quality-of-care CLD and the likelihood that it will receive an HCI score of 3. To determine this likelihood, we proposed comparing these numbers to the respective averages of all other hospices for the indicators. The average number of quality-of-care CLDs for hospices is a little less than 0.5. Most hospices have zero quality-of-care CLDs. While a quality-of-care CLD of one is larger than the average (0.5), the magnitude of difference between the one quality-of-care CLD in Hospice A and the 0.5 quality-of-care CLDs for the average hospice is not very large. When considering HCI, the average HCI score for all hospices is 8.9 (a higher HCI score indicates better performance on the measure). An HCI score of three is a large difference from the average of 8.9, and as a result, it is unlikely that a hospice will receive this kind of score if it was an average HCI performer. The likelihood of observing a value different from the average is the type of information we proposed to include to determine poor performers. By standardizing the indicators, we shift our interpretation from what value they received to an estimation of how likely they are to receive the value if they were an average hospice. This approach would improve the algorithm's ability to identify those hospice programs with the most unlikely values across our four indicators and those that are the poorest performers across indicators compared to all other active hospices in the SFP analytic file.

The previous fictitious example illustrates how indicators are standardized. We proposed to adopt the most common standardization method, which would be applied to each of the indicators for a specific hospice (hospice indicators). For each indicator, this would be done by taking the indicator's observed value for the hospice and subtracting that indicator's average value for all hospices. We would then divide this number (the difference) by the standard deviation, a common measure of data variance, to tell us how clustered data are around the average (see the following equation).

$$Standardized\ Value = \frac{Hospice\ Value - Overall\ Average}{Standard\ Deviation}$$

As a function of this proposed approach, all indicators are centered with a mean of zero and a standard deviation of one. The transformed indicator would represent how many standard deviations better or worse than average a hospice's observed value is. The standardized scores under this proposed approach are additive, and their sum represents how many standard deviations above or below average the hospice is across all indicators.

(1) Proposed Weighting of the Standardized Values

The proposed standardization discussed earlier allows an indicator's data to be compared to another standardized indicator. Therefore, we would be comparing how different the observed value is from the average value to make all indicators mathematically equal. We proposed to weight each indicator by multiplying an indicator by a constant value to account for their relative importance in the methodology.

As part of our consideration for determining the weights for each indicator, the TEP and stakeholder listening sessions offered considerations related to weighting the data sources. In discussing the weighting of substantiated complaints, quality-of-care CLDs, and HCI, the TEP and stakeholders agreed that they represent relevant dimensions of care quality but did not raise concerns or discuss whether one of these indicators was more or less indicative of care quality

relative to another. However, the TEP and stakeholders emphasized the importance of patient and caregiver perspectives represented by the CAHPS measures, noting they are the most integral dimension of hospice care quality. As discussed in the SFP TEP report on page 15, ''some TEP members argued that the valuable perspectives of families and caregivers on the CAHPS Hospice Survey justified weighting it more than other data sources.'' Based on the feedback from the TEP and stakeholder listening sessions, we proposed to weight the CAHPS Hospice Survey Index by twice that of the other measures (that is, multiply the standardized value CAHPS Hospice Survey Index by two).

(2) Proposed Approach for Missing CAHPS Data

In three of the four indicators used in the algorithm, data exhibit an exceptional amount of concentration around the average value for the indicator. We proposed replacing missing values in quality-of-care CLDs, substantiated complaints, and HCI with the average value for each of those indicators for an individual hospice to assign a score to that hospice (see the discussion of standardization in this section of the final rule). In other words, we proposed to assign hospices missing any of these three indicators a value of zero for that indicator after standardization, which is equivalent to the average value.

The CAHPS Hospice Survey Index is distinct from these other three indicators for several reasons warranting separate treatment for its missingness. First, the CAHPS Hospice Survey Index does not exhibit the same high concentration around the average value as the other measures. This means that there is more variability in the CAHPS Hospice Survey Index than in the other indicators. As a result of this increased variability, it is less likely that missing values would be close to the average value if they were observable. Second, more hospices are missing CAHPS Hospice Survey data than are missing data for other indicators in the algorithm. In our review of the CY 2019–2021 analytic file (excluding January 1–June 30, 2020), there is CAHPS Hospice Survey data for only about 49 percent of all SFP-eligible hospices. Due to reporting exemptions for small and/or newer hospices, those missing values are disproportionately from that cohort of providers. Because of this trend, it is difficult to draw any conclusions about the missing values given that there are no data from small hospices by which we can compare if the smaller/newer hospice CAHPS average is similar to those for which we have observed data. Third, hospices with fewer than 50 distinct beneficiaries can file for an exemption from reporting CAHPS. If we replace missing CAHPS Hospice Survey measure values with the average value, poor performing small hospices could benefit from being small by opting into being treated as an average hospice by becoming exempt from reporting their poor CAHPS Hospice Survey measure values. While this action is highly unlikely, the ability of small hospices to request an exemption is a consideration; however, we do not believe the proposed algorithm creates incentives for providers to either request an exemption or withhold CAHPS Hospice Survey reporting altogether. For these reasons, we proposed a different treatment for CAHPS Hospice Survey missingness. Instead of replacing missing CAHPS Hospice Survey measure scores with the average values for those measures, we proposed to run hospices with data for CAHPS Hospice Survey measures through a version of the algorithm that considers the CAHPS Hospice Survey Index, and for those hospices that do not have CAHPS Hospice Survey data, through a version of the algorithm that does not consider the CAHPS Hospice Survey Index. To make the two resulting scores comparable, we then average the scores based on the total number of indicators used to calculate the score. We believe this approach mitigates concerns regarding a potential incentive to request an exemption or withhold CAHPS Hospice Survey data.

For the hospices without CAHPS Hospice Survey data, we proposed to divide their scores by three because their score was calculated from three indicators: quality-of-care CLDs, substantiated complaints, and HCI. For the hospices with CAHPS Hospice Survey data, we proposed to divide their scores by five because the weight on the CAHPS Hospice Survey Index means it is mathematically counted twice, so the indicators will be quality-of-care CLDs, substantiated complaints, HCI, and the CAHPS Hospice Survey Index, which is counted twice due to the weight of two on the indicator. This approach to handling missing CAHPS data is beneficial because it does not make assumptions about the values for missing CAHPS data.

- *With CAHPS Hospice Survey Index:*

$$CLDs\ over\ 3\ years + Complaints\ over\ 3\ years - HCI + 2(CAHPS\ Index) = \frac{Score}{5}$$

- *Without CAHPS Hospice Survey Index:*

$$CLDs\ over\ 3\ years + Complaints\ over\ 3\ years - HCI = \frac{Score}{3}$$

(3) Example Results

To illustrate how the proposed algorithm would behave, we discuss later in this section how two example hospices' (Hospice A's and Hospice B's) algorithm scores would be produced based on their indicator values. As discussed previously, the methodology will be one step in determining whether a hospice is selected for the SFP.

Hospice A is a large hospice, serving 500 beneficiaries on average over the last 3 years. Over the past 3 years, they received zero quality-of-care CLDs, two substantiated complaints, and an HCI score of nine. At the same time, their CAHPS Hospice Survey Index measure is 44.5, which is larger than the average value of 28, which may indicate a quality concern. When we standardize these values to examine how different they are from the average hospice, we find that their quality-of-care CLD standardized value is zero, their substantiated complaint standardized value is 0.6, their HCI is 0.1, and their CAHPS Hospice Survey Index is 2.4. As we suspected, three of their indicators

are closely in line with the average hospice. Only their CAHPS Hospice Survey Index of 2.4 tells us that their bottom-box scores for the four quality measures is 2.4 standard deviations away from the average hospice. We would then include these four indicators in the algorithm: 0 + 0.6 − 0.1 + (2*2.4) = 5.3. As explained previously, for hospices with CAHPS data, we would divide their scores by five, and since Hospice A has a CAHPS Hospice Survey Index, the final value would be divided by five. Hospital A's final algorithm score is: 5.3/5 = 1.06. We then take this score and compare it to all other scores generated from all hospices and put them in order from highest to lowest, and we find that Hospice A ranks at 331. Because of the algorithm's emphasis on CAHPS, Hospice A's poor CAHPS Hospice Survey Index would make it more likely to be identified as a candidate, but because Hospice A performed well on the other three indicators, it would be less likely to be selected as a SFP participant compared to other hospices.

Hospice B is a mid-sized hospice serving an average of 120 distinct beneficiaries over the past 3 years. It has not reported CAHPS Hospice Survey data across the four measures. They received 42 substantiated complaints, 15 quality-of-care CLDs, and an HCI of 10. The number of substantiated complaints and quality-of-care CLDs are quite high even though they have achieved all 10 indicators of HCI. After we standardize, Hospice B's quality-of-care CLD value is 9.2, its complaint rate is 16.4, and its HCI is 0.9. We would calculate Hospice B's score in the following way: 9.2 + 16.4 − 0.9 = 24.7. As explained previously, for hospices without CAHPS® data, we would divide their scores by three, and since Hospice B does not have a CAHPS Hospice Survey Index, this final value would be divided by three: 24.7/3 = 8.2. When comparing this score of 8.2 to all other hospices, we find that Hospice B has the highest algorithm score among all hospices, indicating it has the poorest quality indicator outcomes. Even though its HCI score is high and we do not know its CAHPS value, Hospice B's high substantiated complaint rate and high number of quality-of-care CLDs would make it more likely to be selected for the SFP.

Comment: Commenters expressed various concerns over the use of CAHPS® Hospice Survey measures and the CAHPS Hospice Survey Index as an appropriate indicator in the proposed SFP algorithm, while also acknowledging the importance of including caregiver voices in the algorithm. Many commenters noted that slightly more than half of hospices do not have publicly available CAHPS data and wondered if not having CAHPS data would make a hospice less likely to be placed in the SFP. Commenters also identified a possible unanticipated consequence of using CAHPS data that weighting the CAHPS Index more heavily in the algorithm may create an undesirable incentive for hospices to not report CAHPS data or to try and influence caregiver responses. A commenter proposed penalizing hospices that do not report CAHPS Hospice survey data by assuming that their CAHPS Index input would fall in the bottom percentile of this measure. Some commenters expressed concern about the reliability and ''subjectivity'' of the CAHPS Hospice Survey data or expressed a preference for claims-based measures, such as the HCI, over survey-based measures. Several commenters also expressed concern that the use of CAHPS may disproportionately impact providers serving underserved communities, as those providers often have poorer CAHPS scores.

Response: We appreciate the commenters' concerns regarding the strengths, limitations, and potential drawbacks of the CAHPS Index.

We acknowledge commenters' concern that the inclusion of CAHPS Hospice Survey data may seem inconsistent with the original purpose of the CAHPS Hospice Survey, but we maintain that this survey data as publicly reported quality measures in the HQRP is appropriate to include for the SFP. The CAHPS Hospice Survey was developed to provide information to patients and caregivers to help them select a hospice program, to aid hospices in quality improvement, and to provide CMS with information for monitoring hospice performance.[150] The use of CAHPS data for the SFP aligns with these foundational goals, as it monitors hospice performance and publicly reports the list of poor performing hospices to aid in patient and caregiver decision-making. While CMS recognizes that the number of providers not reporting the data is a limitation of the CAHPS Hospice Survey data, the CAHPS data nonetheless represent an essential component to identifying provider-level issues in care delivery that will be addressed by participation in the SFP.

The proposed rule included two versions of the algorithm. The first version calculated scores for hospices that *do* have publicly reported CAHPS Hospice Survey Data. The second version calculated scores for hospice providers that *do not* have publicly reported CAHPS Hospice Survey data. This approach produced comparable scores that consider the CAHPS data when it is available without speculating about what the missing values of CAHPS might be for those 51 percent of providers that do not currently report CAHPS Hospice Survey data.

The TEP and stakeholder listening sessions emphasized the importance of the caregiver perspective. As was presented to stakeholders, each algorithm input is intended to capture an integral concept of poor care delivery. When questioned for feedback, all TEP members strongly believed CAHPS Hospice Survey data were critical to include in the SFP algorithm, and some even believe that the valuable perspectives of family and caregivers justified weighting it more heavily compared to the other algorithm inputs. It was further mentioned that not only was the caregiver perspective very important, but that it would capture aspects of quality that are not found in the inspection survey or claims-based data. These opinions were expressed again after presenting the TEP with potential data issues such as the high amount of missing provider-level CAHPS Hospice Survey data. As a result of this stakeholder emphasis, CMS proposed to weight the CAHPS Hospice Survey Index as twice that of other inputs, so that it accounts for 40 percent of the proposed algorithm score among providers with CAHPS Hospice Survey data.

Initial analyses demonstrated that this approach does not significantly help or hurt providers with or without CAHPS Hospice Survey data. In examining the algorithm scores described in the proposed rule, there was not a statistically significant difference in the share of providers with and without CAHPS Hospice Survey data that were deemed eligible for SFP selection (that is, those that fell in the bottom 10 percent). Among the 2,929 hospices that reported CAHPS Hospice survey data, 293 (10 percent) were in the bottom 10 percent. While among the 3,014 hospices that did not report CAHPS Hospice Survey data, 302 (10 percent) fell in the bottom 10 percent. This is consistent with expectations, as there is no evidence suggesting that providers that report CAHPS Hospice Survey data deliver significantly better or worse care than those that do not report. To put it another way, these initial results demonstrate that there is no incentive

[150] CAHPS Hospice Survey. (2022). *CAHPS Hospice Survey Fact Sheet. https://www.hospicecahpssurvey.org/globalassets/hospice-cahps4/home-page/cahps_hospice_survey_fact_sheet_january-2022.pdf.*

for providers to withhold reporting their CAHPS values as there is no intrinsic benefit to doing so within the structure of the algorithm—providers that need SFP intervention are just as likely to be identified when they have CAHPS data as when they do not have CAHPS data. As a result, CMS believes the best course moving forward is through the algorithm as proposed. We remain open to continued discussions with interested parties and will make potential refinements in the future to these policies, as determined necessary.

We believe that this evidence should further ease the concerns expressed by commenters regarding providers choosing not to report CAHPS Hospice Survey data. As described previously, the proposed approach provides no incentive for providers to opt out of reporting because it is unlikely that suppressing CAHPS data would help providers avoid SFP eligibility. Among providers that *did not* have publicly reported CAHPS Hospice Survey data in August 2023 data, nearly 98 percent did not meet the requirements to report data due to being a low volume or a new hospice. Additionally, if the required quality data in the HQRP is not reported by each designated submission deadline, beginning in FY 2024, the hospice will be subject to a payment reduction of 4 percentage points from its annual payment update (APU) to deter against non-reporting (86 FR 42528). CMS will monitor the rates of exemption and non-reporting of CAHPS Hospice Survey data and evaluate whether changes to the algorithm are necessary for future rulemaking should these rates drastically increase.

CMS also appreciates commenters' concerns that providers may seek to influence caregiver survey responses if CAHPS Hospice Survey data are used to help identify poor performing hospices. The CAHPS Hospice Survey contains guidelines governing how providers are permitted to communicate about the survey with patients and caregivers, preventing them from unfairly influencing how caregivers respond.[151] If providers wish to encourage caregivers to complete the survey, they are required to encourage all caregivers to do so. Providers are not allowed to attempt to influence CAHPS responses in any way, including asking the questions before the survey is administered, offering benefits for favorable responses, offering incentives for completing the survey, or contacting caregivers directly regarding survey responses.

CMS does not believe it would be beneficial to penalize hospices that do not report CAHPS Hospice Survey data by assigning them a score from the bottom percentile. The vast majority of providers that do not report CAHPS Hospice Survey data do not report because of size (that is, fewer than 50 survey-eligible patient/family caregiver pairs during the reference year) or newness. Providers should not be punished for their size or newness. Still, as noted earlier, CMS will monitor the number of non-exempt providers that choose not to submit CAHPS Hospice Survey data and evaluate whether changes to the algorithm are necessary for future rulemaking if the numbers of such hospices grow significantly. Additionally, as noted earlier, if a non-exempt hospice provider chooses not to submit data, the provider will be subject to a payment reduction of 4 percentage points from their APU (beginning in FY 2024) as another deterrent against non-reporting (86 FR 42528).

With respect to commenters' concerns about the reliability of CAHPS Hospice Survey data, presently, there is no empirical evidence to suggest that the CAHPS Hospice Survey data are statistically unreliable. The CAHPS Hospice Survey was developed to produce standardized information about patient and caregiver experiences of care that allows for meaningful comparison across hospices.[152] An analysis of CAHPS Hospice Survey based on the data reported by 2,500 hospice providers participating in the survey's national implementation found the CAHPS measures to be both valid and reliable.[153] The HQRP public reporting requirements are designed to ensure that each CAHPS component measure is a reliable indicator of hospice quality in that domain. We seek to include CAHPS Hospice Survey data *in addition to* the claims-based HCI because the two data sources measure different aspects of hospice quality and complement each other.

We appreciate commenters' concerns that the way CAHPS Hospice Survey data are collected might systematically disadvantage providers that provide care to historically underserved populations. This type of potential disadvantage could occur if the CAHPS Hospice Survey design or data collection process systematically scored providers serving underserved populations worse than providers *of the same quality* that deliver care to populations that are not underserved. This exact concern has been investigated in the scholarly literature on the CAHPS Hospice Survey and there is presently no evidence to demonstrate that such a bias exists.[154]

One study examined the effects of caregiver and decedent characteristics on CAHPS Hospice Survey scores to determine if there is a need to adjust the reported scores by these characteristics to better measure caregivers' experiences.[155] The authors aimed to identify patient and caregiver characteristics of the populations that different providers serve and how those factors were related to CAHPS Hospice Survey responses in ways that may not reflect underlying differences in quality of care. The authors analyzed 915,442 patients across 2,513 providers between April 2015 and March 2016 and estimated the association between decedent and caregiver characteristics and the response percentile of the caregiver's CAHPS Hospice Survey. Decedent characteristics included age at death, gender, race/ethnicity, education, payer for hospice care, primary diagnosis, final setting of care, and length of final episode of hospice care. Caregiver characteristics included age, education, gender, language spoken at home, language of survey completion, and relationship to the decedent. The results of this analysis found that the payer for hospice care, caregiver education, and survey language/language spoken at home were the characteristics that were most associated with CAHPS Hospice survey scores and the authors recommended adjusting provider-level CAHPS results for these

[151] Centers for Medicare and Medicaid Services. (2022). *CAHPS Hospice Survey Quality Assurance Guidelines, Version 9.0. https://www.hospicecahpssurvey.org/globalassets/hospice-cahps4/quality-assurance-guidelines/cahps-hospice-survey-quality-assurance-guideline-v9.0-september-2022.pdf.*

[152] Centers for Medicare and Medicaid Services. (2022). *CAHPS Hospice Survey Quality Assurance Guidelines, Version 9.0. https://www.hospicecahpssurvey.org/globalassets/hospice-cahps4/quality-assurance-guidelines/cahps-hospice-survey-quality-assurance-guideline-v9.0-september-2022.pdf.*

[153] Rebecca Anhang Price, Brian Stucky, Layla Parast, Marc N. Elliott, Ann Haas, Melissa Bradley, and Joan M. Teno. Development of Valid and Reliable Measures of Patient and Family Experiences of Hospice Care for Public Reporting. Journal of Palliative Medicine. Jul 2018.924–932. *http://doi.org/10.1089/jpm.2017.0594.*

[154] Davlyatov, G., He, M., Orewa, G., Qu, H., & Weech-Maldonado, R. (2023). Are Hospice Google Ratings Correlated With Patient Experience Scores? Evidence from a National Hospice Study. The American Journal of Hospice & Palliative Care, 10499091231160186. *https://doi.org/10.1177/10499091231160186.*

[155] Parast, L., Haas, A., Tolpadi, A., Elliott, M.N., Teno, J., Zaslavsky, A.M., & Price, R.A. (2018). Effects of Caregiver and Decedent Characteristics on CAHPS Hospice Survey Scores. *Journal of Pain and Symptom Management,* 56(4), 519–529. *https://doi.org/10.1016/j.jpainsymman.2018.07.014.*

factors. There was not strong evidence that other adjustments were required. All of the authors' recommended case mix adjustments are currently incorporated in the CAHPS Hospice Survey data reporting.[156] [157] These adjusted data are used in the proposed SFP algorithm.

A second study compared CAHPS Hospice Survey responses of caregivers for Black, Hispanic, and white patients.[158] This study compared the experiences of Black patients and Hispanic patients to white patients who received care from the same hospice providers. The authors found that, on average, the CAHPS Hospice Survey scores that providers received from caregivers of Black and Hispanic patients were *better* than white patients. However, the average CAHPS Hospice Survey scores were lower for providers who cared for more Black patients and Hispanic patients, which suggests that these populations receive hospice care from poorer quality providers. Together, these findings serve as evidence *against* bias in the methodology of the CAHPS Hospice Survey and support the conclusion that lower CAHPS Hospice Survey scores for providers caring for underserved populations may be reflective of lower quality care delivery.

A third study found that there is a strong association between CAHPS Hospice Survey scores and the Google Ratings of hospice providers.[159] This may suggest that both CAHPS Hospice Survey data and Google Ratings measure similar aspects of caregiver experience, which in turn increases confidence about the reliability of the CAHPS Hospice Survey data. The authors further found that providers located in areas with higher racial and ethnic minority populations had both worse CAHPS Hospice Survey scores and lower Google Ratings, which further supports the conclusion that lower CAHPS Hospice Survey scores for these providers are reflective of concerning care quality rather than bias in the CAHPS Hospice Survey process.

The evidence generated by these studies leads us to conclude that providers that receive a poor algorithm score are delivering a level of care that warrants further attention. The intention of this process is to improve care delivery across all hospice providers, including within those providers that serve historically underserved populations.

Final Decision: After considering public comments, CMS is finalizing the inclusion of CAHPS Hospice Survey data in the SFP algorithm as proposed, which includes using the BBVs of four CAHPS Hospice Survey measures to create the Hospice CAHPS Index, standardizing the CAHPS Index, double weighting the CAHPS Index in the algorithm, and using two versions of the algorithm to address missing CAHPS Hospice Survey data (See 42 CFR 488.1135(b).) We remain open to continued discussions with interested parties and will make potential refinements in the future to these policies, as determined necessary.

Comment: Many commenters expressed appreciation for the inclusion of a claims-based measure in the SFP algorithm but noted concerns about the number of hospices that did not have publicly reported HCI data and whether missing HCI data would make a hospice less likely to be a candidate for the SFP. Commenters also expressed concerns with the methodological choice to assign hospices with missing HCI scores a value equal to the overall mean of hospices reporting HCI scores. Specifically, commenters were concerned that assigning a mean value could result in poor performing hospices receiving a higher HCI score than they might if they had a publicly reported HCI score. Some commenters also voiced a concern that a hospice, in order to avoid SFP placement, may choose not to report HCI if, for example, they had a poor score.

Response: We appreciate the comments regarding the HCI; as correctly noted by commenters, approximately 21 percent of hospices did not have a publicly reported HCI score.[160] Hospice providers that do not have HCI scores are likely to be small (fewer than 20 discharges over 2 years), new (insufficient data to observe 20 discharges), or both. Of the 1,287 hospices without publicly reported HCI scores, 1,209 (94 percent) had fewer than 11 discharges per year.

In conducting preliminary analyses, hospice providers that did not have a publicly reported HCI score were significantly less likely to be identified in the candidate list of the SFP. This suggests that the algorithm may be limited in its ability to identify poor performing hospices with under 20 discharges over two years. For hospices without publicly reported HCI scores, their algorithm scores are most related to their performance on the condition-level deficiency and substantiated complaint inputs because providers without an HCI score are typically too small to have publicly reported CAHPS data. Providers that have persistently discharged fewer than 20 patients every two years would continue to be assigned the average HCI in future years and be assessed primarily by their number of substantiated complaints and condition-level deficiencies. New hospice providers will presumably have publicly reported HCI scores in future years of data. We acknowledge the potential limitations of HCI data, but the benefits of using the HCI score, including that it is based on claims data, that it captures care processes occurring at a hospice, and that it has no additional data reporting burden, outweigh the concerns. Alternative approaches to including claims data may be considered in future rulemaking.

As noted in the proposed rule, when hospice providers do not have a publicly reported HCI score, they are assigned an HCI score equal to the mean (average) score among providers reporting an HCI score. The way missingness in HCI is generated and the distribution of publicly reported HCI scores motivated the decision to assign the mean value. In the publicly reported HCI data, provider-level missingness occurs in one of two ways. First, if the hospice provider is new then it is automatically granted an exemption and does not generate an HCI score. Second, if the provider has less than 11 claims, then its HCI score is not reported to protect the anonymity of its beneficiaries. Unlike other HQRP measures, the HCI score is a claims-based measure, and providers cannot avoid reporting it. As a result, missingness is driven by factors that we presently assess are not related to the quality-of-care delivery. Among providers with available data, the average HCI score was nine out of a

[156] Hospice CAHPS Survey. *Calculating CAHPS® Hospice Survey Top-, Middle-, and Bottom-Box Scores. https://www.hospicecahpssurvey.org/globalassets/hospice-cahps4/public-reporting/scoring-and-analysis/cc-previous-documents/pr-calculations/steps-for-scoring-cahps-hospice-survey-measures-for-website-2018q3-final.pdf.*

[157] CAHPS Hospice Survey. (2020). *Updates to the Case-Mix Adjustment Approach for Publicly Reported CAHPS® Hospice Survey Results. https://www.hospicecahpssurvey.org/globalassets/hospice-cahps4/public-reporting/scoring-and-analysis/cc-previous-documents/pr-calculations/updates-to-cahps-hospice-survey-cma-over-time_march-2020.pdf.*

[158] Price, R.A., Parast, L., Haas, A., Teno, J.M., & Elliott, M.N. (2017). Black And Hispanic Patients Receive Hospice Care Similar To That Of White Patients When In The Same Hospices. Health Affairs (Project Hope), 36(7), 1283–1290. *https://doi.org/10.1377/hlthaff.2017.0151.*

[159] Davlyatov, G., He, M., Orewa, G., Qu, H., & Weech-Maldonado, R. (2023). Are Hospice Google Ratings Correlated With Patient Experience Scores? Evidence from a National Hospice Study. The American Journal of Hospice & Palliative Care, 10499091231160186. *https://doi.org/10.1177/10499091231160186.*

[160] From August 2022 Hospice Public Refresh, which contains data from 04/01/2019–12/31/2019; 07/01/2020–9/30/2021 (excludes first two quarters of 2020).

maximum (best) value of ten. Roughly 90 percent of hospices had an HCI score of seven or higher. Due to the idiosyncratic generation of missingness in the HCI data and the high clustering around the mean for those with HCI data, we conclude that, absent other information, it is reasonable to assume that a non-reporting hospice's HCI score would be close to the average HCI score. This approach also avoids unduly punishing or rewarding small and/or new providers in the algorithm just for being small or new. As noted in the proposed rule, HCI scores are standardized in the algorithm to allow compatibility with other inputs. Therefore, providers receive positive values reflecting how much their HCI score is higher than the mean, or negative values reflecting how much their HCI score is lower than the mean.

Calculation of the HCI score is automatic and based only on claims data. Hospice providers of sufficient size that participate in the HQRP cannot opt out of having a publicly reported HCI score, meaning there is no risk of providers choosing not to report this measure. Additionally, as noted previously, if the required quality data in the HQRP is not reported by each designated submission deadline, the hospice will be subject to a payment reduction of 4 percentage points from its APU (beginning in FY2024) to deter against non-reporting (86 FR 42528).

Final Decision: After considering public comments, we are finalizing without modification the inclusion of the HCI score, the standardization of the HCI score, and how missing HCI scores are handled in the SFP algorithm, specifically by replacing a hospice's missing score with zero after standardization which is equivalent to replacing it with the average value. (See 42 CFR 488.1135(b).) We remain open to continued discussions with interested parties and will make potential refinements in the future to these policies, as determined necessary.

Comment: Many commenters believe that both survey data measures, condition-level deficiencies (CLDs) and complaints should be scaled in the algorithm based on the size of a hospice (for example, per 100 beneficiaries). There were also concerns about the backlog in accreditation survey completion largely due to the COVID–19 Public Health Emergency (PHE). Commenters also questioned the accuracy of survey data given possible issues of duplicated CLDs or substantiated complaints, along with issues related to staffing shortages and surveyor training at both state agencies and accrediting organizations. Commenters offered the following suggestions on how to better include survey data in the SFP algorithm: by using surveys older than 36-months to reduce the number of hospices with missing survey data and including two additional types of CLDs in the algorithm.

Response: We appreciate the comments regarding the survey data measures. In testing the proposed algorithm, we determined that there was not a linear relationship between the number of CLDs identified in hospice surveys and the average number of beneficiaries that a CLD provider served each year. Using CLDs and complaints as a rate per 100 beneficiaries, for example, relies on the assumption that there is an identifiable linear relationship between those two indicators and the number of beneficiaries a hospice serves. For example, such an assumption would suggest that two providers of the same quality would have different numbers of CLDs based solely on the number of beneficiaries they serve. Providers of all sizes have the same opportunity to have a CLD cited in that any CLD can be cited on a provider's accreditation or standard inspection survey, in which all providers must participate, with the majority of providers regardless of size having no CLD citations over the last 3 years. While we agree that large hospices have more opportunities to receive complaints than small hospices because they serve more patients, this does not change the opportunity for substantiation (that is, a complaint cannot be substantiated if the surveyor does not find evidence that supports the complaint). This is why we are counting substantiated complaint surveys because, as the TEP indicated, these complaints have been reviewed and confirmed with an on-site survey. Additionally, we will also continue to monitor the relationship between CLDs, complaints, and size, but the current evidence does not suggest that CLD citations increase as providers take on more beneficiaries.

CMS appreciates commenters' concerns about the timeliness and quality of survey data. The COVID–19 PHE has led to a backlog of routine surveys, but this backlog is anticipated to clear over the next year as state survey agencies (SAs) and accreditation organizations (AOs) prioritize surveys of hospices that have not had a survey in 36 months. In the proposed SFP algorithm, providers that did not have available survey data were assigned the mean number of CLDs and substantiated complaints for purposes of algorithm scoring. There is no significant association between missing survey data and the probability of being a candidate for the SFP.

As noted by many commenters, CMS has implemented improvements to surveyor training guidelines via a revised SOM, Appendix M. CMS continually monitors surveyor training to ensure it is up to date with regulations and requirements. A revised SOM Appendix M and Surveyor Basic Training for hospice programs has been fully implemented as of May 2023. All AO and SA surveyors were required to take the updated surveyor training (see 42 CFR 488.1115(a)). CMS has an active process for identifying and remedying inconsistencies. We are currently working on developing surveyor skills review (SSR) trainings to test surveyor competency.

Some commenters also had a concern that complaints may be ''double counted'' if a complainant submitted to both a state agency and accreditation organization. There is a possibility that a substantiated complaint might be counted twice as part of the calculation if a specific complaint is investigated by both the SA and AO on separate dates. We will monitor the data to determine the incidence of such an occurrence and evaluate whether changes to the algorithm are necessary for future rulemaking.

We thank commenters for the suggestions on additional ways to incorporate survey data into the SFP algorithm. While using surveys that are more than 36 months old would have the potential to reduce the number of hospices with missing survey data, this would also introduce concerns that the algorithm is using outdated information when assessing hospice quality. Therefore, only the most recent standard survey will be included in the SFP algorithm. Regarding the suggestion to include CLDs related to two additional Conditions of Participation: § 418.106—Drugs and Biologicals, Medical Supplies, and Equipment, and § 418.100—Organization and Administration of Services, we will consider these suggestions for future iterations of the algorithm pending additional analyses.

Comment: Commenters who used publicly available data to assess the distribution of complaints and CLDs stated they could not replicate our analysis of these distributions.

Response: The SFP algorithm methodology will assist with approximating scores but will not be fully replicable due to variations in timeframes of data updates or acquisition.

Final Decision: After considering public comments, we are finalizing the inclusion of unscaled CLDs and unscaled substantiated complaints from 3 consecutive years of data, the standardization of both inputs, and replacing a hospice's missing CLDs or substantiated complaints with zero after standardization which is equivalent to replacing it with the average value in the SFP algorithm as proposed. (See 42 CFR 488.1135(b).) We remain open to continued discussions with interested parties and will make potential refinements in the future to these policies, as determined necessary.

Comment: Some commenters expressed concern that due to the lack of HCI and CAHPS data for a large number of providers, many hospices would be excluded from the SFP algorithm.

Response: As mentioned in the proposed rule, the proposed algorithm methodology captures a vast majority of hospices (97.6 percent of all active hospice providers) as a hospice is included if they have any one of the indicators and meet the other inclusion criteria (that is, are active and located in the United States, including territories).

Comment: Many commenters requested additional information on how CMS would monitor and review the SFP program as it is implemented. A commenter also worried that CMS risks penalizing hospice providers that provide high-quality care if all providers received high scores in the algorithm.

Response: We plan to monitor the algorithm inputs for changes to the measures, including the addition or removal of measures, that would affect the results of the SFP algorithm. This will include continued monitoring of providers that opt-out of reporting quality measures, input metrics exhibiting signs of ''topping out'', large swings in input summary statistics and distributions, input outliers, and provider recidivism. The proposed hospice SFP intends to improve overall provider performance in those providers that are delivering poor care to beneficiaries. The hospice SFP is not intended to arbitrarily enroll providers that perform well. As part of our continued monitoring, CMS will evaluate how potential SFP providers will be differentiated from providers that do not need additional attention. As the proposed SFP improves care delivery across providers, CMS may consider changing components of the program such as the number of SFP eligible providers or the number of SFP participants if warranted.

Comment: Many commenters expressed confusion around why the algorithm, as described in the proposed rule, differed in many ways from the algorithm presented to the TEP, as noted in the SFP TEP Report.[161]

Response: The purpose of convening the SFP TEP was to seek ideas and input from a diverse group of hospice experts through thoughtful discussion on all aspects of the SFP, including the algorithm. Feedback provided by the SFP TEP, along with feedback received from additional stakeholder listening sessions, helped to inform CMS' development of the proposed SFP methodology and other criteria. Based on that feedback, CMS made decisions regarding the final specifications to the proposed SFP to ensure the best use of the available data.

Final Decision: After considering public comments received, we are finalizing the use of Medicare data sources (Hospice Survey Data and HQRP data), the approach to preparing the data, data source standardization, addressing missing CAHPS and HCI data, and data source weights for the SFP algorithm as proposed. (See 42 CFR 488.1135(b).) We remain open to continued discussions with interested parties and will make potential refinements in the future to these policies, as determined necessary.

e. Proposed Selection Criteria

Based on public comment in the CY 2022 HH PPS final rule and recommendations from the SFP TEP and other stakeholders, we proposed a SFP selection process that utilizes a no-stratification approach. In addition, we considered the input of the SFP TEP and stakeholders, who expressed that the selection approach should identify the poorest performing hospices, regardless of characteristics, such as size or location, and therefore favored an approach with no stratification by state or otherwise.

We proposed at § 488.1135(b) that hospices with AO deemed status that are placed in the SFP would not retain deemed status and would be placed under CMS or, as needed, SA oversight jurisdiction until completion of the SFP or termination.

We proposed that the number of hospices selected to participate in the SFP would be determined in the first quarter of each calendar year. The claims-based quality measure data used in the algorithm is not available until November of each calendar year. This data is needed to run the algorithm, which is used to establish the aggregate score from which SFP participants are selected. As an SFP selectee, a hospice would not be removed from the SFP until they either meet the criteria for graduation or are terminated from the Medicare program.

Comment: Several commenters questioned how CMS will use discretion to select hospice programs for the SFP from a list of 10 percent of highest scoring hospices.

Response: We will select the poorest performing hospices, from the 10 percent selectee list based on the finalized SFP algorithm score, in sequential value. As the focus of the SFP is to encourage improvement through increased oversight, not on hospices already on an enforcement path, hospices under an active enforcement action, for which they are already on a 6-month termination track or subject to other remedies, would not be considered for selection into the SFP for that designated period.

Comment: A commenter questioned if CMS would examine the 300 hospices cited in the OIG report [162] specifically for consideration for the SFP.

Response: We will utilize the finalized algorithm to select hospices for SFP enrollment.

Comment: Several commenters urged CMS to provide a preview period of data or delay implementation of the SFP.

Response: We finalized most CAA, 2021 hospice provisions in the CY2022 Home Health Prospective Payment System Rate Update, effective January 1, 2022, except for the SFP. SFP implementation was delayed at that time to allow stakeholder feedback in its development. The SFP is the final CAA provision to be implemented, and we believe further delay would likely impact patient and family health and safety. Hospices are aware of their status for each element used in the algorithm and had opportunities to preview these elements prior to the use in the algorithm. We will continuously assess the finalized algorithm's effectiveness and the program's overall impact.

Comment: A commenter suggested CMS develop an outline of expectations for providers who are selected for the SFP. They suggest this outline should include surveys every six months, the provision of technical assistance, the role of enforcement remedies, and the SFP completion requirements. Additionally, the SFP should allow

[161] Abt Associates. (2022). *2022 Technical Expert Panel and Stakeholder Listening Sessions: Hospice Special Focus Program Summary Report. https://www.cms.gov/files/document/2022-technical-expert-panel-tep-and-stakeholder-listening-sessions-hospice-special-focus-program.pdf.*

[162] *Hospice Deficiencies Pose Risks to Medicare Beneficiaries. https://oig.hhs.gov/oei/reports/oei-02-17-00020.pdf?utm_source=summary-page&utm_medium=web&utm_campaign=OEI-02-17-00020-PDF.*

struggling providers to partner with CMS to better understand the hospice regulations and their implementation.

Response: CMS will send a letter to hospice programs selected for the SFP, which will detail steps about completion the SFP. Hospice programs selected for the SFP would receive a survey every 6 months that follows the usual survey procedures, including plans of correction and revisits if needed. A deemed hospice program selected for the SFP would have its deemed status removed while in the SFP and would be placed under CMS oversight (for example, CMS or SA surveys) until the hospice completes the SFP.

While CMS is not providing direct technical assistance, we will ensure that SFP hospices are aware of the various resources and tools available to assist them in improving quality.

Comment: A commenter stated that CMS may wish to consider the size of the provider in some cases; for example, if a large provider caring for many beneficiaries scores in the 10 percent of all providers with the poorest performance on the algorithm, prioritizing the inclusion of the large provider in the SFP may have the potential to improve care for many beneficiaries. The commenter also noted, at the same time, small providers should not be exempt from selection for the SFP just because of their size if the care they furnish raises significant quality concerns.

Response: We appreciate the commenters suggestions. However, as discussed previously, all hospices will be ranked by their scores and selected for SFP participation. The number of selected hospices, annually, will be based on program resources.

Comment: A commenter questioned if a third party will carry out the hospice SFP activity and how CMS will evaluate the program and measure success.

Response: CMS continues to consider the TEP's recommendation to use a third party, but regardless of whether CMS uses a third party for the initial implementation of the SFP, we will continue to consider whether that is the most effective approach to operating the SFP. We will maintain the ultimate responsibility for the implementation and evaluation of the SFP. We will monitor the finalized algorithm's effectiveness at selecting hospices and the SFP's overall impact and evaluate whether changes to the algorithm are necessary.

Final Decision: After considering public comments, we are finalizing the SFP selection criteria as proposed. (See 42 CFR 488.1135(b)). We remain open to continued discussions with interested parties and will make potential refinements in the future to these policies, as determined necessary.

f. Proposed Survey and Enforcement Criteria

As indicated in section 1822(b)(2) of the Act, once in the SFP, a hospice must be surveyed ''not less than once every 6 months.'' Based on the TEP discussion, TEP members agreed with the 6-month recertification survey frequency for hospices in the SFP, and we proposed this frequency at proposed § 488.1135(c). Additionally, SFP hospices would be subject to one or more remedies specified in § 488.1220, and progressive enforcement remedies, as appropriate, at the discretion of CMS and consistent with 42 CFR part 488, subpart N. When CMS chooses to apply one or more remedies specified in § 488.1220, the remedies would be applied on the basis of noncompliance with one or more conditions of participation and may be based on failure to correct previous deficiency findings as evidenced by repeat condition-level deficiencies. The enforcement remedies could be imposed for an SFP hospice with condition-level deficiencies on a SFP survey or complaint survey while in the program. Furthermore, if subsequent surveys also result in the citation of a condition-level deficiency or deficiencies for an SFP hospice, the enforcement remedies imposed could be of increasing severity. Increasing severity could mean a higher CMP than was imposed for the earlier noncompliance or increasing from one remedy to more than one remedy being imposed. CMS would use its discretion on a case-by-case basis to determine what remedies are most appropriate given the survey results, and the hospice may be subject to remedies of increasing severity.

Comment: Some commenters expressed concerns about variability between surveyors and among states that may occur when varying disciplines are represented on survey teams. Several commenters stated that these discrepancies can lead to variances in survey findings.

Response: All SA and AO surveyors must successfully complete CMS Basic Hospice Surveyor Training and any additional training as specified by CMS regardless of profession or discipline. All active SA and AO surveyors have completed this training, updated in early 2023, to ensure consistent skills and knowledge. We encourage informing the applicable CMS Location for any specific concerns about surveyor variability.

Comment: A commenter stated that there is a lack of consistent staffing across SAs and AOs, which could have the inadvertent effect of delaying the timely surveying of hospice providers as is prescribed in the proposed rule, thereby making it more difficult for a provider to graduate from the SFP.

Response: We will provide oversight to ensure adherence to survey processes and schedules.

Comment: A commenter questioned how CMS will ensure that SAs comply with the survey timeframes required for the SFP and how this will be enforced. Additionally, the commenter questioned if hospice SFP providers will have a mechanism to report if they have not received their required surveys within the 18-month timeframe.

Response: We continue to consider the TEP's recommendation to use a third party. Whether or not CMS uses a third party for the initial implementation of the SFP, we will identify the most effective and efficient approach to operating the SFP.

We will provide oversight to ensure adherence to survey processes and schedules. We will provide a letter to hospices selected for the SFP outlining the process and designating a single point of contact regarding any questions or concerns, including those regarding SFP survey schedule timeliness.

Comment: Several commenters urged CMS to consider technical assistance (TA) for hospices in the SFP to support their performance improvement. Commenters pointed to discussions in the CY22 HH PPS final rule and the TEP recommendations report, where technical assistance was discussed. The commenters noted that the TEP report strongly recommended that TA be mandatory for hospices that are part of the SFP and that a list of approved TA providers, which should include state and national hospice associations, should be made available. A commenter noted that technical assistance was not mentioned in the proposed rule but rather there was an exclusive focus on enforcement remedies.

Response: We appreciate the commenters' suggestions and note that we already provide educational materials that address the regulations and survey process, which are free to providers. These materials include, but are not limited to, the CMS Hospice Basic Surveyor Training available to surveyors and providers on the Quality, Safety and Education Portal (QSEP) and four provider-specific quality-in-focus (QIF) hospice trainings on the QSEP public access page. As the hospice SFP progresses, CMS will continue to assess the need for additional educational

opportunities/materials for all hospices. Additionally, hospice programs can secure TA and private consulting services that are separate from the SFP.

Final Decision: After considering public comments, we are finalizing the SFP survey and enforcement criteria as proposed. (See 42 CFR 488.1135(d).)

g. Proposed SFP Completion Criteria

The TEP generally agreed that to complete and graduate from the SFP, SFP hospices should have no CLDs cited for two consecutive 6-month recertification surveys in an 18-month timeframe. TEP members also suggested that SFP hospices should have no substantiated complaints and less than a defined number of standard-level deficiencies (SLDs) on two consecutive 6-month recertification surveys within the 18-month timeframe to complete the SFP. TEP members recommended a stepwise completion process, with SFP hospices preliminarily graduating after completing two consecutive 6-month recertification surveys within the 18-month timeframe in accordance with all proposed completion requirements at § 488.1135(d). We considered the TEP's recommendations. However, we proposed that SFP hospices have no CLDs for *any* two SFP surveys in an 18-month period. Therefore, we proposed at new § 488.1135(d) that a hospice will have completed the SFP if it has, in an 18-month timeframe, no CLDs cited or IJ's for any two 6-month SFP surveys, and has no pending complaint survey triaged at an immediate jeopardy or condition-level, or has returned to substantial compliance with all requirements. If there are complaint investigations or a 36-month recertification survey for a hospice while in the SFP, the SFP timeline may extend beyond the 18-month timeframe. The official completion date would be the date of the CMS notice letter informing the hospice of its removal from the SFP. After completing the SFP, hospice programs would receive a 1-year post SFP survey and then would start a new standard 36-month survey cycle.

Comment: A commenter suggested CMS should take action to ensure providers who graduate from the SFP are removed in a manner consistent with the proposed timeframe.

Response: Hospices are released from the SFP upon CMS notification of program completion based on the completion criteria at proposed § 488.1135(d). We will publish updates on the CMS SFP web page as expeditiously as possible as hospices complete the SFP.

Comment: A commenter questioned how CMS will ensure that SAs comply with the survey timeframes required for the SFP and how this will be enforced. Additionally, the commenter questioned if hospice SFP providers will have a mechanism to report if they have not received their required surveys within the 18-month timeframe.

Response: We will provide oversight to ensure adherence to survey processes and schedules. We will provide a letter to hospices selected for the SFP outlining the process and designating a single point of contact regarding any questions or concerns, including those regarding SFP survey schedule timeliness.

Final Decision: After considering public comments, we are finalizing the SFP completion criteria as proposed. (See 42 CFR 488.1135(d).)

h. Proposed Termination Criteria

We proposed that a hospice in the SFP that fails any two SFP surveys, by having any CLDs on the surveys, in an 18-month period, or pending complaint investigations triaged at IJ or condition-level, would be considered for termination from the Medicare program as proposed at new § 488.1135(e). This criterion would apply to all hospices, regardless of geographical location, and reflects some TEP recommendations. CMS would issue the termination notice letter to the hospice program in accordance with 42 CFR 489.53. Depending on the deficiencies that brought a hospice into the SFP, CMS recognizes that a provider may need a reasonable period to achieve substantial compliance. But, if the hospice is not able to achieve substantial compliance for surveys conducted during the SFP, they would be considered for termination from the Medicare program. Those providers that are unable to resolve the deficiencies that brought them into the SFP and cannot meet the completion criteria of having no CLDs cited for any two SFP surveys during an 18-month period, would be placed on a termination track. If a hospice in the SFP has an IJ-level deficiency cited during a survey, CMS would follow the requirements at § 488.1225.

Comment: A commenter noted that potential termination in the Medicare program is so severe that some hospices may rather incur a 4 percent payment penalty than risk having to shut down the hospice if terminated from the Medicare program and questioned if CMS considered how the proposed the SFP might incentivize hospices to withhold data rather than face the penalty of termination.

Response: We appreciate the comments and will monitor hospice data submission to see if it appears that the SFP has a significant impact on hospice data submission, and evaluate whether changes to the algorithm are necessary.

Final Decision: After considering public comments, we are finalizing the SFP termination criteria as proposed. (See 42 CFR 488.1135(e).)

i. Public Reporting of SFP Information

Public reporting of the proposed SFP includes making accessible both general information about the SFP program and hospices selected for SFP. Section 1822(a)(2)(B) of the Act requires hospice survey findings to be ''prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates.''

We proposed in new § 488.1135(f) to publicly report, at least on an annual basis, the hospice programs selected for the SFP under proposed § 488.1135(b). This information would be posted on a CMS public-facing website at *https://www.cms.gov/medicare/quality-safety-oversight-certification-compliance/hospice-special-focus-program*, or a successor website. Specifically, we proposed that the website include, at a minimum, general information, program guidance, a subset consisting of 10 percent of hospice programs based on the highest aggregate scores determined by the algorithm, and SFP selections from the 10 percent subset as determined by CMS, and SFP status as proposed in the definitions at § 488.1105.

Comment: Some commenters noted that CMS may be exceeding its authority in posting both the bottom 10 percent list and the SFP participant list because the statute does not suggest that both lists should be displayed. However, other commenters supported the publication of both lists and believe it would be important information to consumers. There were also comments expressing concern about how often the SFP information would be updated and whether a hospice should still be included in publicly reported SFP lists even after their completion of the program.

Response: CMS appreciates the comments regarding public reporting of the SFP. As stated in the proposed rule, we intend to publish the list of SFP participants (those selected for the program) along with the list containing the 10 percent of hospices with the highest (worst) algorithm scores from which the SFP participants were chosen. We do not believe we are exceeding our authority in posting the

10 percent of hospices with the highest (worst) algorithm scores because the statute states that survey reports, enforcement actions, and *any other information determined appropriate by the Secretary* shall be published on a CMS public website in a manner that is prominent, easily accessible, readily understandable, and searchable. We agree with commenters that this information can serve as a useful tool for consumers looking for hospice care and is similar to information posted publicly for the nursing home Special Focus Facility (SFF) program. The SFF program also posts information about nursing homes that have been terminated from the Medicare program as well as those that have graduated from the SFF program as key resources for consumers and other interested parties. We intend to follow a process similar to that of the SFF in order to ensure that analogous information is available for the hospice SFP. The list will be reported annually beginning at program implementation. As the program continues, we will publish periodic updates as hospices complete the program.

Final Decision: After considering public comments, we are finalizing the public reporting guidelines regarding SFP status as proposed. (See 42 CFR 488.1135(f)).

VII. Changes Regarding Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

A. Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

1. Background

a. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, December 8, 2003), mandates the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) for contract award purposes to furnish certain competitively priced DMEPOS items and services subject to the CBP—

- Off-the-shelf (OTS) orthotics, for which payment would otherwise be made under section 1834(h) of the Act;
- Enteral nutrients, equipment, and supplies described in section 1842(s)(2)(D) of the Act; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

For a list of product categories included in the DMEPOS CBP, please refer to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Round-2021/PCs.* Areas in which the CBP are not implemented are known as non-competitive bidding areas (non-CBAs). We use the term ''former CBAs'' to refer to the areas that were formerly CBAs prior to a gap in the CBP, to distinguish those areas from ''non-CBAs.'' More information on why there was a gap in the CBP from January 1, 2019, through December 31, 2020, can be found in the November 14, 2018 final rule titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS,'' (83 FR 56922).

b. Fee Schedule Adjustment Methodology for Non-CBAs

Section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information on the payment determined under the Medicare DMEPOS CBP to adjust the fee schedule amounts for DME items and services furnished in all non-CBAs on or after January 1, 2016. Section 1834(a)(1)(F)(iii) of the Act requires the Secretary to continue to make these adjustments as additional covered items are phased in under the CBP or information is updated as new CBP contracts are awarded. Similarly, sections 1842(s)(3)(B) and 1834(h)(1)(H)(ii) of the Act authorize the Secretary to use payment information from the DMEPOS CBP to adjust the fee schedule amounts for enteral nutrition and OTS orthotics, respectively, furnished in all non-CBAs. Section 1834(a)(1)(G) of the Act requires the Secretary to specify the methodology to be used in making these fee schedule adjustments by regulation, and to consider, among other factors, the costs of items and services in non-CBAs (where the adjustments would be applied) compared to the single payment amounts for such items and services in the CBAs.

The methodologies set forth in § 414.210(g) account for regional variations in prices, including for rural and non-contiguous areas of the United States. In accordance with § 414.210(g)(1), regional adjustments to fee schedule amounts for each state in the contiguous United States and the District of Columbia, are determined based on the definition of region in § 414.202, which refers to geographic areas defined by the Bureau of Economic Analysis (BEA) in the Department of Commerce for economic analysis purposes (79 FR 66226). Under § 414.210(g)(1)(i) through (iv), adjusted fee schedule amounts for areas within the contiguous United States are determined based on regional prices limited by a national ceiling of 110 percent of the regional average price and a floor of 90 percent of the regional average price (79 FR 66225). Under § 414.210(g)(1)(v), adjusted fee schedule amounts for rural areas are based on 110 percent of the national average of regional prices. Under § 414.210(g)(2), fee schedule amounts for non-contiguous areas are adjusted based on the higher of the average of the single payment amounts for CBAs in non-contiguous areas in the United States, or the national ceiling amount.

Under existing rules, ZIP codes for rural, non-rural, and non-contiguous areas are used to establish geographic areas that are then used to define non-CBAs for the purposes of the DMEPOS fee schedule adjustments. A rural area is defined in § 414.202 as a geographic area represented by a postal ZIP code, if at least 50 percent of the total geographic area of the area included in the ZIP code is estimated to be outside any Metropolitan Statistical Area (79 FR 66228). A rural area also includes a geographic area represented by a postal ZIP code that is a low population density area excluded from a CBA in accordance with section 1847(a)(3)(A) of the Act at the time the rules in § 414.210(g) are applied. Non-contiguous areas refer to areas outside the contiguous United States—that is, areas such as Alaska, Guam, and Hawaii (81 FR 77936).

Section 3712 of the of the CARES Act (Pub. L. 116–136, as enacted on March 27, 2020) revised the fee schedule amounts for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs through the duration of the emergency period described in section 1135(g)(1)(B) of the Act. Specifically, this emergency period is the Public Health Emergency (PHE) for COVID–19, including renewals of the PHE.

Section 3712(a) of the CARES Act directed the Secretary to implement § 414.210(g)(9)(iii) (or any successor regulation), to apply the transition rule described in such section to all

applicable items and services as planned through December 31, 2020, and through the duration of the emergency period described in section 1135(g)(1)(B) of the Act, if longer. Therefore, section 3712(a) of the CARES Act continued our policy at § 414.210(g)(9)(iii) of paying for DMEPOS items and services furnished in rural and non-contiguous non-CBAs based on a 50/50 blend of adjusted and unadjusted fee schedule amounts through December 31, 2020, or through the duration of the emergency period, whichever is longer. This fee schedule adjustment in rural and non-contiguous areas results in fee schedule amounts that are approximately 66 percent higher than the fully adjusted fee schedule amounts previously paid for DMEPOS items and services furnished in non-rural areas in the contiguous United States.

Section 3712(b) of the CARES Act directed the Secretary to increase the fee schedule amounts for DMEPOS items and services furnished in non-CBAs other than rural and non-contiguous non-CBAs through the duration of the COVID–19 PHE (the emergency period described in section 1135(g)(1)(B) of the Act). Beginning March 6, 2020, the payment rates for DME and enteral nutrients, supplies, and equipment furnished in these areas was based on 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount until the end of the emergency period, which results in higher payment rates as compared to the fully adjusted fee schedule amounts under § 414.210(g)(9)(iv). This increased payments so that they are approximately 33 percent higher than the payments at the fully adjusted fee schedule amounts.

In the May 8, 2020, interim final rule with comment period (IFC) (85 FR 27550) 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'' (hereinafter referred to as the ''May 2020 COVID–19 IFC''), conforming changes were made to § 414.210(g)(9), consistent with section 3712(a) and (b) of the CARES Act.

The final rule entitled, ''Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas'' published in the December 28, 2021 **Federal Register** (86 FR 73860) (hereinafter CY 2022 DMEPOS final rule), established fee schedule adjustment methodologies for items and services furnished in non-CBAs on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later.

The CY 2022 DMEPOS final rule explained that the 50/50 blended rates in non-contiguous non-CBAs will continue to be paid, but the 50/50 blend would no longer be a transition rule under § 414.210(g)(9) and would instead be the fee schedule adjustment methodology for items and services furnished in these areas under § 414.210(g)(2) unless revised in future rulemaking. For items and services furnished in non-contiguous non-CBAs, the fee schedule amounts for such items and services furnished on or after the effective date of the CY 2022 DMEPOS final rule (February 28, 2022), or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, would be adjusted so that they are equal to a blend of 50 percent of the greater of the average of the SPAs for the item or service for CBAs located in non-contiguous areas or 110 percent of the national average price for the item or service determined under § 414.210(g)(1)(ii) and 50 percent of the unadjusted fee schedule amount for the area, which is the fee schedule amount in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment (86 FR 73873).

As explained in the CY 2022 DMEPOS final rule, the 50/50 blended rates in rural contiguous areas will continue to be paid, but the 50/50 blend would no longer be a transition rule under § 414.210(g)(9) and would instead be the fee schedule adjustment methodology for items and services furnished in these areas under § 414.210(g)(2) unless revised in future rulemaking. For items and services furnished in rural contiguous areas on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, the fee schedule amounts would be adjusted so that they are equal to a blend of 50 percent of 110 percent of the national average price for the item or service determined under § 414.210(g)(1)(ii) and 50 percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for DME and medical supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment (86 FR 73873).

For items and services furnished on or after February 28, 2022, or the date immediately following the termination of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) (that is, the COVID–19 PHE), whichever is later, in all other non-rural, non-CBAs within the contiguous United States, the fee schedule amounts would be equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1)(iv).

2. Current Issues

Section 4139 of Division FF, Title IV, Subtitle D of the CAA, 2023 sets the fee schedule adjustment methodologies for non-competitive bidding areas through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act or December 31, 2023, whichever is later. The federal PHE for COVID–19, declared by the Secretary under Section 319 of the Public Health Service Act, expired at the end of the day on May 11, 2023. We proposed to make conforming changes to the regulation at 42 CFR 414.210(g)(9) to account for these changes.

Specifically, section 4139(a) of the CAA, 2023 directs the Secretary to implement 42 CFR 414.210(g)(9)(v) (or any successor regulation), to apply the transition rule described in the first sentence of such section to all applicable items and services furnished in areas other than rural or noncontiguous areas through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) or December 31, 2023, whichever is later. This continues the policy set forth by section 3712(b) of the CARES Act, which requires CMS to pay for these DMEPOS items and services furnished in areas other than rural or noncontiguous areas based on 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount until the end of the emergency period. This

increases payments so that they are approximately 33 percent higher than the payments at the fully adjusted fee schedule amounts.

Section 4139(b) of the CAA, 2023 directs the Secretary to not implement 42 CFR 414.210(g)(9)(vi) of title 42, Code of Federal Regulations (or any successor regulation) until the date immediately following the last day of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), or January 1, 2024, whichever is later. This change has the effect of continuing the policy at § 414.210(g)(9)(vi), but changes the February 28, 2022 date in the regulation to January 1, 2024. That is, the fee schedule amount for all non-CBAs is equal to the adjusted payment amount established under paragraph (g) of this section only until the date immediately following the last day of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), or January 1, 2024, whichever is later.

Additionally, section 4139 of the CAA, 2023 does not affect the current adjusted fee schedule amounts in former CBAs. In accordance with § 414.210(g)(10), the fee schedule amounts in the former CBAs will continue to be based on the single payment amounts from 2018 increased by update factors for subsequent calendar years until new competitive bidding contracts are in place.

2. Final Changes

We received several comments supporting the conforming changes to the regulations related to implementation of section 4139 of the CAA, 2023.

We thank the commenters for their support of the proposed changes. We are finalizing the proposed conforming changes to § 414.210(g)(9), consistent with requirements in section 4139(a) and 4139(b) of the CAA, 2023. First, section 4139 of the CAA, 2023 does not change the current policy under § 414.210(g)(9)(iii) of paying for DMEPOS items and services furnished in rural and non-contiguous non-CBAs based on a 50/50 blend of adjusted and unadjusted fee schedule amounts through the duration of the PHE for COVID–19. While section 4139 of the CAA, 2023 does not specifically mention § 414.210(g)(9)(iii), we believe that section 4139(b) of the CAA, 2023 prohibits implementation of the regulation language in § 414.210(g)(vi) until the date immediately following the last day of the PHE, or January 1, 2024. This regulation applies the transition rules for the adjusted payment amount in the non-CBAs established under paragraph (g) of § 414.210 to items and services furnished in ''all areas,'' and it also provides for extension of the transition 50/50 blended rates in rural, non-contiguous areas and non-rural areas through December 31, 2023, if the PHE ends prior to that date. We are finalizing the revision of § 414.210(g)(9)(vi), as described in this rule. Further, we are finalizing, the proposed revision of § 414.210(g)(9)(iii), to state that for items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) or December 31, 2023, whichever is later, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount. We are finalizing the conforming changes to § 414.210(g)(2) for the rural and non-contiguous areas in order to reference the December 31, 2023 date specified in section 4139 of the CAA, 2023.

We are finalizing the revision of § 414.210(g)(9)(v) to state that for items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020 through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) or December 31, 2023, whichever is later, the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under this section and 25 percent of the unadjusted fee schedule amount. We are finalizing the proposal to remove outdated text from § 414.210(g)(9)(v) that states ''for items and services furnished in areas other than rural or noncontiguous areas with dates of service from the expiration date of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), through December 31, 2020, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.'' This is text that was added in the May 2020 COVID–19 IFC (85 FR 27571), as section 3712(b) of the CARES Act required CMS to pay the higher fee schedule amounts for the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), but it did not specify the fee schedule amounts that should be in effect if the emergency period ends before December 31, 2020. If not for section 3712(b) of the CARES Act, CMS would have paid the fully adjusted fee schedule amounts for DME items and services furnished in non-rural and contiguous non-CBAs until December 31, 2020. As such, § 414.210(g)(9)(v) specified that the fee schedule amounts in non-rural and contiguous non-CBAs would again be based on 100 percent of the fee schedule amounts adjusted in accordance with § 414.210(g)(1)(iv) if the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) ended before December 31, 2020. As this situation no longer applies and is in the past, we are finalizing the proposal to remove this obsolete text from § 414.210(g)(9)(v).

We are finalizing the proposal to revise § 414.210(g)(9)(vi) to state that for items and services furnished in all areas with dates of service on or after the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, or January 1, 2024, whichever is later, the fee schedule amount for the area is equal to the adjusted payment amount established under paragraph (g) of this section. Finally, we are finalizing the proposal to make conforming changes to § 414.210(g)(2) for the rural and non-contiguous areas in order to specify the December 31, 2023 date specified in section 4139 of the CAA, 2023.

Finally, section 4139(c) of the CAA, 2023 authorizes the Secretary to implement the provisions of this section by program instruction or otherwise. Given that the PHE for COVID–19 ended on May 11, 2023, which is prior to when the proposed changes to the regulations would be finalized, we stated in the proposed rule that we intend to issue program instructions or other subregulatory guidance to effectuate the changes, as previously described (88 FR 43767). We stated that we believed this approach will serve to ensure a smooth transition after the end of the PHE for COVID–19. We issued Transmittal 12068 and 12228, which updated the quarterly DMEPOS Fee Schedule and included a discussion of the changes required by section 4139 of the CAA, 2023.[163] [164]

B. Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

1. Statutory Authority

Effective for items furnished on or after January 1, 2024, section 4133(a)(1)

[163] *https://www.cms.gov/files/document/r12068cp.pdf.*

[164] *https://www.cms.gov/files/document/r12228cp.pdf.*

of Division FF, Title V, Subtitle D of the CAA, 2023 amends section 1861 of the Act, adding subparagraph (JJ) to subsection (s)(2) and coverage under a new benefit category under Medicare Part B for lymphedema compression treatment items as defined in new subsection (mmm) of section 1861 of the Act. Section 4133(a)(2) of the CAA, 2023 amends section 1833(a)(1) of the Act, adding subparagraph (GG) to indicate that the amount paid for lymphedema compression treatment items defined in section 1861(mmm) of the Act shall be equal to 80 percent of the lesser of the actual charge or the amount determined using the payment basis established by the Secretary under paragraph (1) of new subsection (z) of section 1834 of the Act. Paragraph (2) of new subsection (z) of section 1834 of the Act prohibits payments under Part B for lymphedema compression treatment items furnished other than at such frequency as the Secretary may establish. Paragraph (3) of new subsection (z) of section 1834 of the Act specifies that in the case of lymphedema compression treatment items that are included in a competitive bidding program under section 1847(a) of the Act, the payment basis under section 1847(a) of the Act shall be the payment basis determined under the competitive bidding program, and the Secretary may use information on the payment determined under the competitive bidding program to adjust the payment amount otherwise determined under section 1834(z) of the Act for an area that is not a competitive bidding area under section 1847 of the Act. Section 4133(a)(3) of the CAA, 2023 amends section 1847(a)(2) of the Act, adding lymphedema compression treatment items to the competitive bidding program under subparagraph (D) of section 1847(a)(2) of the Act. Finally, section 4133(b)(3) of the CAA, 2023 amends section 1834 of the Act under subsections (a)(20)(D) and (j)(5) to mandate application of the DMEPOS quality standards and accreditation and DMEPOS supplier enrollment and supplier standards requirements, respectively, to suppliers of lymphedema compression treatment items.

2. Background

Currently, Medicare Part B does not include coverage for lymphedema compression treatment items other than compression pumps and accessories that meet the definition of DME covered under the DME benefit category under section 1861(n) of the Act. Section 4133 of the CAA, 2023 amends the Act to establish a new Part B benefit category for lymphedema compression treatment items.

The lymphatic system is an integral component of the human circulatory system and consists of lymphatic vessels, lymph nodes and associated lymphoid organs.[165] [166] The International Society of Lymphology defines lymphedema as ''an external (and/or internal) manifestation of lymphatic system insufficiency and deranged lymph transport'' and is ''a symptom or sign resulting from underlying lymphatic disease.'' [167] The Centers for Disease Control and Prevention (CDC) defines lymphedema as swelling due to a buildup of lymph fluid in the body.[168] According to the National Institutes of Health (NIH) National Library of Medicine, lymphedema is a chronic disorder characterized by swelling under the skin caused by the inability of protein rich lymph fluid to drain, usually due to a blockage or damage to the lymph system.[169] Additionally, according to the National Lymphedema Network, this swelling commonly occurs in the arm or leg, but it may also occur in other body areas including the breast, chest, head and neck, and genitals.[170] Lymphedema develops when a body region, where lymphatic vessels and lymph nodes are missing or impaired, becomes overloaded with lymphatic fluid. Lymphedema is a chronic condition with no definitive curative treatment that can become progressive, so early detection and institution of decompressive measures are essential in avoiding its potentially disabling sequela.[171] [172] [173] [174] The gradual accumulation of plasma and cellular components into the interstitial tissue space leads to a chronic inflammatory process that can result in long-term tissue changes and permanent structural damage to the affected anatomical site and its overlying skin layer.[175] [176] [177] These changes also make the patient more susceptible to skin and potentially disabling or life-threatening soft tissue infections.[178] [179] The physical manifestations of lymphedema are tissue swelling, pain, heaviness and difficulty using the affected body part.[180]

Lymphedema occurs in four stages. Stage one may have no outward signs or symptoms but is evidenced by abnormal flow through the lymphatic system. When stage two is reached, there is some swelling that may be alleviated by elevation or compression. Stage three is diagnosed by swelling of an area that does not resolve with elevation and there may be skin thickening and scarring. The fourth stage is characterized by severe swelling and skin abnormalities.[181] Infections such as cellulitis and sepsis may result from lymphedema due to the dense protein rich nature of the lymphatic fluid and requires treatment with antibiotics.[182] Lymphedema is treated in two phases: an acute ''intensive'' phase (Phase 1) and a maintenance phase (Phase 2). In Phase 1 ''the individual is typically

[165] Aspelund A, Robciuc MR, Karaman S, Makinen T, Alitalo K. Lymphatic System in Cardiovascular Medicine. Circulation Research. 2016. Volume 118(3). 515–530.

[166] Suamia H, Scaglioni MF. Anatomy of the Lymphatic System and the Lymphosome Concept with Reference to Lymphedema. Seminars in Plastic Surgery. 2018 Feb; 32(1): 5–11.

[167] International Society of Lymphology Executive Committee. The Diagnosis and Treatment of Peripheral Lymphedema. Lymphology 28 (1995).

[168] *Lymphedema CDC.gov. https://www.cdc.gov/cancer/survivors/patients/lymphedema.htm.*

[169] Lymphedema. Bryan C. Sleigh; Biagio Manna, September 2018. Found at *https://www.ncbi.nlm.nih.gov/books/NBK537239/.*

[170] *https://lymphnet.org/what-is-lymphedema.*

[171] Korpan MI, Crevenna R, Fialka-Moser V. Lymphedema a Therapeutic Approach in the Treatment and Rehabilitation of Cancer Patients. American Journal of Physical Medicine and Rehabilitation. 2011. May. 90(suppl). S69–S75.

[172] Preston NJ, Seers K, Mortimer PS. Physical therapies for reducing and controlling lymphoedema of the limbs. Cochrane Database of Systematic Reviews 2004, Issue 4. Art. No.: CD003141.

[173] The International Society of Lymphology. The Diagnosis and Treatment of Peripheral Lymphedema: 2020 Consensus Document of the International Society of Lymphology. Lymphology. 2020. 53: 3–19.

[174] King M, Deveaux A, White H, Rayson. Compression garments versus compression bandaging in decongestive lymphatic therapy for breast cancer-related lymphedema: a randomized controlled trial. Support Care Cancer. 2012; 20: 1031–1036.

[175] Korpan MI, Crevenna R, Fialka-Moser V. Lymphedema a Therapeutic Approach in the Treatment and Rehabilitation of Cancer Patients. American Journal of Physical Medicine and Rehabilitation. 2011. May. 90(suppl). S69–S75.

[176] Warren AG, Brorson H, Borud LJ, Slavin SA. Lymphedema A Comprehensive Review. Annals of Plastic Surgery. 2007. Vol 59, No. 4. 464–472.

[177] Ly CL, Kataru RO, Mehrara B. Inflammatory Manifestations of Lymphedema. Int J Mol Scie. 2017. Jan; 18(1): 171.

[178] Grada AA, Phillips TJ. Lymphedema, Pathophysiology and clinical manifestations. J Am Academ Dermatol. 2017;77: 1009–20.

[179] Bakar Y, Tugral A. Lower Extremity Lymphedema Management after Gynecologic Cancer Surgery: A Review of Current Management Strategies. Ann of Vasc Surg. 2017. Vol. 44; 442–450.

[180] Warren AG, Brorson H, Borud LJ, Slavin SA. Lymphedema A Comprehensive Review. Annals of Plastic Surgery. 2007. Vol 59, No. 4. 464–472.

[181] The Johns Hopkins Hospital *https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/treating-lymphedema.*

[182] *https://www.cancerresearchuk.org/about-cancer/coping/physically/lymphoedema-and-cancer/infection-lymphoedema#;~:text=Infection%20in%20people%20with%20lymphoedema,and%20will%20need%20antibiotic%20treatment.*

wrapped with medical short-stretch compression bandages. In Phase 2, one goal is for the patient to be able to wear gradient pressure garments during the day and compression bandaging or alternatives (like nighttime garments) at night.[183] Studies have shown that gradient compression garments are effective in reducing and/or preventing progression of lymphedema in the arm and leg.[184] They have also shown to be effective in maintaining limb circumference.

Gradient compression garments designed for daytime use, while an individual is awake, are different than those for nighttime use, when an individual is asleep. Gradient compression garments meant for daytime (waking) provide a higher level of compression, and use of them while sleeping could cause new or additional damage to the affected tissue.[185] Additionally, gradient compression garments appropriate for daytime use can inadvertently become repositioned at night while the individual is sleeping and cause a tourniquet effect, essentially cutting off circulation to the limb and resulting in further swelling.[185] In contrast, gradient compression garments made for nighttime use or times of low activity offer milder compression and are less snug against the skin.[186] Wearing gradient compression garments designed for nighttime use may also help with skin abnormalities resulting from lymphedema and can help prevent a phenomenon called ''creeping refill,'' where swelling reoccurs during sleep.[187] Generally, more serious cases require gradient compression garments for both daytime and nighttime use. Various types of nighttime garments have been designed as alternatives to the daytime compression system garments. Nighttime garments apply gentle gradient pressure to the limb through a garment with a foam liner and a series of adjustable straps. The garments are non-elastic and provide low resting pressure on the limb, making them safe to wear while sleeping at night.[188] Many of these garments are custom-made, but there are ready-to-wear options available as well. The elastic fibers of daytime compression garments will break down with wear. Because nighttime garments are made of inelastic components, compared to the day-time garments, they do not commonly break down with wear and last longer. While proper care will increase the lifespan of nighttime garments, they will need to be replaced sometime within 1 to 3 years if used daily. Studies showed if the garments are used with aftercare regimen, that is, they are in minimum contact with moisturizer during use, they could last longer.[189] In meetings with CMS, some clinicians and lymphologists indicated that they believe that the nighttime garments are quite durable and can last for 2 to 3 years because the materials are more durable than the materials used with the daytime garments. They also indicated that previous versions used strapping in addition to more durable foam materials and could last for up to 5 years. In comparison, daytime garments are elastic garments that are typically made of breathable elastic fabrics such as nylon, cotton, spandex or natural rubber to provide compression and therefore have a much shorter lifespan of approximately 6 months.[190]

Gradient compression garments are either standard fit or custom-fit. Standard compression garments are also referred to as ready-made or ready-to-wear and are widely available pre-made, off-the-shelf and in a range of standard sizes. Individuals with mild or moderate lymphedema can often use standard fit garments. Standard gradient compression garments are easier to measure and are readily available at retailers without requiring a prescription, but they do not conform as well to limbs or provide homogenous compression. Standard fit compression wear for all gradient compression garments come in different compression classification ranges specified in mmHg. While there are no national standards for gradient compression hosiery,[191] the most common compression classification ranges for hosiery in the U.S. include: 8–15 mmHg (mild), 15–20 mmHg (medium or over the counter), 20–30 mmHg (firm or medical class 1), 30–40 mmHg (extra firm or medical class 2), and 40–50 mmHg (medical class 3).[192] For all compression ranges, the highest compression is at the ankle or wrist, and compression slowly decreases as it moves up the extremity. Some manufacturers' compression class pressure ranges for hosiery may be different from the compression class ranges used for upper limb gradient compression garments.[193]

Alternatively, custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom-made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual's symptoms.[194] The type of gradient compression garment prescribed is influenced by the site and extent of the swelling, together with the individual's comfort, lifestyle, preferences, and ability to apply and remove garments. Poorly fitting gradient compression garments may not contain or resolve the lymphedema, can cause tissue damage, may be uncomfortable, and can dissuade a patient from long-term usage and adherence.[195]

Custom-fit gradient compression garments are typically required when an individual has severe shape distortion and/or short, long, or bulky limbs.[196] In addition, individuals with complex lower limb and torso lymphedema often

[183] Korpan MI, Crevenna R, Fialka-Moser V. Lymphedema: a therapeutic approach in the treatment and rehabilitation of cancer patients. Am J Phys Med Rehabil. 2011 May;90(5 Suppl 1):S69–75. doi: 10.1097/PHM.0b013e31820be160. PMID: 21765266.

[184] Yasuhara H, Shigematsu H, Muto T. A study of the advantages of elastic stockings for leg lymphedema. Int Angiol. 1996 Sep;15(3):272–7. PMID: 8971591. *https://pubmed.ncbi.nlm.nih.gov/8971591/.*

[185] Lymphedema Products, LLC. (2019, September 11). *Day Compression vs Night Compression. Lymphedemaproducts.com. https://www.lymphedemaproducts.com/blog/day-vs-night-compression-wear/.*

[186] Caring Touch Medical, Inc. *Can You Sleep in a Lymphedema Sleeve? Caringtouchmed.com. https://www.caringtouchmed.com/can-you-sleep-in-a-lymphedema-sleeve/.*

[187] Mastectomy Shop. *Can You Sleep in a Lymphedema Sleeve? Mastectomyshop.com. https://www.mastectomyshop.com/blogs/can-you-sleep-in-a-lymphedema-sleeve/.*

[188] McNeely, M. L. *et al.* Nighttime compression supports improved self-management of breast cancer related lymphedema: A multicenter randomized controlled trial. *Cancer* 128, 587–596 (2021).

[189] Macintyre, Lisa Ph.D.; Gilmartin, Sian BSc; Rae, Michelle BSc; Journal of Burn Care & Research: September/October 2007—Volume 28—Issue 5—pp 725–733.

[190] Mukhopadhyay, A., & Shaw, V. P. (2022). Reliability analysis of stretchable workwear fabric under abrasive damage: Influence of stretch yarn composition. *Journal of Natural Fibers, 20*(1).

[191] Lymphedema Framework. Best Practice for the Management of Lymphoedema. International Consensus. London. MEP Ltd, 2006. *https://www.woundsme.com/uploads/resources/content lowbar;11160.pdf.*

[192] Lymphedema Products, LLC. *Determining Compression Levels. Lymphedemaproducts.Com. https://www.lymphedemaproducts.com/blog/how-to-determine-compression-levels-for-your-garments/.*

[193] Lympoedema Framework. Best Practice for the Management of Lymphoedema. International Consensus. London. MEP Ltd, 2006. *https://www.woundsme.com/uploads/resources/content_11160.pdf.*

[194] *https://www.forwardhealth.wi.gov/kw/html/3485_Compression_Garments.html.*

[195] Doherty DC, Morgan PA, & Moffatt CJ (2009). Hosiery in Lower Limb Lymphedema. *J Lymphoedema,* 4(1), 30–37. *https://www.woundsme.com/uploads/resources/content_11160.pdf.*

[196] Chang M–H, Chang DW, & Patel KM (2022). ''Lymphedema Risk Reduction and Management'' in *Principles and Practice of Lymphedema Surgery,* 2nd Ed., 78–90. *https://www.sciencedirect.com/topics/medicine-and-dentistry/compression-garment.*

require custom-fit gradient compression garments, as do those who need special adaptations or when there is need for varying levels of pressure within the same garment.[197] Some studies indicate that approximately 50 percent of lymphedema patients require custom-fit gradient compression garments versus standard fit gradient compression garments for effective treatment, although estimates vary.[198] [199]

3. Current Issues: Scope of the Benefit for Lymphedema Compression Treatment Items

In the CY 2024 HH PPS proposed rule (88 FR 43654), we proposed to implement a new benefit category established at section 1861(s)(2)(JJ) of the Act for ''lymphedema compression treatment items'' defined at section 1861(mmm) of the Act as standard and custom fitted gradient compression garments and other items determined by the Secretary that are—

- Furnished on or after January 1, 2024, to an individual with a diagnosis of lymphedema for the treatment of such condition;
- Primarily and customarily used to serve a medical purpose and for the treatment of lymphedema, as determined by the Secretary; and
- Prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist (as these terms are defined in section 1861(aa)(5)) to the extent authorized under State law).

In response to the CY 2024 HH PPS proposed rule (88 FR 43654), we received a number of comments from individuals health care providers and suppliers, medical associations, and medical device companies. More comments were received from healthcare consulting and medical technology organizations. In this section, we provide the proposed payment methodology, and a summary of the comments we received as well as our responses.

We proposed that any other items covered under this new benefit category in addition to gradient compression garments must also use compression in treating lymphedema since the specific category of medical items to be covered under section 1861(s)(2) of the Act are ''lymphedema compression treatment items.'' Similarly, we proposed that this benefit category is limited to compression treatment items and does not include professional lymphedema treatment services or other services not directly related to the furnishing of the lymphedema compression treatment items. Payment for any covered professional service related to these items would be made under the Medicare Physician Fee Schedule. The statute limits the benefit to items used for the treatment of lymphedema as determined by the Secretary, and we proposed that this includes items used to treat all types or diagnoses of lymphedema, but does not include the same items when used to treat injuries or illnesses other than lymphedema. In other words, if a gradient compression garment or other lymphedema compression treatment item is furnished to treat an injury or illness other than lymphedema, those items would not be classified under the Medicare benefit category for lymphedema compression treatment items. The following is a summary of the comments we received and our responses.

Comment: A commenter recommended that CMS work with suppliers and manufacturers of compression garments, and the clinical community who have expertise in providing services to patients with lymphedema in developing the scope of benefit and payment for lymphedema compression treatment items. A commenter stated that the need for custom fit supplies should be based on the medical expertise of the prescribing healthcare provider and patients should not face undue burdens. A commenter expressed concern that the proposed provisions in this rule would not remove barriers to eligibility for custom garments.

Response: We are appreciative of these comments. During the process of developing scope of benefit, payment, and coding policies for the new benefit for lymphedema compression items, we consulted with medical professionals, suppliers, manufacturers, trade organizations, and patients via public comments and meetings. Concerning coverage and the determination of a specific beneficiary's medical need for lymphedema compression treatment items, these concerns are outside the scope of this rulemaking. The final rule implements the new benefit category for lymphedema compression treatment items established under section 4133 of the CAA, 2023, and does not address coverage for these items or the Medicare coverage process or criteria.

Comment: A commenter urged CMS to reconsider the interpretation section 4133 of the Consolidated Appropriations Act, 2023. The commenter stated that Congress intended to make lymphedema compression treatment items available and accessible to Medicare beneficiaries with illnesses other than lymphedema. The commenter supports Congress' intent to expand patient access to lymphedema compression treatment items and urged CMS to ensure that its coverage and payment policies are consistent with and promote Congress' intent of expanding patient access to lymphedema compression treatment items. Another commenter stated that phlebolymphedema is lymphedema secondary to chronic venous insufficiency and that all patients with CVI (CEAP scores C3–C6) should be considered lymphedema patients.

Response: Section 4133 of the Consolidated Appropriations Act, 2023 establishes section 1861(mmm)(1) of the Act, stating that the new benefit is to be ''furnished to the individual with a diagnosis of lymphedema for the treatment of such condition''. As such, we are finalizing the proposed rule to limit the scope of the new benefit for lymphedema compression treatment items to items furnished to an individual with a diagnosis of lymphedema and not illnesses other than lymphedema.

In accordance with section 1861(mmm)(2) of the Act we are defining, in addition to the standard and custom fitted gradient compression garments that are included in the scope of the benefit, what ''other items as determined by the Secretary'' are included within the scope of the benefit. We proposed that other compression items used to treat lymphedema that would be covered under this benefit category in addition to gradient compression garments would include ready-to-wear, non-elastic, gradient compression wraps with adjustable straps such as the items described by HCPCS code A6545. In addition, we proposed that clinicians (or other qualified professionals) that furnish these items become enrolled and accredited as DMEPOS suppliers to bill for these items as lymphedema compression treatment items per section 1834(j)(5)(E) of the Act or payment for the items applied during phase one of decongestive therapy would not be allowed. We also note that while these items may be covered under the new

[197] Doherty DC, Morgan PA, & Moffatt CJ (2009). Hosiery in Lower Limb Lymphedema. *J Lymphoedema,* 4(1), 30–37. *https://www.woundsme.com/uploads/resources/content_11160.pdf.*

[198] Lymphedema Advocacy Group (2021 Apr). ''Cost and Utilization of Lymphedema Compression Garments.'' *https://lymphedematreatmentact.org/wp-content/uploads/2021/04/Cost-and-Utilization-of-Lymphedema-Compression-Garments.pdf.*

[199] Boyages J, Xu Y, Kalfa S, Koelmeyer L, Parkinson B, Mackie H, Viveros H, Gollan P, & Taksa L (2017). Financial cost of lymphedema borne by women with breast cancer. *Psychooncology,* 26(6), 849–855. doi: 10.1002/pon.4239. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5484300/.*

Part B benefit for lymphedema compression treatment items, the professional services associated with applying these items would need to be covered under a different Medicare benefit category for Medicare payments to be made for these services. We specifically solicited comments on the topic of coverage of compression bandaging items under the new benefit for lymphedema compression treatment items. We also solicited comments on whether the professional services of applying these bandages could be covered under another Medicare benefit category, such as outpatient physical therapy services under section 1861(p) of the Act or physician services under section 1861(s) of the Act. The following is a summary of the comments we received and our responses.

Comment: Several commenters thanked and supported CMS for the inclusion of compression bandaging systems being covered during the intensive/decongestive phase of the treatment. However, many commenters were concerned about the proposal that compression bandaging systems applied in a clinical setting as part of phase one decongestive therapy would be covered to the exclusion of their coverage during other phases of the treatment despite being critical to improvement and maintenance phases of treatment. Several commenters requested CMS consider including coverage of bandaging not only for the initial acute or decongestive phase (Phase 1), but also for the maintenance phase (Phase 2) of treatment for patients who use compression wraps and bandaging systems in addition to the coverage of daytime and nighttime garments.

A few commenters shared concerns over terms used in the proposed rule. A commenter recommended that CMS eliminate a reference to ''bandaging systems'' and replace with language that includes ''lymphedema bandages and related supplies such as foam rolls or sheets, lining materials.'' Several commenters indicated that patients need ''sets of garments'' as opposed to individual garments.

Many commenters requested CMS ensure inclusion of bandaging for various body parts including stretch bandages, firm bandaging, custom and adjustable wraps, bandage liners, night garments, Kinesio tape, Circaid wraps, Ready wraps, digital bandaging, elastic and non-elastic wraps, rolls of gauze bandaging, wraps for foot, calf, knee, thigh, hand, arm, Velcro bandage/compression systems, all knit type garments, compression socks/sleeve/gloves/gauntlets/pantyhose/thigh highs, standard fitted compression garments for the chest and back, such as compression bras which are able to hold a breast prosthesis; and toe caps that may be used for long term treatment, nighttime or other phases of treatment.

Response: We appreciate the comments on a variety of different viewpoints on bandaging, bundling payments and how to approach payment for therapists and other skilled professionals. We understand and agree that bandaging may be provided at different phases of the beneficiary's treatment of lymphedema and the use of bandaging can continue at various stages of lymphedema as long as medically necessary. We are clarifying that payment for compression bandaging systems under this benefit category is not limited to Phase 1 (acute or decongestive therapy) but is also available under Phase 2 (maintenance therapy). With regards to payment, we note that currently a therapist who applies compression bandaging supplies during Phase 1 of treatment can bill for the service of applying the bandages using CPT codes 29581 and 29584. It is important to note, however, that if the CPT codes are billed and paid for a particular date of service, then billing for the bandaging supplies used during that date of service using the HCPCS A codes is not allowed and would be denied as it would result in duplicate payment of the supplies since the Medicare payment amounts for codes 29581 and 29584 include payment for the compression bandaging supplies.

We are finalizing the proposal to cover gradient compression wraps with adjustable straps and compression bandages under the new benefit as well as accessories necessary for the effective use of gradient compression garments and wraps with adjustable straps. In response to comments about ensuring inclusion of bandaging for various body parts we are adding more HCPCS codes, in addition to those originally proposed, to be clearer about the inclusion of bandaging and accessories for the various body parts. Detailed discussion on HCPCS coding is included in section 4 ''Healthcare Common Procedure Coding System (HCPCS) Codes for Lymphedema Compression Treatment Items'' and a list of HCPCS codes being added is included in Table FF–A 2.

With regard to the reference to ''compression bandaging systems'', we are finalizing the use of the term ''compression bandaging systems'' in our regulations at 42 CFR 410.36(4)(iii) for lymphedema compression treatment items that are comprised of a combination of individual lymphedema compression bandages and related supplies as well as kits that can include both lymphedema bandages and related supplies used to create the compression bandaging system.

Comment: Many commenters requested that CMS provide separate payment for the measurement and fitting services to ensure that patients receive the best care for their individual needs and that clinicians, therapists, and certified fitters are paid fairly and directly for the service they provide in all settings where fittings may be provided. Some commenters suggested they had greater trust in therapists than in general DMEPOS suppliers for garment measurement, believing that therapists provided more accurate measurements. Some commenters suggested precedent with orthotics and prosthetics for separate codes specifically for fitting services (with varying recommendations for the specific codes that could be created), and these codes may also assist in reimbursement in the event follow-up visits are needed to assess possible re-fitting as limb size may change significantly over time (for example, HCPCS level 1 code 97760 ''Orthotic management and training'' when services are not provided by a DMEPOS supplier).

A commenter expressed concern that DMEPOS suppliers may not be prepared for the influx of referrals for lymphedema compression treatment garments, and that only separate payment for fitting services would alleviate wait times or other access issues.

At the same time, many commenters expressed concerns with aspects that would arise from separate payment for fitting services. A commenter expressed concern that the patient receive clear and correct pricing for each garment, regardless of how the fitting services are provided. A commenter stated that therapists may use multiple garment suppliers which may create complications in arranging for separate payment for fitting.

A commenter believed the proposal to implement a separate fitting component where payment is made to a therapist for taking measurements would be difficult for suppliers, particularly those that maintain a physical office where patients can attend a complimentary fitting appointment with a trained fitter.

Several commenters expressed concern with responsibility for replacement of ill-fitting garments if separate payment for fitting services were established. While most commenters believe that separately paid fitters should not bear financial responsibility for garments that do not fit as expected, a commenter

recommended that if the garment matches the written fitting order, the fitter should bear responsibility for the cost of replacement in the event of a poor fit. A commenter specifically recommended that since the supplier retains responsibility for replacement or alteration of an ill-fitting garment, their payment should include the cost of fitting. A commenter noted that improperly measured garments could be altered (so full replacement may not be necessary) and that even with accurate measurement there is no guarantee of proper fit since there can be reduction or increase in the patient's condition during the weeks between measuring and receipt of the garment.

A few commenters support the proposal to bundle payment for fitting and garments and that it be coordinated by enrolled DMEPOS suppliers A commenter indicated that if DMEPOS suppliers are enabled to act as administrator of payments for these services it would allow DMEPOS suppliers to set rates and administer payments without oversight or infrastructure to address non-payments, appeals and other unforeseen billing and reimbursement circumstances. Several commenters shared concerns that DMEPOS suppliers may not be ideal or have adequate training for measuring, assisting in choices or educating patients with certain circumstances such as lymphedema in sensitive areas, compression choices based on sensitivities or personal challenges in doffing and donning, or reach and balance concerns and may lead to delay and regression in treatment. A few commenters believe DMEPOS suppliers will have financial incentives that do not account for patient needs or preference. A few commenters indicated there is a difference between the measuring and fitting services provided by a DMEPOS supplier as compared to a therapist and indicated that when DMEPOS suppliers perform the measuring services the garment is typically sent to the patients home and the supplier is not required to follow-up with the patient whereas with therapists the garment is sent to the therapists office where they ensure the garment fits properly and the patient's comfort and functional needs are met leading to higher rates of compliance. A commenter indicated that the differences should be acknowledged in the payment.

Response: We appreciate the many concerns commenters expressed both in support and against the idea of separate payment for fitting services. In the proposed rule, we noted that therapists often take measurements of affected body areas and perform other fitting services related to the furnishing of gradient compression garments. These measurements are an integral part of furnishing the custom garments and in some cases, the standard garments, and the suppliers of the garments are responsible for fitting the garments they furnish. Typically, DMEPOS suppliers are responsible for all aspects of furnishing the item, including fitting and measuring services. Following that approach, a supplier receiving payment for furnishing a lymphedema compression treatment item to a beneficiary has responsibility for ensuring that any necessary fitting, training (how to appropriately don/doff and maintain), and adjustment services are provided as part of furnishing the item. The supplier receiving payment for the garment may work out an arrangement with the therapist for the fitting component that is an integral part of furnishing the item. Although we solicited comments on the option of paying separately for the fitting component furnished by the therapist and then backing this payment out of the payment for the garment, we did not propose this policy. We did not propose this policy because of the many complexities associated with this policy and the comments reinforced that this is a very complicated alternative that requires careful analysis and consideration. We do not believe we are in a position to implement such a policy in 2024, but it is something we could consider under future rulemaking if we believe it would improve the administration of this new DMEPOS benefit category.

As part of the DMEPOS supplier standards, a supplier must accept return of substandard items. In cases where a mistake is made in measuring and fitting the beneficiary for gradient compression garments, resulting in the furnishing and payment for custom gradient compression garments that do not properly fit the patient, the risk would be assumed by the fitter and not the supplier to accept return of the garments and cover the cost of two replacement garments. Again, we did not propose to make separate payment for the fitting services under this benefit when furnished by a supplier other than the supplier of the garments; however, we specifically solicited comments on the topic and comments on options to resolve the issues we outlined previously. We recognize that there is not necessarily a standard industry practice for the fitting and training components for furnishing lymphedema compression garments and sought comment on whether there are best practices in this space that CMS should consider further in the future. We also solicited comments on whether any HCPCS Level I (Current Procedural Terminology or CPT®) codes may describe the services of the therapist in these scenarios. The following is a summary of the comments we received and our responses.

Comment: A commenter recommended a specific proposal where the 20 percent beneficiary copay would be directed to the fitter for these services while the supplier of the garment would receive 80 percent of the allowed payment amount for the garment.

Response: The CAA, 2023 did not modify or exempt lymphedema compression treatment items from the normal copay requirements that apply to Medicare items and services, so we do not intend to direct that beneficiaries make copayments for these items to fitters rather than the DMEPOS suppliers of the items.

Comment: A few commenters are concerned that having DME suppliers administer payment for these services may open a window for abuse of Federal anti-kickback laws in the industry.

Response: With regard to the concerns raised by the commenters about the Federal anti-kickback statute, while all applicable parties must comply with this law, such concerns are outside the scope of this rulemaking.

Comment: A few commenters requested CMS to require non-clinician fitters to complete a training program, while a few other commenters requested CMS to adopt quality standards for non-clinician fitters of lymphedema compression treatment items. Alternatively, a few commenters recommended CMS provide a separate payment to clinicians for providing DME services and did not support DME suppliers administrating payment for these critical services. A commenter requested clarification from CMS on whether private practice physical (PT) and occupational therapists (OT) are exempt from proposed surety bond requirements if the business is solely owned and operated by the PT or OT's. This commenter requested CMS to premise payment on enrolling as a DME supplier. Some commenters expressed concern that CMS may have omitted from the proposal the full range of medical professionals who provide fitting services. Some commenters recommend that CMS support the establishment of an industry-standard licensing or certification process for fitting services to ensure training in garment selection, fabric type, compression class and the necessary

options for specific disease states, and presentation, while other commenters expressed concern with limiting fitting services to certain licensed health professionals in a way that may reduce access in areas of the country already struggling with a lack of lymphedema treatment professionals.

Response: Suppliers of lymphedema compression treatment items are required to become enrolled DMEPOS suppliers, which in turn requires the supplier to obtain a surety bond, become accredited, and be in compliance with the DMEPOS supplier standards and quality standards. Medical professionals that currently provide fitting services are able to enroll in Medicare as DMEPOS suppliers and receive such bundled payment for garments and related supply services provided to beneficiaries. We will consider whether specific quality standards for suppliers of lymphedema compression treatment items should be added to the DMEPOS quality standards in the future. With regards to the comment requesting exemption from the surety bond requirements, we note that section 1834(a)(16) of the Act requires DMEPOS suppliers to maintain a surety bond of at least $50,000 as a condition for the receipt or renewal of a Medicare provider number.

Comment: Several comments noted that fitting may be required not only for patients wearing custom garments, but also ready-to-wear products, although some comments specifically noted that the time required to fit for custom garments is longer. Some commenters stated that patients sometimes require multiple visits to ensure a proper fit, particularly for patients with more complex cases. A few commenters also noted that in certain complex cases it may be necessary for the supplier or manufacturer to interact with the therapist to co-engineer a custom garment, so CMS should ensure appropriate reimbursement for this type of work. A commenter urged CMS to collect and make public data on where beneficiaries are accessing lymphedema products, whether through suppliers or therapists, and to implement an auditing process to ensure that therapists are being adequately reimbursed.

Response: We appreciate these comments. Payment for all services necessary for furnishing a gradient compression garment are included in the rates paid by Medicaid State agencies and we proposed to use the average Medicaid payment rate plus twenty percent as the payment basis for Medicare (when such Medicaid rates are available). Therefore, Medicare payments likewise include payment for all services necessary for furnishing the gradient compression garment, which is consistent with how Medicare payment is made for other DMEPOS items and services. We intend to closely monitor access to lymphedema compression treatment items and related services necessary for the effective use of these items to ensure that the Medicare payments for these items are appropriate.

Comment: A few commenters raised concerns that bundling payment for a lymphedema compression treatment item that is supplied by a DMEPOS supplier where the measuring and fitting of the item is performed by a therapist or other practitioner would require the therapist or practitioner to enter into a financial relationship with the DMEPOS supplier that would implicate the physician self-referral law at section 1877 of the Act. A commenter requested that CMS clarify that a financial relationship between a DMEPOS supplier and a therapist or a practitioner who performs the fitting component of the service would be permissible under the physician self-referral law.

Response: Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

The physician self-referral law would be implicated only if the therapist or practitioner who provides the fitting component of a service is a physician or the immediate family member of a physician (as defined at § 411.351) and there is a financial relationship between the therapist or practitioner and the DMEPOS supplier. Where the physician self-referral law is implicated, a physician's referrals to the DMEPOS supplier with which the physician (or the immediate family member of the physician) has the financial relationship will not be prohibited if all the requirements of an applicable exception are satisfied. We note that several statutory and regulatory exceptions may be applicable to the type of financial relationship described by the commenters.

We are finalizing the proposal to include payment for fitting services in the overall payment for lymphedema compression treatment garments that CMS will make to Medicare-enrolled DMEPOS suppliers that furnish lymphedema compression treatment items to Medicare beneficiaries.

Finally, there are accessories such as zippers in garments, liners worn under garments or wraps with adjustable straps, and padding or fillers that are not compression garments but may be necessary for the effective use of a gradient compression garment or wraps with adjustable straps. There are also accessories like donning and doffing aids for different body parts such as lower limb butlers or foot slippers that allow the patients to put on the compression stockings with minimum effort and are not used with compression bandaging systems or supplies.

We proposed that accessories necessary for the effective use of gradient compression garments and gradient compression wraps with adjustable straps would also fall under this new benefit for lymphedema compression treatment items. For example, a liner that is used with a garment because it is needed to prevent skin breakdown could be covered under the new benefit because it is necessary for the effective use of the garment. We solicited comments on the topic of coverage of accessories necessary for the effective use of gradient compression garment or wraps with adjustable straps, including what HCPCS codes should be established to describe these items, as well as comments on whether there are additional items other than the gradient compression garments, gradient compression wraps with adjustable straps, and compression bandaging supplies that could potentially fall under the new benefit category for lymphedema compression treatment items. The following is a summary of the comments we received and our responses.

Comment: All commenters supported the addition of accessories to the items and services covered under the Medicare benefit category for lymphedema compression treatment items. Several commenters thanked and supported CMS's proposal to include accessories such as donning and doffing aids that assist patients with putting on compression items. Several commenters indicated that lymphedema treatment items are customizable and vary widely

by patient but are especially important for Medicare recipients who are more likely to have multiple co-morbidities that restrain their strength and range of motion. A few commenters indicated the need to account for layering garments as recommended by clinicians. A few commenters described these items as part of a ''build'' of a garment/solution and suggested they have unique HCPCS codes to support the ''build.''

Several commenters requested clarification on the term ''padding'' suggesting this should be itemized for the sake of comprehensiveness and include foam sheets, foam rolls, cotton or synthetic padding, stockinette, customized foam cutouts, and chip pads as well as Swell Spots or similar quilted items to be used under clothing. A commenter suggested padding be listed according to use (that is, skin protection and cushioning, compression, fibrosis). A commenter indicated that the proposed definition in 42 CFR 410.36(a)(4) needs additional language to better describe the wide range of accessories that are necessary for effective use of medically necessary lymphedema compression treatment items.

Many commenters indicated the need for coverage of aids that facilitate use and enhance compliance rates such as: adhesive roll on, fasteners and closures, bandage liners, donning and doffing aids (such as limb butlers, foot slippers, liners, silicone donning lotions, and bandaging supplies), padding, skin barrier stocking, accessories which are attached to and modify the lymphedema treatment garment, and accessories which are separate from the lymphedema garments such as oversleeves and undersleeves. Many commenters made suggestions on the range of accessories for which HCPCS codes are needed. Many commenters identified the following accessories for HCPCS code development: stockinettes, customized foam cutouts, foam pads, foam chips, bandage rollers (manual and motorized), bandaging liners, medium-stretch bandages, under-bandage pads and bandage liners, and short-stretch bandages, securing tape, donning and doffing aids such as wire frame butlers, easy slide sleeves, donning gloves, lubricants and adhesives, garment washing fluid, oversleeves, strap extenders, lobe straps, tape measures, garter belts, zippers, pull loops, silicone bands, comfort/flexion zones, outer jackets, and fitting lotion.

A few commenters indicated that padding is generally durable but only some is washable and that materials break down over time and need replacement every 1 to 2 years. The commenter indicated bandages lose their stretch and need replacing at least every 4 to 6 weeks. A few commenters requested CMS clarify that lymphedema compression treatment items and pneumatic compression pumps may be covered concurrently if medically necessary. A commenter suggested that supporting the cost of donning and doffing aids would benefit patients who lack the mobility to don and doff the garments themselves.

Response: We appreciate the detailed lists and comments that the commenters have provided to us on the types of accessories as well as suggestions for accessory HCPCS codes. We thank commenters for the support of our proposal to cover accessories necessary for the effective use of gradient compression garments and gradient compression wraps with adjustable straps, including donning and doffing aids, under the new lymphedema compression treatment items benefit. We recognize that the form accessories may take in relation to the garments and wraps is varied with some accessories part of the garment as furnished such as zippers and others separate such as liners worn under garments or wraps. We believe the proposed definition of accessories for lymphedema compression treatment items at 42 CFR 410.36(a)(4) captures the variance in form and range of accessories that are needed for the effective use of garments and wraps with adjustable straps. We also believe that additional specification in terms of type or use on the term ''padding'' that is provided as an example in the definition is not necessary to clarify the scope of the benefit and are finalizing the definition as proposed. Concerning HCPCS codes to describe these items, as commenters note, there is a wide array of accessories on the market that can be used to facilitate effective use of the garments or wraps. Given the number and types of accessories available, we have initially established a not otherwise specified code for accessories, as shown in Table FF A 2, that will be effective January 1, 2024 for use in identifying accessories used in conjunction with lymphedema garments and wraps. We believe it is important to have a code in place on January 1, 2024 for identifying such items and we refer readers to the public HCPCS process, described at *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings,* as a means for modifying the code set in the future. Since Medicare coverage determinations have not been developed at this time for different types of accessories used in conjunction with lymphedema garments and wraps, the coverage determinations for any claims submitted for these items must be made on an individual, claim-by-claim basis, beginning on January 1, 2024. We note that one code for these accessories is all that will be needed to process claims for these items and services. Should CMS develop an NCD or LCDs with specific medical necessity criteria for different types of accessories in the future, we would add codes for the different types of accessories addressed in these coverage determinations for Medicare claims processing purposes. With respect to concurrent coverage of lymphedema compression treatment items and pneumatic compression pumps, DME MACs will continue to make determinations on the medical necessity of items and services, including items that fall under the new benefit category for lymphedema compression treatment items and existing benefit categories.

4. Healthcare Common Procedure Coding System (HCPCS) Codes for Lymphedema Compression Treatment Items

HCPCS codes are divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I of the HCPCS is comprised of Current Procedural Terminology (CPT), a numeric coding system maintained by the American Medical Association (AMA). HCPCS Level II is a standardized coding system that is used primarily to identify drugs, biologicals and non-drug and non-biological items, supplies, and services not included in the CPT codes, such as ambulance services and DMEPOS when used outside a physician's office. As shown in Table FF–A 1, there are currently HCPCS Level II codes for compression garments (stockings, sleeves, gloves, and gauntlets) and compression wraps with adjustable straps that may be used in the treatment of lymphedema and other conditions.

BILLING CODE 4120–01–P

TABLE FF-A 1: EXISTING HCPCS CODES FOR COMPRESSION TREATMENT ITEMS

Code	Description
A6530	Gradient compression stocking, below knee, 18-30 mmhg, each
A6531	Gradient compression stocking, below knee, 30-40 mmhg, each
A6532	Gradient compression stocking, below knee, 40-50 mmhg, each
A6533	Gradient compression stocking, thigh length, 18-30 mmhg, each
A6534	Gradient compression stocking, thigh length, 30-40 mmhg, each
A6535	Gradient compression stocking, thigh length, 40-50 mmhg, each
A6536	Gradient compression stocking, full length/chap style, 18-30 mmhg, each
A6537	Gradient compression stocking, full length/chap style, 30-40 mmhg, each
A6538	Gradient compression stocking, full length/chap style, 40-50 mmhg, each
A6539	Gradient compression stocking, waist length, 18-30 mmhg, each
A6540	Gradient compression stocking, waist length, 30-40 mmhg, each
A6541	Gradient compression stocking, waist length, 40-50 mmhg, each
A6545	Gradient compression wrap, non-elastic, below knee, 30-50 mmhg, each
A6549	Gradient compression stocking/sleeve, not otherwise specified
S8420	Gradient pressure aid (sleeve and glove combination), custom made
S8421	Gradient pressure aid (sleeve and glove combination), ready made
S8422	Gradient pressure aid (sleeve), custom made, medium weight
S8423	Gradient pressure aid (sleeve), custom made, heavy weight
S8424	Gradient pressure aid (sleeve), ready made
S8425	Gradient pressure aid (glove), custom made, medium weight
S8426	Gradient pressure aid (glove), custom made, heavy weight
S8427	Gradient pressure aid (glove), ready made
S8428	Gradient pressure aid (gauntlet), ready made
S8429	Gradient pressure exterior wrap
S8430	Padding for compression bandage, roll
S8431	Compression bandage, roll

BILLING CODE 4120–01–C

The items described by HCPCS codes A6531, A6532, and A6545 are covered by Medicare under the Part B benefit for surgical dressings at section 1861(s)(5) of the Act, when used in the treatment of an open venous stasis ulcer. Total allowed charges for these three codes in 2022 was approximately $2.5 million, with around $1.9 million for the non-elastic, below knee, gradient compression wrap with adjustable straps described by code A6545, $500,000 for the below knee, gradient compression stocking code A6531, and $100,000 for the below knee, gradient compression stocking code A6532. We did not propose to change this policy with this rule, but we addressed the codes for items when they are covered under Medicare Part B as surgical dressing versus when they are covered under Medicare Part B as lymphedema compression treatment for billing and claims processing purposes. We therefore proposed to add three new HCPCS codes for use when billing for A6531, A6532, and A6545 items used as surgical dressings. The proposed codes are as follows:

- A—Gradient compression stocking, below knee, 30–40 mmhg, used as surgical dressing in treatment of open venous stasis ulcer, each
- A—Gradient compression stocking, below knee, 40–50 mmhg, used as surgical dressing in treatment of open venous stasis ulcer, each
- A—Gradient compression wrap with adjustable straps, non-elastic, below knee, 30–50 mmhg, used as surgical dressing in treatment of open venous stasis ulcer, each

The surgical dressing fee schedule amounts for codes A6531, A6532, and A6545 would be applied to the three new codes. The remaining discussion in this section addresses the coding for the lymphedema compression treatment items.

For gradient compression stockings, we proposed to use existing codes A6530 through A6541, and code A6549 from Table FFA–1. For codes A6530 through A6541, we solicited comments on whether we should maintain the three pressure level differentiations in the codes and whether these differentiations should be something other than 18–30, 30–40, and 40–50 mmHg. We also solicited comments on whether there is a better way to describe the body areas these garments cover rather than ''below knee,'' ''thigh-length,'' ''full-length/chap style,'' and

''waist-length.'' For each code, we proposed to add a matching code for the custom version of the garment. For example, if we continue to use codes A6530 through A6532 for below knee stockings with the current descriptions, we would add corresponding codes for the custom versions of these garments, such as the following:

- A—Gradient compression stocking, below knee, 18–30 mmhg, custom, each
- A—Gradient compression stocking, below knee, 30–40 mmhg, custom, each
- A—Gradient compression stocking, below knee, 40–50 mmhg, custom, each

For gradient compression garments for the upper extremities and areas of the body, we proposed to use existing codes A6549 and S8420 through S8428. We proposed renumbering codes S8420 through S8428 as ''A'' codes rather than S codes. We proposed removing the words ''ready-made'' and revising ''custom made'' to ''custom'' for the codes for the upper extremity gradient compression garments and replacing the word ''pressure'' with ''compression,'' in order to be consistent with the wording for the codes for the lower extremity garments. We proposed to add the word ''arm'' in front of the word ''sleeve'' for the upper extremity garments. We also proposed to add a code for a custom gauntlet. Finally, we proposed to add the word ''each'' to the description for each code. We proposed that if no other changes are made, the new codes would be as follows:

- A—Gradient compression arm sleeve and glove combination, each
- A—Gradient compression arm sleeve and glove combination, custom, each
- A—Gradient compression arm sleeve, each
- A—Gradient compression arm sleeve, custom, medium weight, each
- A—Gradient compression arm sleeve, custom, heavy weight, each
- A—Gradient compression glove, each
- A—Gradient compression glove, custom, medium weight, each
- A—Gradient compression glove, custom, heavy weight, each
- A—Gradient compression gauntlet, each
- A—Gradient compression gauntlet, custom, each

We solicited comment on whether separate codes are needed for mastectomy sleeves or whether these items can be grouped together under the same codes used for other arm sleeves (S8422 thru S8424). We solicited comments on whether there is a need to retain codes S8420 through S8428, in addition to the renumbered A code versions, for use by other payers other than Medicare. If these codes are retained, they would be invalid for Medicare use, but could be used by other payers in lieu of the new A codes.

We also proposed to add the following new codes for other upper body areas:

- A—Gradient compression garment, neck/head, each
- A—Gradient compression garment, neck/head, custom, each
- A—Gradient compression garment, torso and shoulder, each
- A—Gradient compression garment, torso/shoulder, custom, each
- A—Gradient compression garment, genital region, each
- A—Gradient compression garment, genital region, custom, each

For all of the codes for the upper extremities and upper body areas, we solicited comments on whether we should establish codes for pressure level differentiations similar to the pressure level differentiations in codes A6530 through A6541, possibly replacing the words medium and heavy weight, as well as whether codes are needed for additional upper body areas.

We proposed the following new codes for nighttime garments:

- A—Gradient compression garment, glove, padded, for nighttime use, each
- A—Gradient compression garment, arm, padded, for nighttime use, each
- A—Gradient compression garment, lower leg and foot, padded, for nighttime use, each
- A—Gradient compression garment, full leg and foot, padded, for nighttime use, each

For gradient compression wraps with adjustable straps, we proposed to use code A6545 in Table FF–A 1 for below knee wraps and solicit comments on whether additional codes or coding revisions are needed for the purpose of submitting claims for gradient compression wraps with adjustable straps. Regarding HCPCS codes for compression bandaging systems, we believe more codes are needed than existing codes S8430 (Padding for compression bandage, roll) and S8431 (Padding for compression bandage, roll), for example, to describe the supplies used in a compression bandaging system consisting of more than two layers. We also believe that specific base sizes should be added to the code, for example ''10cm by 2.9m'' rather than the vague unit of ''roll'' and are soliciting comments on HCPCS coding changes needed to adequately describe the various compression bandaging systems used for the treatment of lymphedema. Finally, as noted in section VII.B.3. of this rule, we solicited comments on HCPCS codes needed to describe accessories necessary for the effective use of gradient compression garments or wraps with adjustable straps. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that flat-knit garments have separate codes from circular-knit garments. A commenter supported development of separate HCPCS codes for circular knit vs flat knit garments as they have different costs and are appropriate for different patients.

Response: While some commenters supported having different codes for flat knit and circular knit garments, we do not believe this differentiation is necessary since it is our understanding that the majority of flat knit garments are custom garments, and the majority of circular knit garments are non-custom. We believe that having separate codes for custom and non-custom codes should be sufficient to address this difference in garment material.

Comment: A few commenters expressed general support for existing compression stocking codes (A6530–41 and A6549). A few commenters indicated that changes to these codes would affect existing processes, knowledge, and experience throughout the insurance industry. A few commenters did not support any changes in these codes. A few commenters supported changes to the A6530–41 and A6549 codes to reflect the different kinds of knits, lengths, and other variations in garments, including the addition of modifiers to describe each criterion when billed with a specific HCPCS code. Other commenters favored establishing new codes with additional textile and technology specifications instead of using the existing compression stocking codes. A few commenters indicated that the number of proposed HCPCS codes was inadequate. A few commenters made suggestions on codes on custom versions of Existing Gradient Compression Stocking Codes (A6530–41 and A6549). A commenter recommended custom nighttime compression garments be available at any compression pressure and custom non-elastic gradient compression wrap at any compression pressure.

A commenter suggested expanding and updating the codes for each type of material (circular knit, flat knit, inelastic wraps) and indicating whether it is ready made or custom made. Many commenters offered suggestions on better ways to describe body areas.

Several commenters suggested adding descriptions that would apply to multiple body areas, including toe and individual toes, calf, foot, ankle, below knee, knee, above knee, thigh, pelvis, and pelvis and thigh(s), genital, head, neck, chest, torso, arm, hand, and finger. Several commenters suggested descriptions for items that apply to a range of body areas, including shorts, thigh to waist length compression shorts, ankle to waist length compression capris, full body suit, biker short and adding ''knee-high'' or ''thigh-high'' to descriptions, combined gauntlet and arm sleeve, and torso only (bodysuits, bras, axillary compression items, vests, abdominal compression items, short-sleeve shirts, and long-sleeve shirts) and chest/torso compression garments. A few commenters noted the need for descriptions that would cover garment items used for multiple body areas. A commenter suggested ''high rise panty'' or ''high rise panty with leg'' or ''bicycle short style'' to clarify that stocking definitions include the buttocks, the foot, open or closed toe, as well as a partial leg on the non-affected side. A commenter indicated the need for a description that would apply to a standard thigh high compression garment on one leg to a custom panty hose with 2 legs of differing lengths and compression levels. A commenter indicated the need for a description that would apply to a garment item that covers an entire limb/body part or is divided into components to allow ease of donning/doffing and best coverage per patient. The description should also be inclusive of all body parts with appropriate codes for each. A few commenters suggested new HCPCS billing codes for items such as custom flat knit compression waist high pantyhose (with multiple compression levels in different body parts) and a groin compression panel option.

Response: We thank the commenters for providing comments on the use of the existing codes (A6530–41 and A6549) and for support of our proposal. After careful review, we believe that retaining the existing longstanding compression stocking codes will work to identify and describe these items and will be less disruptive across all payer settings than establishing new HCPCS codes that would replace the existing codes. Some commenters suggested separate new codes or modifications to the existing codes to distinguish custom versions of garments, different types of textiles (flat and custom knit), different pressure designations or different body areas. We thank commenters for supporting our proposal to add a matching code for the custom version of each garment and are adding these new codes for use on January 1, 2024. We also proposed use of existing not otherwise specified code A6549 and are finalizing this along with a change to the code descriptor from ''stocking/sleeve'' to ''garment'' to clarify its use as a gradient compression garment code. We thank commenters for the numerous suggestions on ways to describe the various body areas that gradient compression areas can cover, including ranges of body areas and descriptions such as ''high rise panty with leg.'' After careful review, we have identified in Table FF–A 2 new codes that we will be finalizing as part of this rule with an effective date of January 1, 2024, including gradient compression garment codes for the genital regions, neck/head and toe caps. In addition to the new codes in Table FF–A 2, we are retaining the following existing codes, with revisions to the descriptors where applicable as noted previously, that are also available to describe lymphedema compression treatment items:

Code	Description
A6530	Gradient compression stocking, below knee, 18-30 mmhg, each
A6533	Gradient compression stocking, thigh length, 18-30 mmhg, each
A6534	Gradient compression stocking, thigh length, 30-40 mmhg, each
A6535	Gradient compression stocking, thigh length, 40 mmhg or greater, each
A6536	Gradient compression stocking, full length/chap style, 18-30 mmhg, each
A6537	Gradient compression stocking, full length/chap style, 30-40 mmhg, each
A6538	Gradient compression stocking, full length/chap style, 40 mmhg or greater, each
A6539	Gradient compression stocking, waist length, 18-30 mmhg, each
A6540	Gradient compression stocking, waist length, 30-40 mmhg, each
A6541	Gradient compression stocking, waist length, 40 mmhg or greater, each
A6549	Gradient compression garment, not otherwise specified

We believe it is important to have a set of codes in place on January 1, 2024, that will generally meet the needs of the majority of patients. However, we recognize that additional refinements may be necessary. As such, the public HCPCS process, described at *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings* is available as a means for modifying the code set in the future.

Comment: Many commenters offered suggestions on changes to the proposal on differentiating pressure levels for HCPCS codes A6530–41 and A6549. A commenter supported the pressure levels described, while adding language to acknowledge that they do not include all pressure levels available. A few commenters supported including compression levels higher than 50 mmHg. A commenter recommended aligning the pressure level differentiations in codes A6530–A6541 to the compression class designations utilized by providers to ensure that higher levels of compression are captured for reimbursement. A few commenters suggested separate treatment of pressure levels for circular and flat knit garments. A commenter suggested including nighttime compression items at any compression pressure. Another commenter suggested including pressure level differentiations with all items for upper extremity and upper body areas. A few commenters suggested use of Mild Pressure, Moderate Pressure, Maximum Pressure across all codes because some vendors use class levels and some use specific levels. A commenter indicated that

ranges of compression be explicitly covered (15–20 mmHg, 20–30 mmHg, 30–40 mmHg, and 40–50 mmHg). A commenter recommended keeping the pressure levels the same for lower and upper extremity garments. A commenter suggested having a standard and custom garment for each pressure level as well as for each garment type. A commenter suggested adding a matching code for the custom version of the garment, dividing custom garments by compression class (18–30 mmHg; 30–40 mmHg; 40–50 mmHg) and custom flat knit garments (15–21 mmHg; 22–32 mmHg; 33–46+ mmHg).

Response: We believe that the existing pressure designations in mmHg generally capture how these items are presented and marketed in the U.S. market. We believe a change to an alternative pressure designation such as mild, moderate or maximum pressure would present more challenges for billing and be more disruptive to the lymphedema market. However, we recognize that the existing pressure ranges that end in 50 mmhg that we proposed may not capture all the pressure levels available, so we are revising the following gradient compression stocking code pressure ranges by removing ''40–50 mmhg'' and adding ''40 mmhg or greater'' to ensure that higher levels of compression are addressed in both the standard and custom versions:

- A—Gradient compression stocking, below knee, 40 mmhg or greater, each
- A—Gradient compression stocking, below knee, 40 mmhg or greater, custom, each
- A—A6535 Gradient compression stocking, thigh length, 40 mmhg or greater, each
- A—Gradient compression stocking, thigh length, 40 mmhg or greater, custom, each
- A—A6538 Gradient compression stocking, full length/chap style, 40 mmhg or greater, each
- A—Gradient compression stocking, full length/chap style, 40 mmhg or greater, custom, each
- A—A6541 Gradient compression stocking, waist length, 40 mmhg or greater, each
- A—Gradient compression stocking, waist length, 40 mmhg or greater, custom, each

Table FF–A2 also includes the five new A codes that instead of finalizing as proposed, we are finalizing by adding ''40 mmhg or greater'' to the stocking code pressure ranges.

Comment: A few commenters expressed general support for the addition of new HCPCS codes for use when billing for A6531, A6532, and A6545 items used as surgical dressings only. Several commenters disagreed with the addition of three new HCPCS codes for use when billing for A6531, A6532, and A6545 items used as surgical dressings. A few commenters suggested that the addition of new codes was unnecessary. Another commenter suggested current HCPCS modifiers are sufficient to differentiate these garments when used for different purposes and was concerned with overcomplicating coding decisions. Several commenters believe it might require a change to existing wound care guidance, affect national and local coverage determinations, and increase administrative burden. A few commenters indicated that the new HCPCS codes would be confused with existing HCPCS codes. A commenter indicated that the addition of new codes would lead to payment errors. A few commenters recommended that existing A6531, A6532, and A6545 codes not be modified for coverage of lymphedema compression garments and that new codes be developed to describe items under the new benefit to avoid confusion.

Response: We appreciate the comments and agree with commenters that establishing new codes for lymphedema compression garments would be preferable to modifying the existing A6531, A6532, and A6545 surgical dressing codes for use under the new benefit as proposed. To avoid confusion and disruption associated with repurposing the existing A6531, A6532, and A6545 surgical dressing codes, instead of finalizing new A codes for the existing A6531, A6532 and A6545 codes under the surgical dressing benefit and retaining A6531, A6532 and A6545 for use under the lymphedema benefit as proposed, we are instead finalizing new A codes for the following gradient compression garment and wrap codes under the lymphedema compression benefit effective January 1, 2024.

- A—Gradient compression stocking, below knee, 30–40 mmhg, each
- A—Gradient compression stocking, below knee, 40 mmhg or greater, each
- A—Gradient compression wrap with adjustable straps, below knee, 30–50 mmhg, each

Additionally, we will revise the descriptors of existing A6531, A6532, and A6545 to clarify their use under the surgical dressing benefit. For example, A6531 would read ''Gradient compression stocking, below knee, 30–40 mmhg, used as surgical dressing, each.''

Comment: On CMS's proposal to use existing A6549 and S8428–S8428 codes, a few commenters supported renumbering S8420 through S8428 to A codes. A commenter suggested replacing the terms ''medium weight'' and ''heavy weight'' with compression values, or, in the alternative, adding section defining the range of compression values that qualify as ''medium weight'' and ''heavy weight.'' A few commenters disagreed with renumbering S–8420 through S8428 to A codes and indicated it could lead to problems with claims payment by private and other payers. A few commenters expressed general support for existing codes for upper extremities and body garments (A6549, S8420–28). A few commenters indicated support for the addition of codes for upper body areas. A commenter supported the addition of codes for non-limb areas of the body. A commenter recommended that existing codes not be changed because they are used across the insurance industry. A few commenters supported differentiating pressure levels for codes for upper extremities and body areas. A commenter agreed with differentiation for upper limb garment, suggesting differentiation by compression ranges (20–30, 30–40, 40–50 mmHg) or compression class level (for example, Class 1, Class 2, Class 3). Another commenter supported the three-pressure level differentiations but indicated the need to distinguish circular-knit and flat-knit compression garments. A commenter suggested the coverage of gradient compression garments such as the compression arm sleeve with shoulder attachment and the compression arm sleeve with gauntlet attachment. A commenter also suggested that the proposed list of arm sleeves needs should include ''A—Gradient compression arm sleeve and gauntlet, custom'' as they believe it is frequently prescribed and indicated. A commenter did not support retention of HCPCS codes S8420–S8428, indicating that they could be included with other code changes effective in 2024. Another commenter also supported the removal of the ''S'' codes due to difficulties obtaining a Medicare denial when other insurers require use of these garment codes for the upper extremities. A commenter supported maintaining HCPCS codes S8420–S8428 because they are used by insurers for diagnoses other than lymphedema. Other commenters noted billing challenges if not all Medicaid and commercial payers adopt the replacement ''A'' codes for HCPCS codes S8420–S8428.

Response: Thank you for your comments on our proposal to use

existing HCPCS code A6549 and to add new ''A'' codes based on the S8420–S8428 codes for upper extremity gradient compression garments. After careful review, we are finalizing the addition of A codes that align with the codes and descriptors of S8420 through S8428 along with the following changes to the A code descriptors: removing the words ''ready-made,'' revising ''custom made'' to ''custom,'' replacing the word ''pressure'' with ''compression,'' adding ''each,'' and adding the word ''arm'' in front of the word ''sleeve'' for the upper extremity garments. We are also finalizing the addition of a code for a custom gauntlet as proposed. Based on commenter input, we will retain codes S8420 through S8428, in addition to the new A code versions, for use by other payers other than Medicare. The ''S'' codes will be invalid for Medicare use, but they could be used by other payers in lieu of the new upper extremity garment ''A'' codes. Similar to the lower extremity gradient compression garments, we did not find a need to further differentiate the proposed upper extremity codes based on circular-knit and flat-knit compression materials. Since the majority of flat-knit garments are custom garments and circular-knit garments are non-custom garments, we do not believe further stratification of the proposed custom and non-custom upper extremity HCPCS codes is necessary for this distinction. While some commenters recommended adding pressure level differentiations such as (20–30, 30–40, 40–50 mmHg) or compression class level (for example, Class 1, Class 2, Class 3) to the upper extremity codes, we believe the long-standing ''S'' codes that are being established as A codes provide a way to identify upper extremity gradient compression garments without further stratification by pressure level. Our review of the cost of these items also does not generally support a need to stratify by pressure level tiers. We will retain the medium and heavy weight terminology in the new sleeve and arm ''A'' codes from the predicate S8422, S8423, S8425 and S8426 codes. The new codes we are finalizing in Table FF–A 2 identify the new gradient compression garment codes we are adding for upper limb and non-limb areas of the body such as the neck and head and the genital regions. In addition to the new codes in Table FF–A 2, we are finalizing the addition of the following new A codes that align with the codes and descriptors of S8420 through S8428, as discussed previously, effective January 1, 2024:

- A—Gradient compression arm sleeve and glove combination, custom, each
- A—Gradient compression arm sleeve and glove combination, each
- A—Gradient compression arm sleeve, custom, medium weight, each
- A—Gradient compression arm sleeve, custom, heavy weight, each
- A—Gradient compression arm sleeve, each
- A—Gradient compression glove, custom, medium weight, each
- A—Gradient compression glove, custom, heavy weight, each
- A—Gradient compression glove, each
- A—Gradient compression gauntlet, each

Comment: Many commenters made suggestions on codes for mastectomy sleeves. Many commenters supported including mastectomy sleeves in the codes for compression sleeves and not creating separate mastectomy codes. Many commenters did not believe it was necessary to distinguish via separate coding patients with breast cancer from patients with other types of lymphedema. A commenter opposed the inclusion of mastectomy or other procedures in the new codes for lymphedema compression treatment items. Another commenter noted that all sleeves for mastectomy are the same as all compression garments used for lymphedema, so they did not see a need for separate codes. A few commenters suggested not using the L8010 HCPCS code for a compression sleeve. Several commenters suggested deleting code L8010.

Response: We appreciate the recommendations provided related to whether separate codes are needed for mastectomy sleeves and if items can be grouped together under the same codes used for other arm sleeves (S8422 thru S8424). After reviewing the comments, we agree that separate codes are not necessary to distinguish mastectomy sleeves from other arm compression sleeves used for lymphedema. We will also continue to consider what to do with regard to the status of existing code L8010 Breast prosthesis, mastectomy sleeve and may announce our views in advance of a future public meeting related to the HCPCS code set.

Comment: A few commenters supported new HCPCS codes for nighttime garments in general. A commenter supported coverage of a nighttime chipped foam compression garment for the body parts that are affected. A few commenters indicated the need for additional codes. A commenter indicated that there should be fewer HCPCS codes for nighttime garments. Another commenter recommended additional codes to reflect nighttime use of padded head/neck garments for lymphedema management. Concerning gradient compression wraps with adjustable straps, a commenter indicated the need for codes for gradient compression wraps for below knee and above knee and a code for a full-leg wrap. Another commenter indicated that gradient compression wraps with adjustable straps should include: foot wraps, calf wraps, knee wraps, thigh wraps, hand wraps, and arm wraps. A commenter indicated that additional HCPCS codes need to be established for wraps for different parts of the body. With respect to other comments related to garments or wraps with adjustable straps, a commenter indicated that the term ''with adjustable straps'' refers to both garments and wraps. The commenter indicated that it might be clearer to eliminate ''with adjustable straps,'' which would indicate coverage for wraps that are adjustable by straps or by other means.

Response: Thank you for your comments on the HCPCS codes for nighttime garments and gradient compression wraps with adjustable straps. We appreciate the support for our proposal to add the following nighttime garment codes and will be finalizing these codes for use effective January 1, 2024.

- A—Gradient compression garment, glove, padded for nighttime use, each
- A—Gradient compression garment, arm, padded for nighttime use, each
- A—Gradient compression, lower leg and foot, padded, for nighttime use, each
- A—Gradient compression garment, full leg and foot, padded, for nighttime use, each

Table FF–A 2 identifies the new nighttime garment HCPCS codes that we are adding to the HCPCS code set effective January 1, 2024, including a bra garment and custom versions of the glove, arm, lower leg and full leg and foot nighttime garments. Regarding gradient compression wrap coding, we proposed to use existing code A6545 to identify below knee gradient compression wraps with adjustable straps. As discussed in a prior response, to avoid confusion with repurposing the existing A6545 code used for surgical dressings, we will establish a new A code to describe below knee gradient pressure wraps with adjustable straps under the new lymphedema benefit for use effective January 1, 2024. We appreciate the commenters input on additional coding for other areas of the body and descriptor language. We

believe that including adjustable straps in the descriptor for gradient pressure wrap with adjustable straps is necessary to help identify the general type of wrap that supplies gradient pressure and are retaining this terminology. Table FF–A 2 includes the new codes we are adding for gradient pressure wraps with adjustable straps and includes wraps for above knee, full leg, and foot.

Comment: Many commenters provided comments on a range of issues related to HCPCS Codes for lymphedema compression items. A few commenters indicated that the number of proposed HCPCS codes was inadequate. Many expressed support for a range of new codes. A few supported a proposal for 229 new HCPCS codes that differentiate between textiles and technologies (circular knit, flat knit, inelastic adjustable wraps). A commenter supported development of a code for each individual component. A commenter indicated that limiting the number of HCPCS codes would not reflect the large variety of lymphedema compression treatment items. Commenters also provided suggestions on codes for bandaging systems. A commenter indicated a need for more codes than the existing S bandaging codes as lymphedema bandaging systems can include: short-stretch compression bandages, stockinette or tubular gauze sleeves, finger/toe bandages, rolled padding (synthetic or foam), adhesive tape, foam pads, chip pads; chip bags. A commenter recommended that HCPCS codes should be added for lymphedema compression bandaging kits for: a single upper limb; two upper limbs; a single lower limb; and two lower limbs. Some commenters supported new codes for bandages and recommended that the descriptors be based on the width and length. A commenter requested that CMS ensure these garments/bandaging/padding are properly identified via the HCPCS codes. Another commenter submitted a list of recommended new HCPCS codes for bandaging system components that were based on size. A commenter indicated that many of the longer and wider bandages specifically used on large lower extremity legs, hips and buttocks are too long or too wide for existing HCPCS code categories and need to correct the description or add a new code. A commenter cited concerns using the same codes as traditional bandaging materials will result in reimbursement that is too low.

Response: We thank the commenters for the detailed HCPCS recommendations for lymphedema compression treatment items. We have identified in the chart 57 HCPCS codes that we are finalizing for lymphedema compression treatment items and accessories, as discussed in the previous responses. We recognize that additional refinements to the code set may be necessary, thus we direct readers to the HCPCS Level II coding process, described at *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings,* which provides a means for modifying the HCPCS code set for lymphedema compression treatment items in the future. Regarding the commenter's request for 229 new HCPCS codes that differentiate between textiles and technologies (circular knit, flat knit, inelastic adjustable wraps), we do not currently see a Medicare program need to add codes at this level of specificity. If commenters continue to believe that coding for one textile vs. another (for example, circular knit vs. flat knit) would still be useful after January 1, 2024, we direct commenters to the HCPCS Level II coding process described previously. We appreciate the suggestions for HCPCS coding changes needed to describe the various compression bandaging systems used for the treatment of lymphedema. We agree with commenters that more codes are needed beyond existing codes S8430 (Padding for compression bandage, roll) and S8431 (Compression bandage, roll) to describe the bandaging systems.

Therefore, after careful review of the comments, we are establishing new HCPCS codes, effective January 1, 2024, to describe the following bandaging system components: upper and lower extremity bandage liners; high density foam rolls; long, medium and short stretch bandages; high density foam sheets and pads; low density channel and flat foam sheets; padded foam and textile; and tubular protective absorption layers with and without padding. These new codes will allow suppliers to separately identify the supplies that are being furnished to the patient as opposed to establishing bandaging kit HCPCS codes delineated by the extremity body type. The list of the new HCPCS bandaging codes and descriptors that we are adding to the HCPCS code set effective January 1, 2024 is available in Table FF–A 2. Similar to the disposition of the other existing S codes, we will retain bandaging codes S8430 and S8431 in the HCPCS code set for use by other payers. We are also establishing a new gradient compression bandaging supply not otherwise specified code, effective January 1, 2024, that will be available for use in identifying bandaging supplies that are not identified by a unique HCPCS code. Since this is a new benefit category, payment for lymphedema compression treatment items will be established in accordance with the requirements at section 1834(z) of the Act and will not be based on the surgical dressing payment requirements for traditional Medicare bandaging at 42 CFR 414.220.

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TABLE FF-A 2: FINAL NEW HCPCS CODES FOR LYMPHEDEMA COMPRESSION TREATMENT ITEMS

Code	Description
AXXXX	Gradient compression stocking, below knee, 18-30 mmhg, custom, each
AXXXX	Gradient compression stocking, below knee, 30-40 mmhg, each
AXXXX	Gradient compression stocking, below knee, 30-40 mmhg, custom, each
AXXXX	Gradient compression stocking, below knee, 40 mmhg or greater, each
AXXXX	Gradient compression stocking, below knee, 40 mmhg or greater, custom, each
AXXXX	Gradient compression stocking, thigh length, 18-30 mmhg, custom, each
AXXXX	Gradient compression stocking, thigh length, 30-40 mmhg, custom, each
AXXXX	Gradient compression stocking, thigh length, 40 mmhg or greater, custom, each
AXXXX	Gradient compression stocking, full length/chap style, 18-30 mmhg, custom, each
AXXXX	Gradient compression stocking, full length/chap style, 30-40 mmhg, custom, each
AXXXX	Gradient compression stocking, full length/chap style, 40 mmhg or greater, custom, each
AXXXX	Gradient compression stocking, waist length, 18-30 mmhg, custom, each
AXXXX	Gradient compression stocking, waist length, 30-40 mmhg, custom, each
AXXXX	Gradient compression stocking, waist length, 40 mmhg or greater, custom, each
AXXXX	Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg, each
AXXXX	Gradient compression wrap with adjustable straps, not otherwise specified
AXXXX	Gradient compression gauntlet, custom, each
AXXXX	Gradient compression garment, neck/head, each
AXXXX	Gradient compression garment, neck/head, custom, each
AXXXX	Gradient compression garment, torso and shoulder, each

Code	Description
AXXXX	Gradient compression garment, torso/shoulder, custom, each
AXXXX	Gradient compression garment, genital region, each
AXXXX	Gradient compression garment, genital region, custom, each
AXXXX	Gradient compression garment, glove, padded, for nighttime use, each
AXXXX	Gradient compression garment, glove, padded, for nighttime use, custom, each
AXXXX	Gradient compression garment, arm, padded, for nighttime use, each
AXXXX	Gradient compression garment, arm, padded, for nighttime use, custom, each
AXXXX	Gradient compression garment, lower leg and foot, padded, for nighttime use, each
AXXXX	Gradient compression garment, lower leg and foot, padded, for nighttime use, custom, each
AXXXX	Gradient compression garment, full leg and foot, padded, for nighttime use, each
AXXXX	Gradient compression garment, full leg and foot, padded, for nighttime use, custom, each
AXXXX	Gradient compression garment, bra, for nighttime use, each
AXXXX	Gradient compression garment, bra, for nighttime use, custom, each
AXXXX	Gradient compression garment, toe caps, each
AXXXX	Gradient compression garment, toe caps, custom, each
AXXXX	Gradient pressure wrap with adjustable straps, above knee, each
AXXXX	Gradient pressure wrap with adjustable straps, full leg, each
AXXXX	Gradient pressure wrap with adjustable straps, foot, each
AXXXX	Gradient pressure wrap with adjustable straps, arm, each
AXXXX	Gradient pressure wrap with adjustable straps, bra, each
AXXXX	Accessory for gradient compression garment or wrap with adjustable straps, not-otherwise specified
AXXXX	Gradient compression bandaging supply, bandage liner, lower extremity, any size or length, each
AXXXX	Gradient compression bandaging supply, bandage liner, upper extremity, any size or length, each
AXXXX	Gradient compression bandaging supply, conforming gauze, per linear yard, any width, each
AXXXX	Gradient compression bandage roll, elastic long stretch, per linear yard, any width, each
AXXXX	Gradient compression bandage roll, elastic medium stretch, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, high density foam roll for bandage, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, high density foam sheet, per 250 square centimeters, each
AXXXX	Gradient compression bandaging supply, high density foam pad, any size or shape, each
AXXXX	Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, low density channel foam sheet, per 250 square centimeters, each
AXXXX	Gradient compression bandaging supply, low density flat foam sheet, per 250 square centimeters, each
AXXXX	Gradient compression bandaging supply, padded foam, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, padded textile, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, tubular protective absorption layer, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, tubular protective absorption padded layer, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, not otherwise specified

Note: Table FF-A 2 does not include the 9 new A codes that align with the codes and descriptors of S8420 through S8428 discussed previously that we are finalizing effective January 1, 2024.

BILLING CODE 4120–01–C

5. Procedures for Making Benefit Category Determinations and Payment Determinations for New Lymphedema Compression Treatment Items

We proposed to implement the new Part B benefit for lymphedema compression treatment items and the initial set of HCPCS codes to identify these items for claims processing purposes, effective January 1, 2024. In the future, as new products come on the market and refinements are made to existing technology, there will be a need to determine whether these newer technology items are lymphedema compression treatment items covered under this new benefit and what changes to the HCPCS are needed to identify these items for claims processing purposes. There will also be a need to establish payment amounts for the newer items in accordance with the payment rules established as part of this rulemaking.

Currently, CMS uses the procedures at 42 CFR 414.114 to make benefit category determinations and payment determinations for new splints and casts, parenteral and enteral nutrition (PEN) items and services covered under the prosthetic device benefit, and intraocular lenses (IOLs) inserted in a physician's office covered under the prosthetic device benefit. CMS uses the same procedures at 42 CFR 414.240 to make benefit category determinations and payment determinations for new DME items and services, prosthetics and orthotics, surgical dressings, therapeutic shoes and inserts, and other prosthetic devices other than PEN items and services and IOLs inserted in a physician's office. These procedures involve the use of the HCPCS public meetings where consultation from the public is obtained on preliminary HCPCS coding determinations for new items and services. Public consultation is also obtained at these meetings on preliminary benefit category determinations and preliminary payment determinations for the new items and services. To ensure appropriate and timely consideration of future items that may qualify as lymphedema compression treatment items, we proposed to use these same procedures to make benefit category determinations and payment determinations for new lymphedema compression treatment items. Future

changes to the HCPCS codes established in section 2 of this rule for lymphedema compression treatment items would also be made using this public meeting process.

We proposed to use the same process described in § 414.240 to obtain public consultation on preliminary coding, benefit category, and payment determinations for new lymphedema compression treatment items. That is, when a request is received for a new HCPCS code or change to an existing HCPCS code(s) for a lymphedema compression treatment item, CMS would perform an analysis to determine if a new code or other coding change is warranted and if the item meets the definition of lymphedema compression treatment item at section 1861(mmm) of the Act. A preliminary payment determination would also be developed for items determined to be lymphedema compression treatment items and are implemented in April or October of each year. The preliminary determinations would be posted on CMS.gov approximately 2 weeks prior to a public meeting. As part of this coding and payment determination process, it may be necessary to combine or divide existing codes; in this situation, we proposed to follow the same process as outlined in 42 CFR 414.236. After consideration of public input on the preliminary determinations, CMS would post final HCPCS coding decisions, benefit category determinations, and payment determinations on CMS.gov, and then issue program instructions to implement the changes.

In addition to these proposals for initial payment determinations for lymphedema treatment items and the proposed process for addressing new lymphedema treatment items, as required by the Act, we also proposed to revise the DMEPOS regulations to include lymphedema treatment items in the competitive bidding process. We proposed changes to 42 CFR 414.402 to add lymphedema treatment items to the definition of ''items'' for competitive bidding, § 414.408 to include lymphedema treatment items in the list of items for which payment would be made on a lump sum purchase basis under the competitive bidding program in accordance with any frequency limitations established under proposed subpart Q in accordance with section 1834(z)(2) of the Act, and § 414.412 to add reference to the proposed subpart Q to the bid rules. The following is a summary of the comments we received and our responses.

We received approximately 14 comments from suppliers, manufacturers, professional, State and national trade associations, beneficiaries and their caregivers related to the proposal to use the same process for benefit category and payment determination for future lymphedema compression treatment items as for new DMEPOS items and the inclusion of lymphedema compression treatment items in the DMEPOS competitive bidding program mandated by section 1847(a) of the Act.

Comment: Commenters opposed the inclusion of lymphedema compression treatment items in the DMEPOS competitive bidding program due to concerns that competitive bidding could result in reduced access to these items for beneficiaries. Commenters supported the proposed use of the existing process for addressing benefit category and payment determinations for DMEPOS for benefit category and payment determinations for lymphedema compression treatment items in the future.

Response: Section 1847(a)(2)(D) of the Act mandates the inclusion of lymphedema compression treatment items in the DMEPOS competitive bidding program, and the proposed changes to the regulation were merely conforming changes to reflect this statutory requirement. We note however, that section 1847(a)(3) of the Act provides discretionary authority to exempt certain areas and items from the DMEPOS competitive bidding program, including rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service, and items and services for which the application of competitive acquisition is not likely to result in significant savings. In addition, section 1847(b)(2) of the Act mandates certain conditions that must be met before contracts can be awarded under the DMEPOS competitive bidding program. A contract may not be awarded to a supplier that does not meet applicable quality and financial standards and State licensure requirements. Contracts may not be awarded in a competitive bidding area unless access to a choice of multiple suppliers in the area is maintained and total amounts to be paid in the area are expected to be less than the total amounts that would otherwise be paid. Section 1847(a)(5) of the Act provides authority for and regulations at 42 CFR 414.420 establish a physician authorization process which requires contract suppliers to furnish specific brands of items the beneficiary's physician or treating practitioner prescribes to avoid an adverse medical outcome for the beneficiary. These requirements and additional terms for contract suppliers that ensure access to quality items and services under the program are spelled out in the regulations at 42 CFR 414.422. CMS closely monitors the DMEPOS competitive bidding program to ensure that all suppliers are in compliance with the terms of their contracts and access to quality items and services is maintained at all times.

We appreciate the comments in support of using the existing DMEPOS process for addressing benefit category and payment determinations for new lymphedema compression treatment items.

After consideration of the public comments, we are finalizing that future items that the public considers to be lymphedema compression items would be addressed by CMS pursuant to the same process as the benefit category and payment determination process for new DMEPOS items (including the HCPCS public meeting process) at 42 CFR 414.240, as proposed. We are also finalizing the conforming changes to 42 CFR 414.402, 42 CFR 414.408 and 42 CFR 414.412 to incorporate lymphedema compression treatment items in the competitive bidding program as proposed.

6. Enrollment, Quality Standards, and Accreditation Requirements for Suppliers of Lymphedema Compression Treatment Items and Medicare Claims Processing Contractors for These Items

Section 1834(a)(20) of the Act requires the establishment of quality standards for suppliers of DMEPOS that are applied by independent accreditation organizations. Section 4133(b)(1) of the CAA, 2023 amends section 1834(a)(20)(D) of the Act to apply these requirements to lymphedema compression treatment items as medical equipment and supplies.

Section 1834(j) of the Act requires that suppliers of medical equipment and supplies obtain and continue to periodically renew a supplier number in order to be allowed to submit claims and receive payment for furnishing DMEPOS items and services. The suppliers must meet certain supplier standards in order to possess a supplier number and are also subject to other requirements specified in section 1834(j) of the Act. Section 4133(b)(2) of the CAA, 2023 amends section 1834(j)(5)(E) of the Act to include lymphedema compression treatment items as medical equipment and supplies subject to the requirements of section 1834(j) of the Act.

Suppliers of DMEPOS meeting the requirements of sections 1834(a)(20) and 1834(j) of the Act, and related implementing regulations at 42 CFR 424.57 must enroll in Medicare or change their enrollment using the paper application Medicare Enrollment Application for DMEPOS Suppliers (CMS–855S) or through the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). For more information on supplier enrollment, go to: *https://www.cms.gov/medicare/provider-enrollment-and-certification/become-a-medicare-provider-or-supplier.*

Regulations at 42 CFR 421.210 establish regional contractors to process Medicare claims for DMEPOS items and services. These contractors are known as Durable Medical Equipment Medicare Administrative Contractors (DME MACs). We proposed to include lymphedema compression treatment items as DMEPOS items that fall within the general text of section 421.210(b)(7) for other items or services which are designated by CMS. Thus, claims for these items would be processed by the DME MACs.

Comment: Many commenters disagreed that fitting specialists like therapists should not have an undue burden of having to apply as a DMEPOS supplier and adhere to enrollment, quality standards and accreditation. A commenter agreed that all those who provide and fit garments should be accredited and should adhere to all quality standards.

Response: We appreciate all the comments in regard to Medicare enrollment, quality standards and accreditation. Section 1834(j)(5)(E) of the Act mandates that to receive Medicare payment for lymphedema items and services, suppliers must enroll in Medicare, receive a supplier number, and meet all of the same supplier standards as a DMEPOS supplier.

We are finalizing Medicare enrollment, quality standards, and accreditation requirements for suppliers of lymphedema compression treatment items as proposed.

7. Payment Basis and Frequency Limitations for Lymphedema Compression Treatment Items

Section 1834(z)(1) of the Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

Based on our research, Medicaid state plans generally classify and provide lymphedema compression treatment items in the same manner as other durable medical equipment and supplies for home health. While State Medicaid Director Letter #18–001 focuses on how states may demonstrate compliance with the restriction on claiming federal financial participation for ''excess'' durable medical equipment spending, it describes how Medicaid state plan payment for the broader category of such items (outside of a managed care contract) is usually made either through established fee schedules, a competitive bidding process of the state's design, or through a manual pricing methodology based on the invoice submitted with each claim.[200] For the purpose of this final rule, we took into account the average Medicaid fee schedule payment amounts across all states that have published fee schedule amounts for these items in developing, in part, an appropriate payment basis for lymphedema compression treatment items under Medicare. These fee schedule payment amounts will be finalized based on the average Medicaid fee schedules in effect at the time this rule is finalized.[201]

The VHA does not have established fee schedules for lymphedema compression treatment items, but rather follows a policy of paying for these items based on the reasonableness of vendor pricing. Based on our conversations with the VHA, we understand that for these items, vendor prices at or below acquisition cost plus 50 percent is typically considered reasonable, while Medicaid state plans typically pay for DMEPOS items that do not have fee schedule amounts at acquisition cost plus 20 to 30 percent. Given this difference in the allowed supplier margin, the amounts determined to be reasonable payment rates for these items by the VHA may be approximated by increasing the average Medicaid payment rate by 20 to 30 percent. While the VHA may not have fee schedule amounts for these items, the Department of Defense's TRICARE system maintains fee schedule amounts for lower-extremity lymphedema compression garments. These amounts are approximately equal to the average Medicaid fee schedule amount plus 20 percent. Therefore, we believe that the average Medicaid fee schedule amount plus 20 percent represents what other government payers such as the VHA and TRICARE consider an appropriate payment basis for these items and a slightly higher payment basis than the average payment rates established by Medicaid state plans that have fee schedule amounts for these items; we sought comments on this. We also conducted a search of internet prices for lymphedema compression treatment items and found these prices to be in line with the TRICARE fee schedule amounts and average Medicaid fee schedule amounts plus 20 percent. We believe that appropriate payment amounts for Medicare for lymphedema compression treatment items would be payment amounts that approximate the payment rates determined to be reasonable by other government payers such as TRICARE, State Medicaid agencies, and, as previously explained, estimates of the payment rates determined to be reasonable by the VHA based on 120 percent of the average Medicaid state plan rates. Because these rates are in line with internet retail prices, we have not closely examined non-government payers.

Having taken into account the payment amounts from the various sources, as previously described, as required by the Act, we proposed to set payment amounts for lymphedema compression treatment items using the following methodology. Where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we proposed to set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we proposed to set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we proposed to base payment amounts based on 100 percent of average internet retail prices for that item. We sought

[200] Available at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd18001.pdf.*

[201] At the time of writing, this would include fee schedule amounts from up to 38 state Medicaid plans.

comment on these payment methodologies and whether further adjustments are appropriate.

As previously noted, payment rates established by Medicaid, the VHA, and TRICARE for the supply of these items includes payment for fitting services and any other services necessary for furnishing the item, including training beneficiaries in the proper use of these items. The cost of these services is also reflected in the price suppliers would charge a beneficiary directly. For these reasons, we believe that our payment methodology will implicitly incorporate payment for these services. As noted earlier, taking measurements of affected body areas and other fitting services necessary for furnishing lymphedema compression treatment items are an integral part of furnishing the items and the suppliers receiving payment for furnishing lymphedema compression treatment items are responsible for ensuring that any necessary fitting services are provided as part of furnishing the items.

The following table presents a preliminary example of what payment amounts may be, based on the proposed methodology described, as previously detailed, and certain HCPCS codes that we proposed to be classified under the Medicare Part B benefit category for lymphedema treatment items. This table reflects the application of our methodology to the underlying data sources as they were available in early 2023.

TABLE FF-A 3: EXAMPLE PAYMENT AMOUNTS FOR LYMPHEDEMA COMPRESSION TREATMENT ITEMS

Code	Description	Example Payment Amount
A6530	Gradient compression stocking, below knee, 18-30 mmhg, each	$37.95
A6531	Gradient compression stocking, below knee, 30-40 mmhg, each	$54.92
A6532	Gradient compression stocking, below knee, 40 mmhg or greater, each	$73.49
A6533	Gradient compression stocking, thigh length, 18-30 mmhg, each	$50.24
A6534	Gradient compression stocking, thigh length, 30-40 mmhg, each	$60.32
A6535	Gradient compression stocking, thigh length, 40 mmhg or greater, each	$68.45
A6536	Gradient compression stocking, full length/chap style, 18-30 mmhg, each	$70.12
A6537	Gradient compression stocking, full length/chap style, 30-40 mmhg, each	$83.26
A6538	Gradient compression stocking, full length/chap style, 40 mmhg or greater, each	$97.81
A6539	Gradient compression stocking, waist length, 18-30 mmhg, each	$92.01
A6540	Gradient compression stocking, waist length, 30-40 mmhg, each	$110.04
A6541	Gradient compression stocking, waist length, 40 mmhg or greater, each	$128.85
Axxxx	Gradient compression arm sleeve and glove combination, custom, each	$369.90
Axxxx	Gradient compression arm sleeve and glove combination, each	$94.55
Axxxx	Gradient compression arm sleeve, custom, medium weight, each	$172.29
Axxxx	Gradient compression arm sleeve, custom, heavy weight, each	$177.98
Axxxx	Gradient compression arm sleeve, each	$58.10
Axxxx	Gradient compression glove, custom, medium weight, each	$283.50
Axxxx	Gradient compression glove, custom, heavy weight, each	$349.33
Axxxx	Gradient compression glove, each	$92.24
Axxxx	Gradient compression gauntlet, each	$42.85

Final payment amounts will be determined in accordance with the methodology as previously detailed based on the most recent data available in late 2023 and will most likely be higher than these example payment amounts. Beginning January 1, 2025, and annually thereafter, these final payment amounts will be updated by the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U) for the 12-month period ending June of the preceding year.

When new items are added to this benefit category, following the process outlined in section 3 of this section of this rule, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We proposed that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We received approximately 62 comments related to the proposed payment methodology: eight from organizations of providers, suppliers, or manufacturers; 15 from individual supply businesses or practices; and 39 from individual beneficiaries, caregivers, or providers. A summary of the major issues raised in these comments and our responses are as follows.

Comment: Several commenters, without specifically voicing concern or support for our proposed payment methodology, emphasized the need to balance payment amounts high enough to support beneficiary access and low enough to ensure that copays remain affordable to beneficiaries.

Response: We agree with these comments and believe that our proposed payment methodology meets

these goals. We share the commenters views that beneficiary copayments will affect access to the products and their health outcomes.

Comment: Some commenters expressed concern that the proposed payment amounts appeared low compared to what the commenters pay out of pocket for specific garments, and some of these commenters also requested limits to the copayment amount (either limited to a specific dollar amount or reduced to zero).

Response: Beneficiary copayment amounts under Medicare are determined by statute, and CMS did not propose to or intend to waive or modify beneficiary copayment amounts for lymphedema compression treatment items in the proposed rule. While we appreciate concerns regarding payment amounts for specific items, many of the items mentioned by commenters were custom garments for which we did not provide example pricing. We expect that custom garments will have payment amounts substantially higher than standard garments. For example, based on our payment methodology, the payment amount for a standard gradient compression arm sleeve would be approximately $58 while the payment amount for a custom gradient compression arm sleeve would be approximately $175. There will always be situations where specific items cost more or less than the Medicare payment amount but our methodology is sound because we believe that most items described by each code will be adequately covered by the payment amount established. As outlined in the DMEPOS Quality Standards, enrolled DME suppliers are required to provide all items as ordered by the prescribing provider.

Comment: Several commenters expressed concern that the proposed payment methodology would result in payment amounts that are below the supplier's cost for furnishing the items, with one noting specifically that average internet pricing may be skewed by large online retailers selling garments that may not be medical-grade garments. The commenters urged the adoption of a more ''real world'' method for payment determination, without offering specific suggestions for an alternate model.

Response: We thank the commenters for sharing this concern. Our methodology is designed to approximate what the VHA pays suppliers for veterans to have appropriate access to lymphedema treatment items, and we are not aware of any access concerns that veterans have experienced. We note that the use of internet retail pricing is a long-established method of determining commercial prices for use in the DME payment determination process. When collecting internet retail prices for use in any such averages, we only consider prices for items that meet the requirements for payment under each code in question. Specifically addressing the commenters' concern, we would exclude from consideration any items that are not medical-grade items, and for this reason we often must exclude retail listings from common consumer internet retailers. We continue to believe that prices from online suppliers of medical-grade products offer real-world examples of commercial pricing for use in the Medicare payment determination process when other payers, such as VHA or State Medicaid agencies, do not have established pricing histories.

Comment: A commenter disagreed with our proposed payment methodology, raising a number of specific concerns. These include concerns that many payers, including Medicaid state plans and TRICARE, have not consistently covered lymphedema compression garments and do not represent large shares of the market, and so these sources would not represent appropriate pricing information. The commenter expressed further concerns that Medicaid pricing may not be available for many proposed codes and may not be at a level sufficient to ensure appropriate patient access. The commenter stated that internet prices may not account for costs of compliance and claims filing faced by Medicare DMEPOS suppliers and that cash-pay transactions have reduced administrative burden, but that customers may face charges in addition to the item price upon check out (such as shipping and handling). The commenter proposed an alternate payment methodology based on the average manufacturer's Minimum Advertised Price (MAP) plus 20 percent, together with recommendations to simplify the calculation of payment amounts by using the average ratio of standard to custom garment prices and the ratio of prices for different compression levels of the same garment type. The commenter separately submitted to CMS confidential commercial MAP amounts to support our analysis of this proposed methodology. Other commenters expressed their support for this commenter's proposal.

Response: We appreciate the comment and the alternative pricing proposal. In developing our payment methodology, we have tried to set payment amounts at a level high enough to ensure beneficiary access, while low enough to ensure that copay amounts do not present a barrier for beneficiaries. As we expressed, we continue to believe that the most appropriate source for Medicare payment determination would be the prices paid by the Veteran's Health Administration (VHA). While the VHA does not publish national fee schedules for these items, we believe that our payment methodology is a good approximation of what the VHA would pay. We recognize that there are gaps in the available data among TRICARE, Medicaid, and other payors. We believe that internet retail prices continue to be the most appropriate source of commercial pricing to fill these gaps, as this has been a longstanding method of pricing used for Medicare DMEPOS items that has not hindered beneficiary access to DMEPOS items. We note that internet retailers often offer free shipping in order to compete with brick-and-mortar businesses. We agree that cash-pay transactions may be administratively simpler than billing insurance. However, suppliers and providers that accept insurance also enjoy a far higher volume; for this reason, it is common practice in healthcare for large insurers to receive a substantial discount off of the cash price, despite the additional administrative burden. We have carefully considered the proposed alternative payment methodology. Our analysis shows that across a representative sample of compression treatment garments, this alternative methodology would result in payment amounts approximately 35 percent higher than our imputed VHA [202] or TRICARE payment amounts. There is no evidence that beneficiaries of the VHA or TRICARE programs experience difficulty accessing compression treatment garments, so it would be difficult to justify the need for such a significantly higher payment amount—and commensurately higher beneficiary copay—for Medicare, potentially resulting in payment amounts that are too high, which, as noted previously, was a concern of other commenters.

Comment: A commenter recommended that decongestive therapy services and the associated supplies be covered by Part A/B MACs or Home Health Services as they believe there would be problems with implementing decongestive therapy services if they are covered by a non-DME MAC contractor while the DME MACs cover the associated supplies since providers and suppliers have up to one year to submit

[202] Imputation based on 120 percent of the average of up to 38 Medicaid state plan fee schedules as currently in effect.

the claim and DME MACs are unable to verify if decongestive therapies were covered to appropriately allow the related supplies.

Response: We are not finalizing our alternative proposal, but we appreciate the comments concerning the implementation problems that could arise with separate payment for the bandaging and fitting therapy services. As stated earlier, while compression bandaging systems are included in the lymphedema treatment items benefit category when applied during Phase 1 (acute or decongestive therapy) and/or Phase 2 (maintenance therapy), payment for decongestive therapy services would not be covered under this lymphedema treatment items benefit category, and so would not fall within the established remit of the Part B MACs.

Comment: A commenter requested that the payment amounts should be set by the individual DME MACs, or alternatively established as the manufacturer's MAP plus 50 percent.

Response: We are required by statute to establish payment amounts for these items. Contractor pricing is generally reserved for situations where we do not have adequate data to establish payment amounts for newly developed items or where codes represent such a disparate variety of items that a single payment amount would prove impractical (such as for ''not otherwise classified'' codes). Regarding the proposal to pay MAP plus 50 percent, as noted earlier, we have not seen evidence that beneficiaries experience difficulties accessing lymphedema treatment garments through the VHA or TRICARE at the payment amounts they set, so we do not believe there is good justification for Medicare to burden beneficiaries with the substantial higher copay implied by the commenter's proposed reimbursement methodology.

Comment: A commenter expressed broad support for the proposed payment methodology, but expressed concern that data may not be available to establish payment amounts for custom garments if it were necessary to use the fallback approach of internet retail pricing.

Response: We appreciate the comment and understand that many common internet suppliers do not offer custom garments or do not make pricing publicly available. However, we believe that a sufficient number of internet suppliers offer public pricing for custom garments to allow for accurate pricing of these items, if this approach were needed.

Comment: A few commenters proposed that, in place of average internet pricing, we use either MAP or average internet pricing plus 30 percent, in order to adequately compensate for suppliers' overhead costs, particularly those with bricks-and-mortar locations.

Response: As noted earlier, when collecting internet retail prices for use in any such averages, we only consider prices for items that meet the requirements for payment under each code in question. Furthermore, we exclude pricing that is not publicly displayed. For this reason, we believe that our methods capture an average internet price that is likely very close to the manufacturers' MAP.

Comment: Several commenters suggested using third party (commercial insurance) payment amounts, as these might avoid possible variation between payment amounts based on the other proposed methods.

Response: We thank the commenters for this suggestion. We believe that as a large government payer, our estimate of what the VHA, another large government payer, pays for these items is the best method for establishing an appropriate Medicare payment basis for these items. Furthermore, use of commercial insurance payment amounts poses a number of practical difficulties. Commercial insurance reimbursement amounts are not freely available, and procuring and processing the necessary data would have jeopardized our ability to meet the January 1, 2024, start date for this benefit.

Comment: A commenter noted support for the proposed annual adjustment of payment amounts based on the CPI–U.

Response: We appreciate this comment.

Comment: A commenter proposed that instead of adjusting based on the CPI–U, we base adjustment on the average change in online prices from year to year.

Response: We thank the commenter for this proposal, but we believe the CPI–U is an adequate approximation of the price changes these items will experience. While we acknowledge that in any given year this method may over- or under-adjust for price changes observed for specific lymphedema compression treatment items, we do not believe that the gains from an alternative methodology outweigh the costs of introducing a new method of annual adjustment to lymphedema payment amounts that differs from those applied to DMEPOS payment amounts.

Section 1834(z)(2) of the Act authorizes the establishment of frequency limitations for lymphedema compression treatment items and specifies that no payment may be made for lymphedema compression treatment items furnished other than at a frequency established in accordance with this provision of the Act. Gradient compression garments are designed differently depending on whether for daytime or nighttime use. Those meant for daytime provide a higher level of compression while those for nighttime offer milder compression and are less snug against the skin. We sought comment on our proposal to cover and make payment for two garments or wraps with adjustable straps for daytime use (one to wear while another is being washed), per affected extremity, or part of the body, to be replaced every 6 months or when the item is lost, stolen, or irreparably damaged, or if needed based on a change in the beneficiary's medical or physical condition such as an amputation, complicating injury or illness, or a significant change in body weight. In order to maintain mobility, patients may require separate garments or wraps above and below the joint of the affected extremity or part of the body. As discussed later in this section of this rule, nighttime garments are inelastic and more durable than the elastic daytime garments and we believe it would be appropriate to replace these garments once per year. We proposed to cover one nighttime garment per affected extremity or part of the body to be replaced once a year or when the garment is lost, stolen, or irreparably damaged, or if needed based on a change in the beneficiary's medical or physical condition such as an amputation, complicating injury or illness, or a significant change in body weight. Lymphedema is a chronic condition that can be stabilized if properly treated. It may also worsen as the result of infection, radiation and chemotherapy, or progression of comorbid conditions such as obesity. At this point, patients may require changes in their garment prescription. Such changes due to medical necessity will not be subject to the frequency limitations, as previously described. In addition, as with DMEPOS items, payment could be made for replacement of garments and other items when they are lost, stolen, or irreparably damaged. Examples of lost items include items left behind after evacuating due to a disaster like a hurricane or tornado. Examples of irreparably damaged items include items that burn in a fire, are exposed to toxic chemicals, or are damaged by some other event and does not include items that wear out over time.

Comment: Commenters expressed appreciation for the new Medicare benefit that covers lymphedema compression items. However, some

commenters suggested that Medicare provide coverage for more than two units of daytime garments or wraps and one nighttime garment or wrap as stated in the proposed rule. They explained that patients may have difficulty keeping up with the daily task of washing and drying compression treatment items, which may prevent them from effectively treating and managing their condition. Also, they stated that since some compression items take a day or more to dry completely, this would leave the patient without a compression item to wear on a daily basis. They also described hygiene concerns associated with the environment, such as sweating from heat in certain regions of the country, that warranted the need to wash garments more frequently.

Response: We appreciate the comments in response to our request for input on our proposal for the frequency limitations for lymphedema compression treatment items and are finalizing changes based on that input. We are making the changes based on the concerns of the commenters related to multiple reasons for needing adequate time to wash and dry compression treatment items, and to be responsive to the needs of Medicare beneficiaries. Specifically, Medicare will cover and pay for three daytime garments or wraps every six months and two nighttime garments or wraps every 2 years. Three units of daytime garments or wraps allows the patient to wear one, wash one, and dry one. Also, Medicare will cover two nighttime garments or wraps every 2 years, allowing the beneficiary to wear one, while a second garment washed during the day is allowed to completely dry and be ready for use the following night.

Comment: Many commenters appreciate and support the provision of the proposed regulation that provides Medicare coverage for compression garments and wraps when these items are lost, stolen, or irreparably damaged, or when there is a change in the patient's medical or physical condition. A commenter believes that the allowance for patients with respect to the number of sets of garments per year should allow for change in style, size, fit and other features to accommodate the patients' clinical progression, as a patient could experience rapid physical changes that require a change in size, style or materials of their compression garments.

Response: We thank the commenters for their support of the proposed rule. If an item is lost, stolen, or irreparably damaged, for example a garment is accidentally ripped by a sharp object, payment can be made for replacement of the garment(s) that has been lost, stolen, or irreparably damaged. Documentation explaining the circumstances of how the garment(s) was lost, stolen, or irreparably damaged should be maintained and may need to be furnished for Medicare claims processing and appeals purposes. If a patient's medical condition has changed enough to warrant the need for a new size or type of garment or wrap, payment can be made for three new daytime garments or wraps and/or two new nighttime garments. Replacement of both the daytime and nighttime garments used for the same area where lymphedema treatment is needed may be necessary in this situation. Documentation explaining the circumstances of the change in the patient's medical or physical condition and why new garments or wraps are needed should be maintained and may need to be furnished for Medicare claims processing and appeals purposes.

Comment: Some commenters support the replacement of compression garments and wraps sooner if the items wear out due to normal wear before the specified time stated in the proposed rule. Also, some commenters suggest that irreparably damaged items and worn items are the same.

Response: We do not agree. As explained in the proposed rule (88 FR 43776), irreparable damage does not include items that have worn out. Examples of irreparably damaged items include items that burn in a fire, are exposed to toxic chemicals, or are damaged by some other event and does not include items that wear out over time.

Comment: A few commenters stated that patients should not have to re-qualify each time they need to reorder supplies. A few commenters suggested careful consideration to cover all items a patient may need such as custom stockings or flat knit compression toe caps for the toes and foot and should be limited to only physical items and not services such as therapy, education or treatment. A few commenters indicated that the number and type of bandages covered should be determined by the treating therapist based on the body part, the severity of the lymphedema, and the patient's body shape and size. A commenter suggested the bandages and garments be separated into two categories and without a cap.

Response: Thank you for sharing your concerns regarding patients' access to lymphedema compression items. The lymphedema benefit includes Medicare coverage of items such as compression garments, wraps, stockings, gauntlets, bandaging and accessories. Once a patient has been furnished a lymphedema compression item, the patient is eligible to receive a replacement as stated in the frequency limitation section of the rule.

With regard to replacement frequencies for compression bandaging systems and supplies, the weekly frequency and overall length of phase one (active) treatment is dependent on the severity of lymphedema. Some patients may require treatment 4 to 5 days per week in phase one while others may only need treatment 2 to 3 days per week. Bandages are used following some form of hands-on decompression to maintain the reduction. Therefore, we did not propose specific replacement frequencies for the compression bandaging systems and supplies. We proposed that the DME MACs would make determinations regarding whether the quantities of compression bandaging supplies furnished and billed during phase one of treatment of the beneficiary's lymphedema are reasonable and necessary. As discussed in section VII.B.3 of this rule, commenters expressed concerns that coverage under the lymphedema benefit category for compression bandaging supplies or systems could continue during the various stages of lymphedema and we clarified that coverage is not limited to Phase 1 (acute or decongestive therapy) but is also available under Phase 2 (maintenance therapy). As a result of this clarification, we are making a conforming change to the regulation text at § 414.1680 to remove ''during phase one of decongestive therapy'' so that determinations regarding the quantity of compression bandaging supplies needed by each beneficiary would be made by the DME MACs regardless of the lymphedema stage.

8. Final Policies

We are finalizing the amendment of 42 CFR 410.36 to add paragraph (a)(4) for lymphedema compression treatment items as a new category of medical supplies, appliances, and devices covered and payable under Medicare Part B, including: standard and custom fitted gradient compression garments; gradient compression wraps with adjustable straps; compression bandaging systems; other items determined to be lymphedema compression treatment items under the process established under § 414.1670; and accessories such as zippers in garments, liners worn under garments or wraps with adjustable straps, and padding or fillers that are necessary for the effective use of a gradient

compression garment or wrap with adjustable straps. In order to maintain mobility, patients may require separate garments or wraps above and below the joint of the affected extremity or part of the body, and we are finalizing that payment may be made in these circumstances. We are finalizing that payment may be made for multiple garments used on different parts of the body when the multiple garments are determined to be reasonable and necessary for the treatment of lymphedema. For example, if it is determined that a beneficiary needs three daytime garments to cover one affected area for the treatment of lymphedema, Medicare would cover and pay for those three garments for that specific affected area, as well as any other areas of the body affected by lymphedema. For the purpose of establishing the scope of the benefit for these items, we are finalizing the following definitions by adding them to 42 CFR 410.2 as they apply to lymphedema compression treatment items:

Gradient compression means the ability to apply a higher level of compression or pressure to the distal (farther) end of the limb or body part affected by lymphedema with lower, decreasing compression or pressure at the proximal (closer) end of the limb or body part affected by lymphedema.

Custom fitted gradient compression garment means a garment that is uniquely sized and shaped to fit the exact dimensions of the affected extremity or part of the body of an individual to provide accurate gradient compression to treat lymphedema.

The definition of ''gradient compression'' would apply to all lymphedema compression treatment items (garments, wraps, etc.) that utilize gradient compression in treating lymphedema. The definition of ''custom fitted gradient compression garment'' would apply to custom fitted gradient compression garments covered under the new benefit category for lymphedema compression treatment items. We believe these definitions are necessary for establishing the scope of this new benefit.

Lymphedema compression treatment item means standard and custom fitted gradient compression garments and other items specified under § 410.36(a)(4) that are—

- Furnished on or after January 1, 2024, to an individual with a diagnosis of lymphedema for treatment of such condition;
- Primarily and customarily used to serve a medical purpose and for the treatment of lymphedema; and
- Prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Social Security Act) to the extent authorized under State law.

After consideration of the public comments received, we are finalizing § 414.1680 with the following modifications to the frequency limitations for lymphedema compression items established in accordance with section 1834(z)(2) of the Act under new subpart Q:

- Three daytime garments or wraps with adjustable straps for each affected limb or area of the body, replaced every 6 months.
- Two nighttime garments for each affected limb or area of the body, replaced once every 2 years.

We are finalizing coverage of replacements of garments or wraps that are lost, stolen, irreparably damaged. If a patient's medical condition has changed enough to warrant the need for a new size or type of garment or wrap, payment can be made for new garments or wraps. We are also finalizing that determinations regarding the quantity of compression bandaging supplies covered for each beneficiary will be made by the DME MAC that processes the claims for the supplies with a modification to remove proposed language referring to ''phase one of decongestive therapy.''

We are modifying and adding to the existing HCPCS codes for surgical dressings and lymphedema compression treatment items as explained in section VII.B.4. of this rule. Future changes to the HCPCS codes for these items based on external requests for changes to the HCPCS or internal CMS changes would be made through the HCPCS public meeting process described at: *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings.*

We are adding § 414.1670 under new subpart Q to use the same process described in § 414.240 to obtain public consultation on preliminary benefit category determinations and payment determinations for new lymphedema compression treatment items. The preliminary determinations will be posted on CMS.gov in advance of a public meeting. After consideration of public input on the preliminary determinations, CMS will post final HCPCS coding decisions, benefit category determinations, and payment determinations on CMS.gov, and then issue program instructions to implement the changes.

We are adding a new subpart Q under the regulations at 42 CFR part 414 titled, ''Payment for Lymphedema Compression Treatment Items'' to implement the provisions of section 1834(z) of the Act. We are adding § 414.1600 to our regulations explaining the purpose and definitions under the new subpart Q. We are adding § 414.1650 and paragraph (a) to establish the payment basis equal to 80 percent of the lesser of the actual charge for the item or the payment amounts established for the item under paragraph (b). Under § 414.1650(b) the payment amounts for lymphedema compression treatment items will be based on the average of state Medicaid fee schedule amounts plus 20 percent. Where Medicaid rates are not available, we will use the average of average internet retail prices and payment amounts established by TRICARE (or, where there is no TRICARE fee schedule rate, the average of internet retail prices alone). In accordance with § 414.1650(c), beginning January 1, 2025, and on January 1 of each subsequent year, the Medicare payment rates established for these items in accordance with section 1834(z)(1) of the Act and § 414.1650(b) would be increased by the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U) for the 12-month period ending June of the preceding year. For example, effective beginning January 1, 2025, the payment rates that were in effect on January 1, 2024 would be increased by the percentage change in the CPI–U from June 2023 to June 2024.

We are also adding § 414.1660 to address continuity of pricing when HCPCS codes for lymphedema compression treatment items are divided or combined. Similar to current regulations at 42 CFR 414.110 and 414.236, we are finalizing that when there is a single HCPCS code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the payment amounts that applied to the single code continue to apply to each of the items described by the new codes. When the HCPCS codes for several different items are combined into a single code, the payment amounts for the new code will be established using the average (arithmetic mean), weighted by allowed services, of the payment amounts for the formerly separate codes.

We are finalizing the revision to the regulations for competitive bidding under subpart F at 42 CFR 414 to include lymphedema compression treatment items under the competitive bidding program as mandated by section 1847(a)(2)(D) of the Act. We are

modifying the list of items that may be included in competitive bidding described in § 414.402 to include lymphedema treatment items and are revising § 414.408 to include lymphedema treatment items in the list of items for which payment would be made on a lump sum purchase basis under the competitive bidding program in accordance with any frequency limitations established under proposed subpart Q in accordance with section 1834(z)(2) of the Act. Finally, we are adding reference to the proposed subpart Q to the bid rules described at § 414.412.

The methodologies for adjusting DMEPOS payment amounts for items included in the DMEPOS Competitive Bidding Program (CBP) that are furnished in non-CBAs based on the payments determined under the DMEPOS CBP are set forth at § 414.210(g). Section 4133(a)(3) of the CAA, 2023 amended section 1847(a)(2) of the Act to include lymphedema compression treatment items under the DMEPOS CBP, and section 4133(a)(2) of the CAA, 2023 amended section 1834 of the Act to provide authority to adjust the payment amounts established for lymphedema compression treatment items in accordance with new subsection z based on the payments determined for these items under the DMEPOS CBP. We believe the methodologies for adjusting DMEPOS payment amounts at § 414.210(g) should also be used to adjust the payment amounts for lymphedema compression treatment items included in the DMEPOS CBP that are furnished in non-CBAs. We see no reason why different methodologies for adjusting payment amounts based on payments determined under the DMEOPS CBP would need to be established for lymphedema compression treatment items. We are therefore adding § 414.1690 to indicate that the payment amounts established under § 414.1650(b) for lymphedema compression treatment items may be adjusted using information on the payment determined for lymphedema compression treatment items as part of implementation of the DMEPOS CBP under subpart F using the methodologies set forth at § 414.210(g).

C. Definition of Brace

1. Background

The Social Security Act of 1965 (the Act) defines the scope of benefits available to eligible Medicare beneficiaries under Medicare Part B, the voluntary supplementary medical insurance program defined by section 1832 of the Act. Section 1832(a)(1) of the Act establishes the Medicare Part B benefit for ''medical and other health services.'' Section 1861(s) of the Act further defines ''medical and other health services'' to include under paragraph (9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes. Artificial legs, arms, and eyes are artificial replacements for missing legs, arms, and eyes and this rule does not address the scope of the Medicare benefit for these items. Section 1834(h)(4)(C) of the Act details the payment rules for particular items and services including specifying that ''the term 'orthotics and prosthetics' has the meaning given to such term in section 1861(s)(9).'' Regulations at 42 CFR 410.36(a)(3) include leg, arm, back, and neck braces under the list of medical supplies, appliances, and devices in the scope of items paid for under Part B of Medicare. However, the term ''brace'' is not defined in the Act or in regulation. Specifically, the term brace is not defined in 42 CFR 410.2 Definitions for supplementary medical insurance benefits for Medicare.

The Medicare program instruction that defines the term brace is located at CMS Pub. 100–02, Chapter 15, § 130 of the Medicare Benefit Policy Manual for Part B coverage of ''Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes.'' Within this instruction, braces are defined as ''rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.'' The Medicare definition of brace in program instructions dates back to the 1970s and was previously located in the Medicare Carriers Manual, HCFA Pub. 14, Part III, Chapter 2, § 2133. This longstanding definition of brace in our program instructions is used for the purpose of making benefit category determinations in accordance with the procedures located at 42 CFR 414.240 (86 FR 73911) regarding when a device constitutes or does not constitute a leg, arm, back, or neck brace for Medicare program purposes.

2. Current Issues

We believe that adding the definition of brace to the regulations at 42 CFR 410.2 is necessary for describing the scope of the Medicare Part B benefit for leg, arm, back, and neck braces. We believe that codifying the definition that is currently located in Medicare program instructions would continue the efficiency of the administration of the Medicare program by providing clarity and transparency regarding the scope of the benefit, for example, whether a specific device is a leg, arm, back, or neck brace as defined in section 1861(s)(9) of the Act, and consequently, payment determinations for such items. We also believe that adding the definition of brace to the regulations would support our benefit category determination process described in 42 CFR 414.240 (86 FR 73911).

The orthopedic industry has long established the attributes of a ''brace.'' We believe the definition of a brace in CMS Pub 100–02, Chapter 15, § 130 adequately captures the attributes of a brace. The words ''rigid'' and ''semi-rigid'' are used to describe the stiffness of a material. Rigid materials are used to eliminate motion but also to support underload. Components of a brace can use semi-rigid materials, which intentionally allow some amount of motion as compared to materials that completely immobilize a part of the body. Braces are typically prescribed to patients during the process of recovery and rehabilitation in order to stop limbs, joints, or specific body segments from moving for a pre-determined period. Braces may also be prescribed for ongoing medical problems that require restriction or limitation of joint movement; removal of weight or pressure from healing or injured joints, muscles, or body parts; or reduction of misalignment and function to reduce pain and facilitate improved mobility.[203] [204]

In order for a brace to properly function, it must utilize a three-point pressure system to provide angular control over anatomical joints.[205] [206] [207] A three-point pressure system places a single force at the area of the deformity, while two counter forces act in the opposing direction. This pressure system requires that a brace be rigid or

[203] Webster, J., Murphy, D., 2019, *Atlas of Orthoses and Assistive Devices,* 5th Edition, Elsevier, Philadelphia, PA. (Chapter 1) *https://www.sciencedirect.com/book/9780323483230/atlas-of-orthoses-and-assistive-devices.*

[204] CHAMPVA OPERATIONAL POLICY MANUAL: CHAPTER:2, SECTION: 17.4. *https://www.vha.cc.va.gov/system/templates/selfservice/va_ssnew/help/customer/locale/en-US/portal/554400000001036/content/554400000008979/021704-ORTHOTICS.*

[205] Webster, J., Murphy, D., 2019, *Atlas of Orthoses and Assistive Devices,* 5th Edition, Elsevier, Philadelphia, PA. (Chapter 18). *https://www.sciencedirect.com/book/9780323483230/atlas-of-orthoses-and-assistive-devices.*

[206] Chalmers, D.D., & Hamer, G.P. (1985). Three-point dynamic orthosis. *Prosthetics and Orthotics International, 9*(2), 115–116. *https://journals.sagepub.com/doi/pdf/10.3109/03093648509164718.https://journals.sagepub.com/doi/pdf/10.3109/03093648509164718.https://journals.sagepub.com/doi/pdf/10.3109/03093648509164718.https://journals.sagepub.com/doi/pdf/10.3109/03093648509164718.*

[207] Article—Spinal Orthoses: TLSO and LSO—Policy Article (A52500) (*cms.gov*).

semi-rigid in structure to apply sufficient relevant force to support, restrict, or eliminate motion of the joint or specific body part. The rigidity level of a brace is dependent on the body part and purpose for which the brace is used. For example, a fully rigid brace is used to eliminate motion and support underload. We believe the definition of brace in CMS Pub. 100–02, Chapter 15, § 130, and our proposed definition of brace, adequately captures the various attributes of a brace.

It is important to note that a rigid or semi-rigid device may look like a brace in that it has metal struts, joints, and cuffs that go over a limb, but may be used for purposes other than bracing the limb. We believe that devices used for purposes other than supporting a weak or deformed body member or restricting or eliminating motion of a diseased or injured part of the body do not fall within the definition of a brace in accordance with Pub 100–02, Chapter 15, § 130 Medicare Benefit Policy Manual, and would not fall within our proposed definition of brace. However, items that are not braces may meet the Medicare Part B definition for durable medical equipment (DME) at 42 CFR 414.202. For example, continuous passive motion devices are covered as DME in accordance with CMS Pub. 100–03, Chapter 1, Part 4, § 280.1 of the Medicare National Coverage Determinations Manual to rehabilitate the knee to increase range of motion following surgery. During continuous passive motion therapy, the joint area is secured to the device, which then moves the affected joint through a prescribed range of motion for an extended period of time. Continuous passive motion devices have metal struts, joints, and cuffs that go over a limb but are not used for the purpose of restricting or eliminating motion in a diseased or injured part of the body or to support a weak or deformed body member. While these devices do not meet the definition of a brace in accordance with Pub. 100–02, Chapter 15, § 130 of the Medicare Benefit Policy Manual, they are covered by Medicare as DME. Similarly, dynamic adjustable extension/flexion devices and static progressive stretch devices are used to stretch an arm or leg or other part of the body to treat contractures and increase range of motion. While these devices may look similar to a brace, they are used for the purpose of treating contractures and are not used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. As a result, dynamic adjustable extension/flexion devices and static progressive stretch devices do not fall under the definition of brace in accordance with CMS Pub. 100–02, Chapter 15, § 130, but are covered by Medicare as DME.

It is also important to note that although braces in the past have typically not included powered devices or devices with power features, technology has evolved to include newer technology devices with power features designed to assist with traditional bracing functions. For example, effective January 1, 2020, code L2006 was added to the HCPCS for a knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (for example, sensors, batteries, charger), any type of activation, with or without ankle joint(s), custom fabricated). CMS classified this device as a brace because it supports a weak or deformed knee by preventing it from buckling under the patient. This brace includes a microprocessor controlled hydraulic swing and stance control knee joint that restricts/affects knee joint kinematics during the swing and stance phases of the gait cycle. There are also powered brace exoskeleton devices that support a patient's weak arms or legs and have been classified as DME in the past. We determined that these devices should be classified as braces due to their use in stabilizing, positioning, supporting and restoring the function of a patient's weak limbs. In addition, upper extremity powered exoskeleton devices used by patients with chronic arm weakness such as from complications of stroke or other neurological/neuromuscular injury and illness to support and assist movement of weak arms were recently introduced to the market. HCPCS codes L8701 (Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated) and L8702 (Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated)) were added to the HCPCS effective January 1, 2019 to describe two categories of these items. These devices support the arm of the patient and allows them to use volitional, intact electromyographic signals in weak muscles to control the device through a normal range of motion. A lower extremity powered exoskeleton device that supports the weak legs of a patient with spinal cord injury (SCI) at levels T7 to L5 to enable the patient to perform ambulatory functions was also recently introduced to the market. Code K1007 (Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors)) was added to the HCPCS effective October 1, 2020 to describe this category of items. The device uses motion sensors with an exoskeleton frame and onboard computer system. Patients using all of the devices, as previously described, are better able to elongate and flex their limbs using the respective device, sometimes in a braced manner and sometimes in a controlled manner of motion, thus improving the functioning of the malformed body member and supporting the weak limbs. Additional information on the items, as previously discussed, can be found at: *www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-1–2022-non-drug-and-non-biological-items-and-services.pdf.*

One additional issue related to leg braces with shoes that are an integral part of the brace. Section 1862(a)(8) of the Act generally excludes orthopedic shoes or other supportive devices for the feet from coverage under the Medicare program. However, longstanding policy at CMS Pub. 100–02, Chapter 15, § 290 of the Medicare Benefit Policy Manual indicates that this exclusion does not apply to such a shoe if it is an integral part of a leg brace, and if that shoe or other supportive device for the feet is an integral part of a leg brace, then the cost of that shoe or device is included as part of the cost of the brace. We proposed to include this exception in the proposed definition of a brace at § 410.2.

We received approximately 55 comments from individuals, health care providers, medical technology manufacturers, patient and medical technology advocacy organizations, academic research institutions, and health care providers employed by the government agencies of the U.S. Department of Veterans Affairs and U.S. Department of Defense.

Comment: Many commenters supported finalizing the definition of brace at 42 CFR 410.2 to be consistent with section 130 of chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100–02) which indicates that a brace includes rigid or semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating

motion in a diseased or injured part of the body. Many commenters also agreed with our discussion in the CY 2024 HH PPS proposed rule (88 FR 43779) that adding the definition in regulations will improve the efficiency of the administration of the Medicare program when considering whether items meet the definition potentially providing faster claims processing and access to these new healthcare technologies for Medicare beneficiaries.

Response: We appreciate the commenters' support for the proposed definition of brace at 42 CFR 410.2.

Comment: A few commenters opposed the proposed definition for brace at 42 CFR 410.2, stating that including in regulations a definition for brace that is many years old will deter innovation in a dynamically changing area of medical technology. The commenters urged CMS to consider an alternative approach and obtain input from a broad range of stakeholders on a definition of brace that focuses on device functionality rather than the materials used in making the brace. The commenters stated material stiffness should not be the key indicator in defining a brace. The commenters explained that by emphasizing materials, the definition will box manufacturers into a corner and limit the use of new materials that would be used if the medical criteria were based on functionality and not rigidity and materials. In addition, rigid materials often add weight to the brace and affect comfort, with the effect that non-compliance with wearing the brace becomes an unintended consequence. The commenters noted manufacturers are trying to build a brace that uses lighter and breathable materials resulting in a brace that patients will wear. Also, the commenters stated with the advancements in materials science and nanotechnology, limiting the definition of brace to items that are rigid or semi-rigid will stifle innovation and adversely impact progress in patient treatment options and care.

Other commenters stated from a functional standpoint, braces are used to enhance the ability to effectively utilize affected upper and lower limbs to better perform activities of daily living. In contemporary practice, orthoses are externally applied devices used to support body segments or joints which are weakened, unstable or mal-aligned, for the purpose of enhancing function and individual independence. These commenters urged CMS to interpret the brace benefit through contemporary orthotic clinical practice when making coding, coverage and payment decisions in the future.

Response: We do not agree with these comments. The proposed definition focuses on the two key functions of a brace, which are to support a weak or deformed body member and restrict or eliminate motion in a diseased or injured part of the body. As discussed in the CY 2024 HH PPS proposed rule (88 FR 43654), the information we gathered during our review supported our proposal to amend regulations at 42 CFR 410.2 to add the definition of brace to be consistent with CMS's longstanding brace policy and information at section 130 of chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100– 02). This discussion explains why a device must be rigid or semi-rigid in order to be able to provide support or restrict or eliminate motion. Rigid refers to material used to eliminate motion but also to support underload. Components of a brace will use semi-rigid materials, which intentionally allow some amount of motion (restricted motion) as compared to materials that completely immobilize. We are not aware of evidence that elastic or non-rigid devices are capable of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. We can consider addressing in future rulemaking should evidence supporting the effectiveness of elastic or non-rigid devices in performing the functions of a brace become available.

Comment: Several commenters recommended to finalize the definition of brace in 42 CFR 410.2 to include the words ''including powered devices''. The commenters recommended the definition of brace should read as follows: Brace means a rigid or semi-rigid device, including powered devices, used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

Response: We thank the commenters for their recommendation, but we do not believe it is necessary to include the words ''including powered devices'' in the definition of brace. As we explained in our proposal in the CY 2024 HH PPS proposed rule (88 FR 43654), certain powered devices perform the key bracing functions of supporting weak or deformed body members and therefore are included in the proposed definition. Therefore, we recognize that a powered device can be included in the definition of a brace. Also, as discussed in the CY 2024 HH PPS proposed rule, new items including powered devices, will be considered for classification under the definition of brace using the processes outlined in regulations at 42 CFR 414.240. These processes require interested parties to submit an application for review of a new item including public consultation on proposed preliminary benefit category and payment determinations and then a final determination can be established on whether the new item meets the definition of brace in accordance with in 42 CFR 410.2.

We are finalizing our definition of brace and adding it to 42 CFR 410.2 as proposed, without modifications.

Comment: Multiple commenters supported the proposal to specify at § 410.36(a)(3)(i)(A) that a brace may include a shoe if it is an integral part of a leg brace and its expense is included as part of the cost of the brace. A commenter requested clarification regarding whether shoes that are integral to a brace are covered as part of the brace and can, in fact, be separately billed under distinct HCPCS L-codes for the shoes alone. The commenter requested clarification to remove any confusion as to the separate reimbursement for the shoes, themselves, that are deemed integral to the function of an orthoses.

Response: We appreciate the commenters' support for our proposal to specify at § 410.36(a)(3)(i)(A) that a brace may include a shoe if it is an integral part of a leg brace and its expense is included as part of the cost of the brace. HCPCS codes L3224 and L3225 are available to submit claims for shoes that are an integral part of a brace.

We are finalizing our proposal without modification to specify at § 410.36(a)(3)(i)(A) that a brace may include a shoe if it is an integral part of a leg brace and its expense is included as part of the cost of the brace.

In the CY 2024 HH PPS proposed rule (88 FR 43780), we noted three HCPCS codes were established to permit billing of the powered upper extremity devices and powered lower extremity exoskeleton devices. Two HCPCS codes were established effective October 1, 2019 which are: L8701 (Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated) and L8702 (Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated). One HCPCS code was established effective October 1, 2020 which is K1007 (Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints

any type, includes all components and accessories, motors, microprocessors, sensors). However, corresponding Medicare benefit category and Medicare payment determinations were not finalized for these HCPCS codes to permit more time for evaluation. We explained that as a result of the proposal to amend the regulations at 42 CFR 410.2 to add the definition of brace, if finalized, these codes would be classified under the definition of brace because they are used to support weak arms and legs. Also, we stated using the processes outlined in regulations at 42 CFR 414.240, we intend to obtain public consultation on the payment determinations for these codes at an upcoming HCPCS Level II public meeting. Additional information on these HCPCS codes can be found in the HCPCS Level II Final Coding, Benefit Category and Payment Determinations First Biannual (B1), 2022 HCPCS Coding Cycle at *www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-1–2022-non-drug-and-non-biological-items-and-services.pdf.* The agenda and dates for a public meeting will be available on the CMS HCPCS website: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.*

Comment: Many commenters supported classification of devices described by HCPCS codes K1007, L8701, and L8702 as braces. Multiple commenters described the use of a powered upper extremity device as supporting a patient when using the device thereby increasing the patient's ability to be more independent resulting in less burden on caretakers and improving participation in family, work, and community activities. Also, many commenters described the use of a powered exoskeleton device as supporting a patient to reduce lower-limb spasticity and contracture of the limbs. Commenters supported the use of powered exoskeleton devices stating improvements also occur for patients' circulation, mental health, and quality of life.

Response: We appreciate the commenters' support for classification of these devices as braces. We agree codifying the definition of brace and clarifying that newer powered devices described by these HCPCS codes will permit Medicare beneficiaries to access these newer technology braces and particularly help those with disabilities associated with muscular and/or neural (for example, spinal cord injuries) conditions.

Comment: Some commenters requested classification of HCPCS codes K1007, L8701, and L8702 under the Medicare brace benefit category effective as of the date that the final rule is published in order to expedite claims processing for items billed using these codes.

Response: We do not agree. These items will be classified as braces effective on the effective date of this final rule, not the publication date.

Comment: Some commenters requested expediting payment determinations for HCPCS codes K1007, L8701, and L8702, including developing and issuing preliminary payment determinations for consideration as part of the second biannual 2023 non-drug and nonbiological items and services HCPCS public meeting in late 2023 or the next subsequent non-drug and nonbiological items and services HCPCS public meeting.

Response: As discussed in the CY 2024 HH PPS proposed rule (88 FR 43654), rather than expedite payment determinations, we intend to use the processes outlined in regulations at 42 CFR 414.240 to obtain public consultation on the preliminary payment determinations for these codes at an upcoming HCPCS Level II public meeting. We recognize the importance of reviewing payment information efficiently on these items in order to establish the payment determinations for these items. We expect to issue a payment determination for consideration as part of the second biannual 2023 non-drug and nonbiological items and services HCPCS public meeting in late 2023 or in the next subsequent non-drug and nonbiological items and services HCPCS public meeting.

3. Final Regulations

We are finalizing our proposal without modification to amend the regulations at 42 CFR 410.2 to add the definition of brace to improve clarity and transparency regarding coverage and payment for the term brace as defined in section 1861(s)(9) of the Act. Also, we believe adding the definition in regulations will improve the efficiency of the administration of the Medicare program when considering whether a new device is a leg, arm, back, or neck brace for benefit category and payment determinations under our review procedures at § 414.240. In addition, we believe that adding the definition of a brace in regulation would expedite coverage and payment for newer technology and powered devices, potentially providing faster access to these new healthcare technologies for Medicare beneficiaries. Also, we are finalizing our proposal without modification to specify at § 410.36(a)(3)(i)(A) that a brace may include a shoe if it is an integral part of a leg brace and its expense is included as part of the cost of the brace.

D. Documentation Requirements for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Products Supplied as Refills to the Original Order

1. Background

Durable medical equipment (DME) is covered as a benefit category under Part B under medical or other health services as described in section1861(s)(6) of the Act and defined under section 1861(n) of the Act. We further defined DME in regulations at § 414.202 as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is not generally useful to a person in the absence of an illness or injury, is appropriate for use in the home, and effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years. Certain items of DME require supplies for effective use. Supplies include, but are not limited to, drugs and biologicals that must be put directly into the equipment to achieve the therapeutic benefit or to assure the proper functioning of the equipment. Examples include oxygen, tumor chemotherapy agents transfused via an infusion pump, or diabetic test strips used with a home glucose monitor.

Prosthetics and orthotics are defined under section 1861(s)(9) of the Act and include leg, arm, back, and neck braces and artificial legs, arms, and eyes—including replacements if required because of a change in the patient's physical condition. These items are referred to collectively as Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

DMEPOS items and supplies may be furnished on a recurring basis to beneficiaries with chronic or longer-term conditions. For such items, the practitioner may be able to forecast and prescribe, at the time of the beneficiary's initial need or during later clinical interaction, the ongoing medical need for DMEPOS items and/or supplies. In other words, the practitioner may be able to determine the beneficiary's expected, ongoing medical need both at the time of the interaction and as anticipated need for later dates of service. In such cases, the practitioner may write an order for immediate use and refills for later dates of service.

Section 1893(a) of the Act authorized the Secretary to promote the program integrity of the Medicare program by entering into contracts with eligible

entities to carry out activities specified in subsection (b) of such section. Section 1893(b)(1) of the Act, authorizes ''[r]eview of activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this title . . . including *medical and utilization review* [emphasis added] . . .''. In response to concerns related to auto-shipments and delivery of DMEPOS supplies that may no longer be needed or not needed at the same level of frequency/volume (for example, stockpiling), CMS instituted policies to require suppliers to contact the beneficiary prior to dispensing DMEPOS refills. In CY 2004, we updated our Medicare Program Integrity Manual to include timeframes related to refillable DMEPOS items.[208] This was done to ensure that the refilled item was necessary and to confirm any changes/modifications to the order. At that time, CMS stated that contact with the beneficiary or designee regarding refills should take place no sooner than 7 days prior to the delivery/shipping date. CMS further stated that subsequent deliveries of refills of DMEPOS products should occur no sooner than 5 days prior to the end of the usage for the current product. This change intended to allow for shipping of refills on ''approximately'' the 25th day of the month in the case of a month's supply, as later clarified and emphasized in preamble discussion in the CY 2005 Physician Fee Schedule final rule (69 FR 66235).

In 2011, due to stakeholder concerns related to burden, we amended the Medicare Program Integrity Manual to state that contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date, and that delivery of the DMEPOS product occur no sooner than 10 calendar days prior to the end of usage for the current product.[209] This is the current policy on DMEPOS refills as described in the Medicare Program Integrity Manual. [210]

We note that while the timeframes are applicable to all refillable items, they are most pertinent to the mail/delivery model because those beneficiaries could potentially be most at risk for receiving unnecessary or unsolicited items and supplies. For beneficiaries calling, texting, or otherwise contacting their pharmacy or retail store and picking up their refills, we note the decreased potential for providing supplies that may not be medically necessary or for which the beneficiary has sufficient supply. For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

Both delivery models are intended to allow for uninterrupted supply of the necessary item(s) and allow for the processing of claims for refills delivered/shipped prior to the beneficiary's complete exhaustion of their supply. We note that prior guidance related to this policy referred to this sort of permissible overlap as refills for items ''pending exhaustion''.

Despite the long-standing programmatic safeguards, compliance with refill procedures continues to cause concerns. As recently as 2019, the HHS Office of Inspector General (HHS OIG) did a national study demonstrating that suppliers did not maintain sufficient refill documentation. [211] In fact, one national DMEPOS supplier was recently revoked from the Medicare program due to billing for refills for beneficiaries that were deceased.[212]

Due to ongoing compliance concerns, and in efforts to promote transparency, we propose to codify our refill documentation requirements. At the same time, we are continuing our efforts to reduce administrative burden. We have worked to identify many obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness. We have also examined our longstanding policies and practices that are not codified in regulations but could be changed or streamlined to achieve better outcomes and reduce provider and supplier burden. Additionally, we are requesting comment on whether there are ways to reduce burden for certain beneficiary populations for future rulemaking.

Our refill policy has primarily been maintained in the Medicare Program Integrity Manual, Local Coverage Determinations, and related articles. We proposed to codify and update our refill policy to maintain program integrity controls while being mindful of supplier burden. We are finalizing the policy as proposed.

2. Provisions of the Regulation

a. Overview

At this time, we believe it is appropriate to codify policies related to refills of DMEPOS items; taking into consideration the need to balance program integrity concerns (for example, stockpiling) against supplier burden concerns. While we continue to believe it appropriate to confirm the medical need for the refill prior to disbursement, we have found that minor deviations in timing are not always reflective of medical need. Therefore, we proposed to strengthen our program integrity requirements to not only require beneficiary contact, but to specify that such contact must result in affirmative response from the beneficiary or designee. We proposed to eliminate the 14-day timeframe, for beneficiary contact, and to rather rely upon a single 30-day timeframe for contact and confirmation of the need for refill. That is, beneficiary contact and confirmation of need for the refill must occur within the 30-day period prior to the end of the current supply. We proposed to remove the term ''pending exhaustion'', which may be subject to interpretation, and instead use the phrase ''the expected end of the current supply.''

We note that documentation of the need for refill, as obtained from the Medicare beneficiary or designee, is not expected to require specific quantities remaining—but rather to simply confirm their need for the next refillable item. This clarification is expected to alleviate any associated burden with the beneficiary or their designee counting supplies. Suppliers contacting the beneficiaries to confirm their need for the refill, shall confirm both that the beneficiary is using the item and requires the refill, as evidenced by the supplier documentation of an affirmative need for the refill. We believe this type of generalized affirmation, in conjunction with our claims processing controls, will provide sufficient program integrity controls.

We proposed to codify our longstanding requirement that delivery of DMEPOS items (that is, date of service) be no sooner than 10 calendar days before the expected end of the current supply. We note that the shipping timeframes have been relied upon for approximately 20 years—to help both suppliers and Medicare Fee-

[208] Internet Only Manual 100–08, Program Integrity Manual (2004), available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R61PI.pdf.*

[209] Internet Only Manual 100–08, Program Integrity Manual (2011), available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R378PI.pdf*

[210] Internet Only Manual 100–08, Program Integrity Manual, Chapter 5, Section 5.2.6—Refills of DMEPOS Items Provided on a Recurring Basis (2022), available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c05.pdf.*

[211] Medicare Improperly Paid Suppliers an Estimated $92.5 Million for Inhalation Drugs, (October 2019), *https://oig.hhs.gov/oas/reports/region9/91803018.pdf.*

[212] Press Release: Mail-Order Diabetic Testing Supplier and Parent Company Agree to Pay $160 Million to Resolve Alleged False Claims to Medicare (August 2, 2021), available at: *https://www.justice.gov/opa/pr/mail-order-diabetic-testing-supplier-and-parent-company-agree-pay-160-million-resolve-alleged.*

for-Service contractors prevent overlapping billings and unnecessary refills. For example, contractors may use this timeframe to set up claims processing edits and alert suppliers when an item is being rendered/billed that was previously rendered and is not yet eligible for refill. We proposed that date of service may be defined as either the date of delivery of the DMEPOS item, or for items rendered via delivery or shipping service, the supplier may use the shipping date as the date of delivery. We proposed the shipping date may be defined as either the date the delivery/shipping service label is created or the date the item is retrieved for shipment by the mail carrier/delivering party; however, such dates should not demonstrate significant variation.

We believe the refill policy ensures that beneficiaries are participating in their health care to confirm they get the DMEPOS item(s) ordered and needed, which prevents individuals from receiving unnecessary supplies. It also protects the Trust Fund from the unnecessary provision of DMEPOS. We elongated the timeframe to 30-days and clarified that the beneficiary need not provide specific remaining quantities to comply. We believe this helps mitigate potential burden. However, we sought comments on if, due to beneficiary burdens, there are certain diagnosis/device combinations that a beneficiary should not need to confirm the need for a refill or confirm the need for refill with the same frequency. In other words, are there beneficiary populations for which we will not expect any fluctuations in the type or quantity of device, due to a permanent disability or health condition, for which the supplier verification of need will prove burdensome? Are there ways that Medicare could better balance the beneficiary burden of responding to supplier outreach (for example, text messaging, phone call to affirm need for recurring supply) when contrasted with the burden of receiving potentially unnecessary items (for example, co-insurance payments)? We will take these comments into consideration for potential future policy changes to our DMEPOS refill policies.

We received 15 comments for our review, as submitted from DMEPOS suppliers, DMEPOS industry groups, and providers treating beneficiaries through the use of DMEPOS. Of those submitted, 10 were responsive to our solicitation questions. The feedback we received is summarized in the following:

Comment: Commenters provided certain chronic conditions, in response to CMS solicitation for consideration for potential future rulemaking, ''. . . for which we would not expect any fluctuations in the type or quantity of device, due to a permanent disability or health condition, for which the supplier verification of need would prove burdensome'' (88 FR 43781). Specifically, commenters shared their belief that certain conditions, such as type I and type II diabetics, beneficiaries with obstructive sleep apnea, and those in need of permanent urinary or ostomy supplies, are the types of beneficiaries which may benefit from additional regulatory consideration. Commenters suggested that the identification of such items would benefit from contractor/stakeholder communications and public posting. Commenters suggested that such persons should not require beneficiary contact prior to refill and should be permitted to ''opt-in'' on an annual basis to authorize continual refills. Commenters suggested that suppliers could help control program integrity concerns by maintaining their responsibility for ensuring that supplies continue to be medically necessary and that there has been no interruption in medical need. Conversely, a commenter shared their concern that the creation of differing refill requirements, absent a universal electronic system, would prove confusing and difficult to effectuate.

Response: CMS thanks commenters for their thoughtful input. We will consider the beneficiary populations for which commenters would not expect any fluctuations in the type or quantity of supplies due to a permanent disability or health condition. We will look at the associated access and burden issues raised, in conjunction with program integrity concerns and the ability to operationalize programmatic instruction, for potential future rulemaking.

Comment: Commenters were generally supportive of our proposal to codify our existing refill requirements, with amendments. The proposed policy extends the timeframe for the supplier to contact the beneficiary and clarifies that such contact: (1) must affirm the need for refill; but (2) does not require beneficiaries to ''count'' their remaining supplies. Commenters were appreciative of our burden reduction efforts for both suppliers and beneficiaries.

Response: We thank commenters for their feedback. This rule finalizes the documentation requirements for DMEPOS products supplied as refills as proposed.

Comment: Commenters were supportive of our proposal to remove the phrase ''pending exhaustion'' and replace it with ''expected end of the current supply'' to ensure clarity.

Response: We appreciate the feedback. This rule finalizes the new terminology as proposed.

Comment: Commenters encouraged CMS to permit, or even require, suppliers to use multiple modes of communication to contact the beneficiaries, such as via phone, text message, or email. Several commenters noted that regardless of the type of communication a DME supplier uses, the DME supplier is still responsible for compliance with any applicable Medicare requirements—including the production of documentation upon request.

Response: We thank commenters for their feedback and clarify that we do not prescribe the mode of communication for contacting the beneficiary to affirm the need for refill. Suppliers are permitted to use any mode of communication so long as the beneficiary affirmation is received, and documentation of the contact is captured and can be provided upon request.

Comment: Commenters requested that suppliers be permitted to bill a single time for a 90-day supply of CGM sensors, as opposed to every 30 days.

Response: CGM billing is outside the scope of the proposed regulation. However, we will take the commenters feedback under advisement.

Comment: Some commenters suggested the adoption of electronic ordering or communication systems, as well as DMEPOS templates. A commenter suggested that CMS establish standards for DMEPOS electronic ordering systems.

Response: We thank commenters for their feedback for our consideration. We note that this is outside the scope of the proposed regulation.

Comment: A commenter suggested that the documentation to support the DMEPOS item supplied as a refill be signed off by the ordering provider. We understood the commenter's request to seek additional, more frequent practitioner verification, in addition to the initial order prescribing the item and refills.

Response: We thank the commenter for their feedback. At this time, we respectfully decline to adopt the suggestion. The suggestion does not align with current clinical practice, and we do not wish to impose additional burden on beneficiaries, providers, and suppliers.

Comment: Commenters suggested we minimize any conflict between Medicare and other payer's documentation requirements to support

DMEPOS products supplied as refills, such as those required of Medicaid and for beneficiaries in Medicare Advantage plans.

Response: While Medicaid and Medicare Advantage requirements are outside the scope of our proposed policy, we agree with reducing burden whenever possible.

Final Rule Action: We are finalizing the documentation requirements for DMEPOS products supplied as refills to the original order, as proposed.

b. Documentation to Support Refill

We proposed to revise § 410.38, paragraph (d), by adding paragraph (d)(4) which outlines the documentation needed to support refill requirements. In paragraph (d)(4)(i), we define refills, date of service, and shipping date for purposes of this section. In paragraph (d)(4)(ii), we proposed that documentation must include the following:

- Evidence of the beneficiary or their representative's affirmative response of the need for supplies, which should be obtained as close to the expected end of the current supply as possible; Contact and affirmative response shall be within 30 calendar days from the expected end of the current supply.
- For shipped items, the beneficiary name, date of contact, the item requested, and an affirmative response from the beneficiary, indicative of the need for refill, prior to dispensing the product.
- For items obtained in-person from a retail store, the delivery slip signed by the beneficiary or their representative or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

In paragraph (d)(4)(iii), we proposed the date of service for DMEPOS items provided on a recurring basis be no sooner than 10 calendar days prior to the expected end of the current supply.

VIII. Changes to the Provider and Supplier Enrollment Requirements

A. Background

1. Overview of Medicare Provider Enrollment

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable federal and state requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (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, 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 billing privileges after it was deactivated in accordance with § 424.540.
- Change of information—The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving the provider's or supplier's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider or supplier meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

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

2. Legal Authorities

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

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

B. Proposed Provisions

1. Provisional Period of Enhanced Oversight

a. Background

Section 1866(j)(3)(A) of the Act states that the Secretary shall establish procedures to provide for a provisional period of between 30 days and 1 year during which new providers and suppliers—as the Secretary determines appropriate, including categories of providers or suppliers—will be subject to enhanced oversight. (Per section 1866(j)(3)(A) of the Act, such oversight can include, but is not limited to, prepayment review and payment caps.) As authorized by section 1866(j)(3)(B) of the Act, CMS previously implemented such procedures through subregulatory guidance with respect to newly enrolling HHAs' requests for anticipated payments (RAP).[213] More recently, in July 2023 we began placing newly enrolling hospices located in Arizona,

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

California, Nevada, and Texas in a PPEO. (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 inquiries regarding (1) the scope of the term ''new'' HHA for purposes of applying a PPEO and (2) when the provisional period commenced. While section 1866(j)(3)(B) of the Act states that we may implement procedures by program instruction, we proposed in the July 10, 2023, proposed rule (88 FR 43654) to clarify these two issues.

First, we proposed in new § 424.527(a) to define 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 our proposed definition because they have historically and generally involved the effective establishment of a new provider or supplier for purposes of Medicare enrollment. We stated that CMS would rely on the codified version of this policy once it becomes effective.

Second, we proposed in § 424.527(b) that the effective date of the PPEO's commencement is the date on which the new provider or supplier submits its first claim (rather than, for example, the date the first service was performed or the effective date of the ownership change). A core reason for this proposal was that we found during the previously referenced HHA PPEO that certain affected HHAs refrained from billing after their placement in the PPEO to circumvent the enhanced oversight mechanism; then, once their PPEO lapsed, the HHA engaged in improper billing without the intended oversight. We believed that proposed § 424.527(b) would help stem this practice because the provider or supplier would be unable to avoid the PPEO by delaying billing until the PPEO's expiration, as was the case with the HHA PPEO.

Although we elected to address the issues in proposed § 424.527 via rulemaking, we noted in the proposed rule that we retained the authority under section 1866(j)(3)(B) of the Act to establish and implement PPEO procedures via sub-regulatory guidance.

b. Comments Received and Final Provisions

Comment: Several commenters supported our proposed PPEO clarifications in new § 424.527.

Response: We appreciate the commenters' support.

Comment: A commenter questioned: (1) how CMS determines the exact length of time within the PPEO's 30-day to 1-year period (for example, 6 months) that a particular provider or supplier remains under a PPEO; and (2) whether CMS uses any specific criteria in this determination. The commenter also suggested a maximum 60-day PPEO timeframe for providers and suppliers with a long history of accreditation; the commenter believed this would reduce the burden on affected providers and suppliers.

Response: While we appreciate these comments, they do not directly pertain to the topics covered in our PPEO proposals. Therefore, we respectfully believe they are outside the scope of this final rule.

Comment: A commenter expressed support for our previously mentioned hospice PPEO for Arizona, California, Nevada, and Texas.

Response: While we appreciate the commenter's support, we respectfully believe this comment is outside the scope of this final rule.

Comment: A commenter sought clarification on all of the following issues:

- Whether the determination as to which providers and suppliers are subject to a PPEO is based on the provider's or supplier's individual circumstances or on whether they meet the new definition of ''new provider or supplier''.
- Whether CMS or, instead, the MAC determines: (1) the providers and/or suppliers to which a PPEO will apply; (2) the length of a PPEO; and (3) whether a PPEO will include prepayment review.
- Whether providers and suppliers have appeal or administrative review rights regarding the application and specifics of a PPEO.
- The criteria that are used in determining the length and other components of a PPEO.

Response: Concerning the first issue, the PPEO applies to new providers and suppliers (as we proposed to define in § 424.527) in the provider or supplier category (for example, hospices in a certain geographic area) that the PPEO encompasses.

We respectfully believe the remaining three issues are outside the scope of this rule.

After reviewing the comments received, we are finalizing our PPEO proposals without modification.

2. Retroactive Provider Agreement Terminations

Under section 1866(a)(1) of the Act, all Medicare providers (as that term is defined in section 1866(e) of the Act) must enter into a provider agreement with the Secretary. Subparts A, B, and E of 42 CFR part 489 contain regulations concerning provider agreements. In accordance with § 489.52, a provider may voluntarily terminate its provider agreement and thus depart the Medicare program. In doing so, and under existing sub-regulatory policy, the provider may request a retroactive termination effective date (for example, retroactive to the date the provider's facility closed). To incorporate this practice into regulation, we proposed in new § 489.52(b)(4) that a provider may request a retroactive termination date, but only if no Medicare beneficiary received services from the facility on or after the requested termination date. This latter caveat would financially protect beneficiaries by helping to ensure that Medicare may still cover the services furnished to them near the end of the provider's operations.

Comment: Several commenters supported our proposed change.

Response: We appreciate the commenters' support.

After reviewing the comments received, we are finalizing new § 489.52(b)(4) without modification.

3. Hospice Screening Category

a. Categorical Risk Screening

Under the authority granted to us by section 6401(a) of the Affordable Care Act (which amended section 1866(j) to the Act), § 424.518 outlines levels of screening by which CMS and its MACs review initial applications, revalidation applications, applications to add a practice location, and applications to report any new owner. These screening categories and requirements are based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a

particular type of provider or supplier. In general, the higher the level of risk a certain provider or supplier type poses, the greater the level of scrutiny with which CMS will screen and review providers or suppliers within that category.

There are three levels of screening in § 424.518: high, moderate, and limited. Irrespective of which level a provider or supplier type falls within, the MAC performs the following screening functions upon receipt of an initial enrollment application, a revalidation application, an application to add a new location, or an application to report a new owner:

- Verifies that the provider or supplier meets all applicable federal regulations and state requirements for their provider or supplier type.
- Conducts state license verifications.
- Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Furthermore, for those at the high screening level, the MAC performs two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who have a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on these 5 percent or greater owners. These additional verification activities are meant to correspond to the heightened risk involved.

There currently are only five provider and supplier types that fall within the high categorical risk level under § 424.518(c)(1): newly/initially enrolling opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018 (hereafter collectively referenced as simply ''OTPs'' unless specified otherwise); newly/initially enrolling HHAs; newly/initially enrolling DMEPOS suppliers; newly/initially enrolling Medicare diabetes prevention program (MDPP) suppliers; and newly/initially enrolling skilled nursing facilities (SNFs).

Hospices are presently in the moderate-risk screening category under § 424.518. However, CMS in recent years has become increasingly concerned about program integrity issues within the hospice community, particularly (though not exclusively) potential and actual criminal behavior, fraud schemes, and improper billing. We outlined in the July 10, 2023, proposed rule numerous criminal and False Claims Act cases involving hospice owners and overseers that have arisen since our initial designation of hospices as moderate risk in 2011. A recent and especially disturbing case we referenced involved the sentencing in January 2022 of the CEO of a Texas hospice agency to over 13 years in prison after pleading guilty to conspiracy to commit Medicare and Medicaid fraud. The CEO admitted that he: (1) billed Medicare and Medicaid for hospice services that were not provided, not directed by a medical professional, or provided to patients who were ineligible for hospice care; and (2) used blank, pre-signed controlled substance prescriptions to prescribe potent drugs even though the CEO was not a medical professional.[214] The CEO's scheme involved other individuals, thirteen of whom (including physicians) also pled guilty to crimes such as conspiracy to commit health care fraud.[215] The Federal Bureau of Investigation special agent in charge stated: ''In addition to causing fraudulent billing for tens of millions of dollars, [the CEO] preyed upon patients and families that did not have a true understanding of [the company] and hospice services. The core of the company was rooted in deception, and the lack of physician oversight allowed [the defendant] to make medical decisions for his own financial benefit.'' [216]

We also noted in the proposed rule the OIG's July 2018 study titled ''Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity'' (OEI–02–16–00570). According to this report, Medicare in 2016 spent about $16.7 billion for hospice care for 1.4 million beneficiaries, an increase from $9.2 billion for less than 1 million beneficiaries in 2006; with this growth, the OIG stated that ''significant vulnerabilities'' have arisen, one of which involves improper activity.[217] The report noted that some such schemes involved: (1) paying recruiters to target beneficiaries who were ineligible for hospice services; and (2) physicians falsely certifying beneficiaries as terminally ill when they were not. The OIG cited several of the cases we outlined in the July 10, 2023, proposed rule as examples of this behavior.[218]

Given the foregoing, we believed that closer screening of hospice owners was necessary. Although not every case of hospice fraud involves or can be attributable to the hospice's owner, we noted that the owner can set the tone for the hospice's operations as a whole. If, accordingly, an owner has a criminal background involving fraud or patient abuse, this could lead to similar activity within the hospice. We also stated in the proposed rule that the increasing number of fraud cases warrants a revisiting of our original assignment of hospices to the moderate risk category. With our obligation to protect the Trust Funds and vulnerable Medicare beneficiaries, we believe more thorough scrutiny of hospice owners is required.

Therefore,we proposed to revise § 424.518 to move initially enrolling hospices and those submitting applications to report any new owner (as described in § 424.518's opening paragraph) into the ''high'' level of categorical screening; revalidating hospices would be subject to moderate risk-level screening. Requiring all hospice owners with 5 percent or greater direct or indirect ownership to submit fingerprints for a criminal background check would help us detect parties potentially posing a risk of fraud, waste, or abuse before it begins. Indeed, we have found our fingerprint-based criminal background checks to be of great assistance in detecting felonious behavior by the owners of high-risk providers and suppliers.

Under our proposal, initially enrolling hospices would be incorporated within revised paragraph (c)(1)(vi). The current language in paragraph (c)(1)(vi) would be included within new proposed paragraph (c)(1)(vii), to which would be added hospices disclosing a new owner.

b. Comments Received and Final Provisions

Comment: Several commenters supported our proposed elevation of hospices to the high-risk screening category.

Response: We appreciate the commenters' support.

After reviewing the comments received, we are finalizing our hospice high-risk screening proposal without modification.

[214] *https://www.justice.gov/usao-ndtx/pr/novus-hospice-ceo-sentenced-13-years-healthcare-fraud.*

[215] *https://www.justice.gov/usao-ndtx/pr/13-novus-healthcare-fraud-defendants-sentenced-combined-84-years-prison#:~:text=Bradley%20Harris%2C%20Novus%20CEO%2C%20pleaded,Dr.*

[216] Ibid.

[217] *https://oig.hhs.gov/oei/reports/oei-02-16-00570.pdf,* p. 1.

[218] Ibid.

4. 36-Month Rule for Changes in Majority Ownership—Hospices

a. Background

The general purpose of a state survey or accreditation review for any Medicare provider or supplier type subject thereto is to determine whether the provider or supplier is in compliance with its regulatorily prescribed conditions of participation or conditions of coverage (hereafter collectively referenced as CoPs). CoPs are federal requirements that a provider or supplier must meet to participate in the Medicare program, and they generally focus on health and safety protections.

Though it is a provider enrollment provision, § 424.550(b)(1) recognizes the importance of the HHA survey and accreditation processes (hereafter sometimes jointly referenced as the ''survey process''), which help confirm the HHA's compliance with the CoPs and the quality and safety requirements they entail. Section 424.550(b)(1) states that if an HHA undergoes a change in majority ownership (occasionally referenced as a ''CIMO'') by sale within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent CIMO, the provider agreement and Medicare billing privileges do not convey to the HHA's new owner. The prospective provider/owner of the HHA must instead: (1) enroll in Medicare as a new (initial) HHA; and (2) obtain a state survey or an accreditation from an approved accreditation organization. As defined in 42 CFR 424.502, a ''change in majority ownership'' occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA during the 36 months following the HHA's initial enrollment or most recent CIMO; this includes an acquisition of majority ownership through the cumulative effect of asset sales, stock transfers, consolidations, or mergers. Under § 424.550(b)(1), a 42 CFR 489.18-level change of ownership and/or 100 percent ownership transfer is not necessary to trigger this ''36-month rule.'' Only crossing the 50 percent ownership threshold is required.

Section 424.550(b)(1) was promulgated in 2009 and modified in 2010. There were two principal objectives behind its establishment.

First, there was a trend in the HHA community whereby an HHA applied for Medicare certification, underwent a survey, and became enrolled in Medicare, but then immediately sold the HHA without having seen a Medicare beneficiary or hired an employee. These brokers, in other words, enrolled in Medicare exclusively to sell the HHA rather than to provide services to beneficiaries. This practice enabled a purchaser of an HHA from the broker to enter Medicare with no survey, which, in turn, sometimes led that owner to soon sell the business to another party. The ''flipping'' or ''turn-key'' mechanism, in short, was used to circumvent the survey process.

Second, we were more broadly concerned about the lack of scrutiny of new owners as a whole, not merely in cases of flipping. If an HHA undergoes a change of ownership, CMS—at the current time—generally does not perform a survey pursuant thereto. Consequently, CMS has no sure way of knowing whether the HHA, under its new ownership and management, is in compliance with the HHA CoPs. Unless CMS can make this determination, there is a risk that the newly purchased HHA, without having been appropriately vetted, will bill for services when it is non-compliant with the CoPs.[219]

We previously outlined in this final rule our growing concerns about improper behavior within the hospice community. Yet, as we explained in the proposed rule and restate here, we are equally concerned about the quality of care furnished in some of these facilities. Indeed, we have seen an increase in the number of hospice changes of ownership (including the types of CIMOs described in 42 CFR 424.550(b)(1)) in recent years, and a number of these ownership changes have occurred within the applicable 36-month timeframe. In fact, some such changes have taken place within only a few months after enrollment or the previous CIMO, akin to what we saw with the ''flipping'' practice outlined in the CY 2010 HH PPS proposed and final rules; specifically, we have received reports that hospices are being sold quickly after enrollment or purchase so that the new owner can avoid any survey. This is because, as had been our concern with HHAs, hospice ownership changes generally do not result in a state survey or accreditation review.

Without knowing whether the facility under its new ownership and leadership is compliant with the hospice CoPs, we cannot determine whether the hospice will furnish proper care to its patients. Beneficiary lives can be endangered if the newly purchased hospice is not committed to furnishing quality services.

For all these reasons, we proposed to expand the scope of § 424.550(b)(1) to include hospice CIMOs within its purview. (We also proposed to expand the aforementioned definition of ''change in majority ownership'' in § 424.502 to include hospices.) We believed that our previously detailed concerns about hospices, such as fraud schemes, patient abuse, improper billing, and potential substandard care require the level of scrutiny that a survey can furnish.

We noted in the proposed rule that § 424.550(b)(2) contains four exceptions to the 36-month rule. Specifically, even if an HHA undergoes a CIMO, the requirement in § 424.550(b)(1) that the HHA enroll as a new HHA and undergo a survey or accreditation is inapplicable if one of the exceptions applies. (For example, § 424.550(b)(2)(iv) exempts an HHA from § 424.550(b)(1)'s requirements if the HHA's CIMO was due to the owner's death.) We promulgated these exceptions because the HHA community had expressed concerns that the 36-month rule could inhibit bona fide HHA ownership transactions; for example, prospective new owners may not wish to have to enroll as a new HHA and will therefore decline to purchase the entity. We believed that our exceptions struck a solid balance between the need for more scrutiny of new owners via the survey process while not inadvertently obstructing legitimate transactions involving legitimate parties. Thus, we deemed it appropriate to also apply these exceptions to hospices.

b. Comments Received and Final Provisions

Comment: Several commenters supported our proposal to expand § 424.550(b)(1) to include hospices.

Response: We appreciate the commenters' support.

Comment: While expressing support for our proposal, a commenter suggested that CMS strengthen it by requiring the hospice to maintain an active census during the 36-month period in question. The commenter believed this would help facilitate ongoing monitoring of the care the hospice furnishes.

Response: We appreciate this comment, will consider the suggestion in the future, and always welcome recommendations from concerned stakeholders regarding means of strengthening Medicare program integrity and improve patient care.

Comment: A commenter referenced existing § 424.550(b)(2)(i), which contains an exception to the 36-month rule if the provider submitted 2 consecutive years of full cost reports since initial enrollment or the last CIMO, whichever is later. (For purposes of this exception, low utilization or no utilization cost reports do not qualify as

[219] Ibid.

full cost reports.) The commenter asked whether: (1) a full cost report can cover a period of less than 12 months if the cost report is not low utilization or no utilization; and (2) if the provider receives less than $200,000 and files a full cost report instead of a low utilization cost report, that cost report is considered a full cost report under § 424.550(b)(2)(i).

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

After reviewing the comments received, we are finalizing our hospice 36-month rule proposal without modification.

5. Deactivation for 12-Months of Non-Billing

a. Background

Regulatory policies regarding the provider enrollment concept of deactivation are addressed in § 424.540. Deactivation means that the provider's or supplier's billing privileges are stopped but can be restored (or ''reactivated'') upon the submission of information required under § 424.540. A deactivated provider or supplier is not revoked from Medicare and remains enrolled. Per § 424.540(c), deactivation does not impact the provider's or supplier's existing provider or supplier agreement; the deactivated provider or supplier may also file a rebuttal to the action in accordance with § 424.546. Nonetheless, the provider's or supplier's ability to bill Medicare is halted pending its compliance with § 424.540's requirements for reactivation.

One of the grounds for deactivating a provider or supplier (outlined in § 424.540(a)(1)) is that the provider or supplier has not submitted any Medicare claims for 12 consecutive months. This provision is designed to help prevent, for instance: (1) questionable businesses from deliberately obtaining multiple numbers so they could keep one 'in reserve' [for future use] if their active billing number is revoked or subject to a payment suspension; and (2) fraudulent entities from obtaining information about discontinued providers or suppliers and then, for example, using the Medicare billing number of a deceased physician.[220]

In the July 10, 2023 proposed rule, we proposed to reduce the 12-month timeframe currently in § 424.540(a)(1) to 6 months. We noted that we have recently detected fraud schemes involving extended periods of non-billing. A common situation involves a provider that: (1) establishes multiple enrollments with multiple billing numbers; (2) abusively or inappropriately bills under one billing number; (3) receives an overpayment demand letter or becomes the subject of investigation; (4) voluntarily terminates the billing number in question; and then (5) begins to bill via another of its billing numbers that is dormant (for example, 6 consecutive months without billing) but nevertheless active, repeating the same improper conduct as before. The problem in this case is that we cannot deactivate the dormant billing number (hence rendering it unusable and inaccessible pending a reactivation) under § 424.540(a)(1) because the applicable 12-month period has not yet expired. We do not believe we can or should wait for a year to elapse before taking deactivation action against these providers and suppliers. To protect the Trust Funds against improper payments, we must be able to move more promptly to deactivate these ''spare'' billing numbers so the latter cannot be inappropriately used or accessed.

However, our concerns in the proposed rule were not limited to these fraud schemes. A lack of billing for an extended period can indicate that the provider or supplier has ceased operations without notifying CMS. Deactivating the number enables us to not only prevent it from being accessed by other parties but also confirm via the deactivation process whether the provider or supplier is in fact operational—specifically, whether the provider or supplier responds with a Form CMS–855 application to reactivate their enrollment. In other words, action under § 424.540(a)(1) helps protect the Medicare program by deactivating the number while verifying whether the provider or supplier remains in existence; if it does, and it subsequently submits a reactivation application, CMS can validate the data thereon to ensure the provider's or supplier's continued credentials and compliance with Medicare requirements. This protective process, we believe, should be available to us upon the expiration of a 6-month non-billing timeframe, for our earlier-referenced concerns exist whenever any extensive period of non-billing occurs. The sooner we can address these non-billing cases, the better we can protect the Trust Funds. For these reasons, we proposed to revise § 424.540(a)(1) to change the 12-month timeframe to 6 months.

We recognized in the proposed rule that certain lengthy periods of non-billing do not involve any improper provider activity. To illustrate, some providers must be enrolled in Medicare to enroll in another health care program; as the provider does not intend to bill Medicare but only the other program, an extended period of Medicare non-billing can result. While CMS retains the discretion, as it always has, to deactivate a provider or supplier if the contingency in § 424.540(a)(1) is triggered, providers and suppliers that are not typically deactivated for 12 months of non-billing should not assume they are more likely to be deactivated under our proposed change to 6 months.

b. Comments Received and Final Provisions

Comment: Several commenters supported our proposed reduction in § 424.540(a)(1) of the non-billing period from 12 months to 6 months. A commenter stated that the impact of the reduction on good-faith providers will be limited because they are very unlikely to go 6 months without billing Medicare.

Response: We appreciate the commenters' support.

Comment: A commenter did not believe § 424.540(a)(1)'s concept of deactivating providers for non-billing enhances program integrity; rather, it merely penalizes legitimate providers. Using HHAs as an example, the commenter explained that many state Medicaid programs require HHAs to be enrolled in Medicare in order to enroll in and bill Medicaid, even though the HHA does not intend to bill Medicare. This means the Medicare enrollment is often deactivated for 12 consecutive months of non-billing, which requires the HHA to reactivate its Medicare enrollment. The commenter believes: (1) this change unfairly burdens good-faith HHAs without reducing fraud; and (2) HHAs will be further burdened by our proposed reduction from 12 to 6 months. (These two concerns were shared by another commenter.) The commenter recommended that CMS, in lieu of deactivation, take other steps to confirm that the non-billing HHA is operational, such as confirming the HHA's licensure and ensuring that the HHA is actively billing Medicaid. In a similar vein, another commenter encouraged CMS to establish provisions that allow a provider or supplier to explain why it has not submitted claims to Medicare for an extended period before CMS deactivates the provider or supplier for non-billing.

Response: We appreciate these concerns and address them as follows:

First, we respectfully disagree that § 424.540(a)(1) does not strengthen program integrity. As we explained in

[220] Ibid. (68 FR 22072).

the proposed rule, deactivating dormant billing numbers helps prevent unscrupulous parties from: (1) improperly accessing and utilizing another provider's billing number to bill Medicare; and (2) utilizing a ''spare'' (though previously unused) billing number to effectively circumvent a CMS-imposed adverse action applied to the provider's principal billing number. This latter consideration is especially critical given, as previously mentioned, the increase in fraud schemes involving providers acquiring multiple billing numbers for such nefarious purposes.

Second, we acknowledged in the proposed and this final rule that some providers must enroll in Medicare (without intending to bill Medicare) as a prerequisite for enrolling in another federal program, such as Medicaid. Yet any deactivation of a provider's billing number is in no manner intended to burden the provider. It is to instead protect the provider and Medicare from the parties described previously that may seek to access the provider's unused billing number and inappropriately bill on the provider's behalf.

Third, we thank the commenters for their recommendations concerning alternative forms of verifying the active status of a non-billing Medicare provider, including affording the provider an opportunity to explain why it has not billed Medicare before deactivation occurs. However, the purposes of § 424.540(a)(1) go well beyond the need to confirm that the provider is operational and compliant with Medicare requirements. We have to ensure that inactive billing numbers cannot be utilized by parties intent on committing fraud and, principally for this reason, we cannot delay action pending the completion of, as the final commenter appears to recommend, a type of pre-deactivation appeals process. We must move as swiftly as possible to protect the Trust Funds from such parties.

After reviewing the comments received, we are finalizing our proposed change to § 424.540(a)(1) without modification.

6. Definition of ''Managing Employee''

a. Background

Consistent with sections 1124 and 1124A of the Act, providers and suppliers are required to report their managing employees via the applicable Medicare enrollment application to enroll in Medicare. We currently define a ''managing employee'' in § 424.502 as a ''general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier (either under contract or through some other arrangement), whether or not the individual is a W–2 employee of the provider or supplier.'' In a proposed rule published in the February 15, 2023 **Federal Register** titled ''Medicare and Medicaid Programs; Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities'' (88 FR 9820), we proposed to revise this definition under our proposed implementation via that rule of section 1124(c) of the Act. We specifically proposed that, for purposes of 42 CFR 424.516(g) and with respect to a SNF, a managing employee also includes a general manager, business manager, administrator, director, or consultant, who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility. As proposed, this SNF-exclusive definition would be in a new paragraph (2) of the managing employee definition in § 424.502; the existing version of the definition would be included within new paragraph (1).

We proposed to further revise this definition in the July 10, 2023 proposed rule. We noted that we have received questions from the hospice and SNF communities regarding whether hospice and SNF facility administrators and medical directors must be disclosed as managing employees on the enrollment application. It has been our experience in overseeing the Medicare provider enrollment process that such individuals indeed exercise managing control over the hospice or SNF. We have long required that they be reported as managing employees.

Accordingly, we proposed adding the following language immediately after (and in the same paragraph as) the current managing employee definition: ''For purposes of this definition, this includes, but is not limited to, a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director.'' We proposed that this change would be reflected in the first paragraph of the revised definition of this term as proposed in the February 15, 2023, proposed rule. That is, the revision described in this section VIII.B.6. of this rule would be added to the end of new paragraph (1) as the latter was proposed in the February 15, 2023 proposed rule.

We stressed that this clarification regarding hospice and SNF facility administrators and medical directors should not be construed as CMS' establishment of a minimum threshold for reporting managing employees of hospices, SNFs, or any other provider or supplier type. Put otherwise, simply because an individual has less managing control within a particular organization than a facility administrator or medical director does not mean that the person need not be disclosed. Any individual who meets the definition of managing employee in § 424.502 must be reported irrespective of the precise amount of managing control the person has. The exclusive purpose of our proposed elucidation was to address specific questions raised by hospices and SNFs concerning whether the individuals at issue must be reported. It was not meant to change existing reporting requirements regarding managing employees and who must be disclosed as such.

b. Comments Received and Final Provisions

Comment: Several commenters supported our proposed revision of the ''managing employee'' definition.

Response: We appreciate the commenters' support.

After reviewing the comments received, we are finalizing our change to this definition as proposed with one exception. Because the previously mentioned February 15, 2023, proposed rule has not been finalized, the revision to this definition we proposed in the July 10, 2023, proposed rule will be applied to the current definition of managing employee in § 424.502. Should our proposed revision to the managing employee definition in the February 15, 2023, be finalized, said revision will be applied to the managing employee definition we are finalizing in the present rule.

7. Previously Waived Fingerprinting of High-Risk Providers and Suppliers

a. Background

During the recent COVID–19 public health emergency (PHE), CMS temporarily waived the requirement for fingerprint-based criminal background checks (FBCBCs) for 5 percent or greater owners of newly enrolling providers and suppliers falling within the high-risk screening category in § 424.518(c). The principal purpose was to facilitate beneficiary access to services by potentially increasing the number of health care providers and suppliers. Given the scope of the emergency, we believed this had to take priority. Nevertheless, we remained concerned during the waiver period about the lack of FBCBCs being performed, since we believe FBCBCs are the surest means of

detecting felonious behavior by the owners of high-risk providers and suppliers. With this in mind, we noted our desire in the July 10, 2023, proposed rule to perform FBCBCs for high-risk providers and suppliers that initially enrolled during the PHE upon their revalidation once the PHE ends. Yet we explained that this was not possible under our existing regulations because the revalidation applications will only be screened at the moderate-risk level. To remedy this, we proposed to add new § 424.518(c)(1)(viii) that would incorporate within the high-screening category revalidating DMEPOS suppliers, HHAs, OTPs, MDPPs, and SNFs for which CMS waived the FBCBC requirement when they initially enrolled in Medicare. However, considering the potential for future emergencies for which CMS might waive FBCBCs under applicable legal authority (such as that for the PHE), we more specifically proposed in new § 424.518(c)(1)(viii) that this high-risk category (which would include hospices with respect to future waivers) would apply to situations where CMS waived FBCBCs, in accordance with applicable legal authority, due to a national, state, or local emergency declared under existing law. We emphasized that our proposal would not obligate CMS to waive the FBCBC requirement in any such emergency.

Along with adding new § 424.518(c)(1)(viii), we proposed to delete current § 424.518(b)(1)(iv), (ix), (x), (xi), (xiii), and (xiv), which individually identify the six previously discussed provider and supplier types (including hospices) as moderate-risk if they are revalidating their enrollment. We would redesignate existing paragraphs (b)(1)(v) through (b)(1)(viii) as revised paragraphs (b)(1)(iv) through (b)(1)(vii). We would also redesignate existing paragraph (b)(1)(xii) as revised (b)(1)(viii), with the former paragraph being deleted.

Revised paragraph (b)(1)(viii) would include both prospective and revalidating OTPs that have been fully and continuously certified by SAMHSA since October 23, 2018. Furthermore, we would establish a revised paragraph (b)(1)(ix) that would include within the moderate-risk category revalidating DMEPOS suppliers, HHAs, OTPs, MDPPs, SNFs, and hospices that underwent FBCBCs: (1) when they initially enrolled in Medicare; or (2) upon revalidation after CMS waived the FBCBC requirement (under the circumstances described in paragraph (c)(1)(viii)) when the provider or supplier initially enrolled in Medicare.

We noted in the proposed rule that CMS under § 424.515(d) can perform off-cycle revalidations; that is, we can revalidate a provider or supplier at any time and need not wait until the arrival of their applicable periodic revalidation cycle. We emphasized that if our proposals regarding fingerprinting waivers were finalized, CMS would reserve the right to conduct off-cycle revalidations of the waived high-risk providers and suppliers.

b. Comments Received and Final Provisions

Comment: Several commenters supported our proposed revisions regarding the fingerprinting of previously waived providers and suppliers in the ''high'' screening category.

Response: We appreciate the commenters' support.

After reviewing the comments received, we are finalizing our proposed changes without modification.

8. Expansion of Reapplication Bar

Section 424.530(f) permits CMS to prohibit a prospective provider or supplier from enrolling in Medicare for up to 3 years if its enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to enroll. The purpose of § 424.530(f) is to prevent dishonest providers and suppliers from submitting false information on their initial application and, after being denied enrollment on this ground under § 424.530(a)(4), simply submitting a new application with correct data.

The existing maximum length of a reapplication bar under § 424.530(f) is 3 years. In the proposed rule, we proposed to expand this to 10 years to account for provider or supplier conduct of particular severity. We explained that we must be able to prevent such problematic parties from repeatedly submitting applications over many years with the goal of somehow getting into the program.

Comment: Several commenters supported our proposed reapplication bar expansion.

Response: We appreciate the commenters' support.

Comment: Although supportive of our proposed change, a commenter expressed concern that a 10-year reapplication bar would be imposed against honest providers and suppliers that inadvertently submitted incorrect information.

Response: We note two things. First, a 10-year reapplication bar would only be used when an analysis using the factors described in § 424.530(f)(2) indicates that it is warranted. Second, we do not apply § 424.530(f) and an associated reapplication bar as a matter of course. Only after a very careful review of the facts and circumstances of the case in question would CMS take this step.

After reviewing the comments received, we are finalizing our reapplication bar proposal without modification.

9. Ordering, Referring, Certifying, and Prescribing Restrictions

a. Background

We discussed previously: (1) the need to increase the maximum reapplication bar to keep dishonest providers and suppliers out of Medicare for longer than 3 years; and (2) our concerns about felonious provider and supplier activity. We believe such provider and supplier behavior should result in restrictions regarding the ordering, referring, certifying, or prescribing of Medicare services, items, and drugs, too. Indeed, such ordering, referring, certifying, or prescribing can involve improper conduct that is as harmful to Medicare beneficiaries as the actual furnishing of services; this includes, for example, the over-prescribing of opioids and the unnecessary ordering of potentially dangerous tests. Consequently, and using our general rulemaking authority under sections 1102 and 1871 of the Act, in the proposed rule we proposed the following two provisions.

First, we proposed to add a new paragraph (3) to § 424.530(f) stating that a provider or supplier that is currently subject to a reapplication bar under paragraph (f) may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs. To enforce this policy, we further proposed in new § 424.530(f)(3) that Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a provider or supplier that is currently under a reapplication bar.

Second, we proposed in paragraph (a) of new § 424.542 that a physician or other eligible professional (regardless of whether he or she is or was enrolled in Medicare) who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs. Akin to § 424.530(f)(3), we proposed in new § 424.542(b) that Medicare does not pay for any otherwise

covered service, item, or drug that is ordered, referred, certified, or prescribed by a physician or other eligible professional (as that term is defined in section 1848(k)(3)(B) of the Act) who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

We stated in the proposed rule that these provisions would apply regardless of whether the provider or supplier has opted-out of Medicare. This is because the conduct associated with a reapplication bar and a felony conviction presents risks irrespective of the provider's or supplier's opt-out status.

b. Comments Received and Final Provisions

Comment: Several commenters supported our proposals regarding prohibitions against ordering, referring, certifying, and prescribing.

Response: We appreciate the commenters' support.

Comment: A commenter stated that in potentially applying proposed § 424.542, CMS should: (1) use a consistent, defined list of felony convictions that CMS has deemed detrimental to Medicare; or (2) defer to the states' professional licensure boards for convictions that would bar an individual from practicing medicine. The commenter believed this would reduce subjectivity in CMS' determinations.

Response: We list certain federal and state felony convictions in 42 CFR 424.530(a)(3) and 424.535(a)(3) for which CMS may, respectively, deny or revoke a provider's or supplier's enrollment under those two provisions. Yet this list is not exhaustive because of the hundreds of additional and more specific types of felonies under federal and state law of which individuals can be convicted. Hence, we must retain our flexibility to consider each felony case on its own facts and circumstances rather than restrict ourselves to a small list of felony offenses. Insofar as the commenter's second suggestion, CMS is ultimately responsible for overseeing the Medicare program and protecting its beneficiaries and the Trust Funds.

After reviewing the comments received, we are finalizing new § 424.542 without modification.

10. Miscellaneous Comments

We also received the following miscellaneous comments.

Comment: A commenter expressed support for CMS' proposed revision to the Form CMS–855A (Medicare Enrollment Application—Institutional Providers; OMB Control No.: 0938–0685) to require providers and suppliers completing that application to disclose whether any of their owning or managing organizations are private equity companies or real estate investment trusts.[221]

Response: While we appreciate the commenter's support, we believe this comment is outside the scope of this final rule.

Comment: A commenter referenced our February 15, 2023, proposed rule that would require Medicare and Medicaid nursing homes to report the data outlined in section 1124(c) of the Act regarding their owners, operators, and associated parties. The commenter recommended that CMS apply the policies in the February 15, 2023, proposed rule to hospices. This could include, for example, requiring hospices to disclose similar data, auditing this data for accuracy (to which the hospice should attest), and analyzing hospice ownership trends to ascertain correlations to the quality of hospice patient care. Other hospice program integrity suggestions the commenter raised included: (1) imposing a temporary moratorium on the enrollment of new hospices in areas where there is an overabundance of hospices compared to established needs; (2) greater frequency of state surveys of high-risk hospices; (3) tighter restrictions on non-operational hospices; and (4) a greater CMS focus on the quality of hospice services and program integrity and less on innocuous technical errors, which the commenter stated risks alienating high-performing hospices.

Response: We appreciate these recommendations and share the commenter's concerns regarding hospice program integrity and quality of care. We will continue to closely monitor the hospice sector, as well as the progress of our new hospice provisions once implemented, and may, as needed, consider additional measures as the commenter suggests.

Comment: A commenter believed that our proposals merely add administrative burden without truly addressing program integrity. The commenter recommended a more targeted approach and for CMS to reconsider its proposals.

Response: We respectfully disagree with the commenter. In both the proposed rule and this final rule, we outlined the reasons for each of our proposals and how they will strengthen program integrity. To illustrate, in our discussion of the 36-month rule, we explained that requiring hospices under new majority ownership to undergo a state survey and enroll as new applicant will help ensure that the hospice is compliant with the CoPs and all enrollment requirements. Moreover, we believe that our provisions are targeted to address specific problems in a manner that will not unduly burden the provider community at large. Consider the following examples:

- Our ''high'' screening level proposals were restricted to: (1) initially enrolling hospices and those submitting applications to report any new owner; and (2) those high-risk providers and suppliers that were previously waived from fingerprinting. We did not, for instance, propose to move all provider and supplier types currently in the ''moderate'' screening category—such as community mental health centers, ambulance suppliers, and independent diagnostic testing facilities—into the ''high'' screening category.
- We limited our expansion of the 36-month rule to hospices. No other provider or supplier type is affected by this change.
- We believe that the regulations at § 424.542 that pertain to ordering, referring, certifying, and prescribing restrictions would only apply to the very limited number of persons and entities: (1) subject to a reapplication bar; or (2) that have committed a felony that CMS deems detrimental to the best interests of Medicare and its beneficiaries.

In short, we are confident that our provisions strike a proper equilibrium between the need to address certain payment safeguard issues with the need to avoid, to the maximum extent possible, overly burdening the many legitimate Medicare providers and suppliers. This has always been, and always will be, a fundamental aim of our provider enrollment rulemaking efforts.

IX. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

[221] 87 FR 76626

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Information Collection Requirements (ICRs)

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

1. ICRs for HH QRP

As discussed in section III. of this final rule, we are finalizing our proposal that HHAs will collect data for one new quality measure, the Discharge Function Score (DC Function) measure, beginning with assessments completed on April 1, 2024 used for public reporting. However, the DC Function measure utilizes data items that HHAs already report to CMS for quality reporting purposes, and therefore, the burden is accounted for in the PRA package approved under OMB control number 0938–1279 (expiration November 30, 2025).

As discussed in section III.C.2. of this final rule, we proposed to remove a measure from the HH QRP, the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Application of Functional Assessment/Care Plan) measure, beginning with admission assessments completed on January 1, 2025. We also proposed to remove OASIS items for Self-Care Discharge Goals (that is, GG0130, Column 2) and Mobility Discharge Goals (that is, GG0170, Column 2) at the start of care and resumption of care timepoints with the next release of the OASIS in 2025. This amounts to a net reduction in 2 data elements. We assumed that each data element requires 0.3 minutes of clinician time to complete. Therefore, we estimated that there will be a reduction in clinician burden per OASIS assessment of 0.3 minutes at start of care and 0.3 minutes at resumption of care.

As stated in section III.C.3. of this final rule, we will adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure beginning with the CY 2025 HH QRP. This proposed assessment-based quality measure will be collected using the OASIS. The OASIS–E is currently approved under OMB control number 0938–1279 (CMS–10387). One data element will need to be added to the OASIS at the transfer of care, death at home, and discharge time points in order to allow for the collection of the Patient/Resident COVID–19 Vaccine measure. We assume this will result in an increase 0.3 minutes of clinician staff time at the transfer of care, death at home, and discharge time points starting with the CY 2025 HH QRP.

As stated in section III.E.3. of this final rule, will remove the M0110—Episode Timing and M2200—Therapy Need OASIS items, effective January 1, 2025. These items are no longer used by the HH QRP, nor are they intended for use by CMS payment, survey or the expanded HHVBP model. The removal of these two items will result in the removal of two data elements at start of care, two at resumption of care, and one data element at follow-up for a total reduction of five data elements.

The net effect of the proposals outlined in this final rule is a reduction in four data elements collected across all time points for the OASIS implemented on January 1, 2025. Table G1 outlines the net change in data elements.

TABLE G1 –NUMBER OF DATA ELEMENTS TO BE ADDED OR REMOVED IN JANUARY 2025

	Data Elements at Each Time Point					
OASIS-E Item	**Start of Care**	**Resumption of Care**	**Follow-up**	**Transfer to an Inpatient Facility**	**Death at Home**	**Discharge – not to an Inpatient Facility**
Self-care/Mobility Goals GG0130/GG0170	-1	-1				
COVID-19 Patient Vaccination				+1	+1	+1
M0110 Episode Timing	-1	-1	-1			
M2200 Therapy Need	-1	-1				
Net Change (-4)	-3	-3	-1	+1	+1	+1

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 $87.52, inclusive of fringe benefits, using the hourly wage data in Table G2. Individual providers determine the staffing resources necessary.

For purposes of calculating the costs associated with the information collection requirements, we obtained mean hourly wages for these from the U.S. Bureau of Labor Statistics' May 2022 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 G2.

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TABLE G2: U.S. BUREAU OF LABOR STATISTICS' MAY 2022 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit (100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$42.80	$42.80	$85.60
Physical therapists (PT)	29-1123	$47.10	$47.10	$94.20
Speech-Language Pathologists (SLP)	29-1127	$43.01	$43.01	$86.02
Occupational Therapists (OT)	29-1122	$44.61	$44.61	$89.22
Miscellaneous Health Technologists and Technicians	29-2090	$25.39	$25.39	$50.78

For purposes of estimating burden, we utilize item-level burden estimates for OASIS–E that will be released on January 1, 2025 compared to the OASIS–E as currently implemented as of January 1, 2023. Table G3 shows the total number of OASIS assessments that HHAs actually completed in CY 2021, as well as how those numbers will have decreased if non-Medicare and non-Medicaid OASIS assessments had been required at that time.

TABLE G3. CY 2021 OASIS SUBMISSIONS BY TIME POINT

Time Point	CY 2021 Assessments Completed
Start of Care	6,561,902
Resumption of Care	919,325
Follow-up	3,666,923
Transfer of Care	1,848,699
Death at Home	49,516
Discharge from agency	5,348,484
TOTAL	18,394,849

Table G4 summarizes the estimated clinician hourly burden for the current OASIS and the OASIS in 2025 with the net removal of four data elements for each OASIS assessment type using CY 2021 assessment totals. We estimated a net reduction of 58,540.1 hours of clinician burden across all HHAs or 5 hours for each of the 11,700 active HHAs.

TABLE G4. SUMMARY OF ESTIMATED CLINICIAN HOURLY BURDEN

OASIS Assessment Type	Clinician Estimated Hourly Burden – OASIS 2023	Clinician Estimated Hourly Burden – OASIS 2025	Net Total
Start of Care	6,266,616.41	6,200,997.39	65,619.02
Resumption of Care	735,460	726,266.75	9,193.25
Follow-up	806,723.06	788,388.44	18,334.62
Transfer of Care	204,983.59	212,600.38	-7,616.79
Death at Home	2,228.22	2,475.80	-247.58
Discharge from agency	3,583,484.28	3,610,226.7	-26,742.42
TOTAL	11,599,495.56	11,540,955.46	58,540.10

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Table G5 summarizes the estimated clinician costs for the current OASIS and the OASIS in 2025 with the net removal of four data elements for each OASIS assessment type using CY 2021 assessment totals. We estimated a reduction in costs of $5,123,430 related to the implementation of the proposals outlined in this final rule across all HHAs or a $438 reduction for each of the 11,700 active HHAs. This reduction in burden will begin with January 1, 2025 HHA discharges.

TABLE G5. SUMMARY OF ESTIMATED CLINICIAN COSTS

OASIS Assessment Type	Clinician Estimated Cost – OASIS 2023	Clinician Estimated Cost –– OASIS 2025	Net Total
Start of Care	$548,454,268.20	$542,711,291.57	- $5,742,976.63
Resumption of Care	$64,367,459.2	$63,562,865.96	- $804,593.24
Follow-up	$70,604,402.21	$68,999,756.27	- $1,604,645.94
Transfer of Care	$17,940,163.80	$18,606,785.26	$666,621.46
Death at Home	$195,013.81	$216,682.02	$21,668.21
Discharge from agency	$313,626,544.19	$315,967,040.78	$2,340,496.59
TOTAL	$1,015,187,851.41	$1,010,064,421.86	-$5,123,429.55

We received no comments on the burden calculations related to the HH QRP proposals and therefore are finalizing this provision without modification.

2. ICRs for HHVBP

The provisions for the expanded HHVBP Model included in this final 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.

We received no comments on these statements and therefore are finalizing without modification.

3. ICRs for Hospice Information Dispute Resolution (IDR) and Hospice Special Focus Program (SFP)

In accordance with 5 CFR 1320.4(a)(2) and (c), the following information collection activities are exempt from the requirements of the Paperwork Reduction Act since they are associated with administrative actions: (1) proposed § 488.1130 Hospice IDR; and (2) proposed § 488.1135 Hospice SFP.

We did not receive any comments on these statements regarding the information collection requirements and therefore are finalizing without modification.

4. ICRs for DMEPOS Refills

In section VII.E. of this final rule, we are finalizing our proposal to codify our refill policy, with some changes. The policy originally arose in response to concerns related to auto-shipments and delivery of DMEPOS products that may no longer be needed or not needed at the same level of frequency/volume. The policy has been historically maintained in the Medicare Program Integrity Manual, sporadically mentioned in certain Local Coverage Determinations (LCDs) and detailed in articles. We proposed to require documentation indicating that the beneficiary confirmed the need for the refill within the 30-day period prior to the end of the current supply. We proposed to codify our requirement that delivery of DMEPOS items (that is, date of service) must be no sooner than 10 calendar days before the expected end of the current supply.

We did not receive any comments on the information collection requirements.

5. ICRs for Provider Enrollment Provisions

Except as explained in this section IX. of this final rule, none of our proposed provider enrollment provisions implicate an ICR burden.

a. High-Risk Screening and Fingerprinting

We proposed to revise § 424.518 to: (1) move initially enrolling hospices (and those undergoing an ownership change as described in § 424.518) into the high-risk screening category; and (2) include within the high-risk screening category revalidating DMEPOS suppliers, HHAs, OTPs, MDPPs, and SNFs for whom CMS legally waived the fingerprint-based criminal background check requirement in § 424.518 when they initially enrolled in Medicare. These changes will result in an increase in the annual number of providers and suppliers that must submit the fingerprints for a national criminal background check (via FBI Applicant Fingerprint Card FD–258) of all individuals with a 5 percent or greater direct or indirect ownership interest in the provider or supplier. The burden is currently approved by OMB under control number 1110–0046. We are not scoring the burden under this ICR section since the fingerprint card is not owned by CMS. However, an analysis of the impact of this requirement can be found in the RIA section of this final rule.

b. Hospice 36-Month Rule

We proposed to expand § 424.550(b) to apply the 36-month rule provisions therein to hospices. This will require a hospice undergoing a change in majority ownership (as defined in § 424.502 and assuming no exceptions apply) to: (1) enroll in Medicare as a new hospice; and (2) undergo a state survey or accreditation. The principal ICR burden of this requirement will involve the completion of an initial Form CMS–855A (OMB control number: 0938–0685) application rather than a Form CMS–855A change of ownership (CHOW) application or a Form CMS–855A change of information application. Consistent with the general time estimates for these three categories of applications, it typically takes a provider approximately 4 hours to complete an initial Form CMS–855A, 4 hours for a CHOW application, and 1 hour for a change of information application. The key ICR burden difference, therefore, will be between submitting an initial application and submitting a change of information (since there is no burden difference between an initial application and a CHOW application).

Based on internal CMS data, we estimate that each year approximately 50 hospices will be required to initially enroll in Medicare due to a change in majority ownership as opposed to simply reporting the sale via a change of information. This will result in an additional Form CMS–855A hour burden of 150 hours (50 × 3 hours), with the 3-hour figure reflecting the difference between initial applications and changes of information. In terms of cost, it has been our experience that Form CMS–855A applications are completed by the provider's office staff. Consequently, we will use the following wage category and hourly rate from the U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*):

TABLE G6: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Office and Administrative Support Workers, All Other	43-9199	20.75	20.75	41.50

This results in an additional Form CMS–855A annual cost burden of $6,225 (150 hours × $41.50).

We anticipate the following additional costs associated with our 36-month rule expansion:

- *Fingerprinting:* As we proposed that hospices will be subject to high-risk level screening under § 424.518, hospices that must initially enroll under § 424.550(b) will have to submit a set of fingerprints for a national criminal background check (via FBI Applicant Fingerprint Card FD–258) from each individual with a 5 percent or greater direct or indirect ownership interest in the hospice. An analysis of the impact of this requirement can be found in section X.C.8.of this final rule.
- *Application Fee:* Under § 424.514, an institutional provider (as that term is defined in § 424.502) that is initially enrolling in Medicare must pay the required application fee. Hospices that are initially enrolling in accordance with the 36-month rule will accordingly have to pay this fee. The application fee does not meet the definition of a ''collection of information'' and, as such, is not subject to the requirements of the PRA. However, the cost is scored under section X.C.8. of this final rule.
- *Provider Agreement:* A hospice that is initially enrolling in Medicare (which will include those doing so in accordance with § 424.550(b)) must also sign a provider agreement per 42 CFR part 489 (Health Insurance Benefits Agreement—CMS Form 1561 (OMB control number 0938–0832)). The applicable May 2022 BLS categories and hourly wage rates for completing this form are as follows:

TABLE G7: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Chief Executive	11-1011	$118.48	$118.48	$236.96
Medical Secretaries and Administrative Assistants	43-6013	$19.84	$19.84	$39.68

We anticipated that 100 hospices per year will have to sign this provider agreement due to our revision to § 424.550(b): the 50 previously referenced hospices that will otherwise have reported the ownership change via a Form CMS–855A change of information and another 50 that will have done so via a Form CMS–855A CHOW application. We anticipate that it will take the hospice 5 minutes at $236.96/hr for a chief executive to review and sign the Form CMS–1561 and an additional 5 minutes at $39.68/hr for a medical secretary to file the document when fully executed. This results in an annual hour burden of 17 hours (100 × 0.166 hours) and a cost of $2,305 (or (($236.96 × 0.0833) + ($39.68 × 0.0833)) × 100).

Combining these initial enrollment application and provider agreement ICR costs associated with a hospice's change in majority ownership results in an annual burden of 167 hours (150 + 17) and a cost of $8,530 ($6,225 + $2,305).

We solicited comments from stakeholders, including hospices, regarding any other ICR costs that may be associated with our proposed expansion of the 36-month rule to incorporate hospices. This could include ICR costs incurred during the survey, accreditation, or certification processes.

c. Remaining Provider Enrollment Provisions

With one exception, we do not believe our other provider enrollment provisions will result in an information collection burden. Concerning the proposal in revised § 424.540(a)(1) to reduce the timeframe in which CMS can deactivate a provider or supplier for non-billing from 12 months to 6 months, an increase in the number of deactivations on this basis could result. However, we are unable to establish an estimate of this number or any associated burden for two reasons. First, fraud schemes and patterns of non-compliance can change and fluctuate, meaning that CMS cannot predict the number of instances in which it will apply § 424.540(a)(1) to address such situations. Second, a deactivation is a purely discretionary action by CMS; that is, CMS can, but is not required to, impose a deactivation if a basis for doing so exists. Accordingly, we are unable to quantify the increase, if any, of cases where we will invoke revised § 424.540(a)(1).

We did not receive comments on our proposed ICR estimates and are accordingly finalizing them without modification.

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 did not receive any comments on the information collection requirements.

X. 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 section 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, required the Secretary to implement a 30-day unit of service, for 30-day periods beginning on and after January 1, 2020. 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 would 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 is the first performance year in which HHAs individual performance on the applicable measures would affect their Medicare payments in CY 2025. In this final rule, we will remove five quality measures from the current applicable measure set and add three quality measures to the applicable measure set. Along with the final revisions to the current measure set, we will revise the weights of the individual measures within the OASIS-based measure category and within the claims-based measure category starting in the CY 2025 performance year. In addition, we will update the Model baseline year from CY 2022 to CY 2023 starting in the CY 2025 performance year to enable CMS to measure competing HHAs performance on benchmarks and achievement thresholds that are more current for the final applicable measure set. Additionally, we will amend the appeals process such that reconsideration decisions may be reviewed by the Administrator. We are 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 rule. We also include an update that reminds interested parties that we will begin public reporting of HHVBP performance data on or after December 1, 2024.

4. Home IVIG Items and Services

Division FF, section 4134 of the CAA, 2023 (CAA, 2023) (Pub. L. 117–328) mandated that CMS establish a permanent, bundled payment for items and services related to administration of IVIG in a patient's home. The permanent, bundled home IVIG items and services payment is effective for home IVIG infusions furnished on or after January 1, 2024. Payment for these items and services is required to be a separate bundled payment made to a supplier for all items and services furnished in the home during a calendar day. This payment amount may be based on the amount established under the Demonstration. The standard Part B coinsurance and the Part B deductible apply. The separate bundled payment does not apply for individuals receiving

services under the Medicare home health benefit. The CAA, 2023 provision clarifies that a supplier who furnishes these services meet the requirements of a supplier of medical equipment and supplies.

5. Informal Dispute Resolution (IDR) and Hospice Special Focus Program (SFP)

The hospice IDR will be an administrative process offered to hospice programs that is conducted by CMS, the SAs, or the accrediting organizations (AOs) as applicable, as part of their survey activities to provide an informal opportunity to address survey findings. The Hospice SFP will be implementing a part of the hospice provisions required under the CAA, 2021 codified in section 1822(b) of the Act, directing the Secretary to create an SFP for poor-performing hospice programs.

6. DMEPOS CAA, 2023-Related Requirements

a. Conforming Changes to Regulations To Codify Change Mandated by Section 4139 of the Consolidated Appropriations Act, 2023

The purpose of the provision related to adjusted fees is to extend the 75/25 blend in non-rural, non-CBAs as described in 42 CFR 414.210(g)(9)(v). The statutory language for this provision is found in section 4139 of the CAA, 2023.

b. Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

The purpose of the provision related to lymphedema compression treatment items is to define in regulation section 4133 of the CAA, 2023 that adds section 1861(s)(2)(JJ) to the Act establishing a Medicare Part B benefit for lymphedema compression treatment items. This provision addresses the scope of the new benefit by defining what constitutes a standard or custom fitted gradient compression garment and determining what other compression items may exist that are used for the treatment of lymphedema and would fall under the new benefit. This rule also implements section 1834(z) of the Act in establishing payment amounts for items covered under the new benefit and frequency limitations for lymphedema compression treatment items.

c. Definition of Brace

The purpose of the provision related to the definition of a brace is to codify in regulations the longstanding definition of brace that exists in Medicare program instructions.

7. Requirements for Refillable DMEPOS

This rule finalizes the documentation requirements to indicate that the beneficiary has confirmed their need for the refill within the 30-day period prior to the end of the current supply. It also codifies our requirement that the delivery of DMEPOS items (that is, date of service) must be no sooner than 10 calendar days before the expected end of the current supply.

8. Provider Enrollment Provisions

Our provider enrollment provisions are needed to strengthen Medicare program integrity. These provisions focus on but are not limited to: (1) subjecting a greater number of providers and suppliers, such as hospices, to the highest level of screening, which includes fingerprinting all 5 percent or greater owners of these providers and suppliers; and (2) applying the change in majority ownership (CIMO) provisions in 42 CFR 424.550(b) to hospices. These changes will help ensure that payments are made only to qualified providers and suppliers and that owners of these entities are carefully screened. As explained in section VIII. of this final rule, we believe that fulfilling these objectives would assist in protecting the Trust Funds and Medicare beneficiaries.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), 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 (as amended by E.O. 14094) and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 amends section 3(f) of Executive Order 12866 to define a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) of $200 million or more in any 1 year. Based on our estimates, OMB'S Office of Information and Regulatory Affairs has determined this rulemaking significant under section 3(f)(1) of E.O. 12866. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Effects of the Changes for the CY 2024 HH PPS

This rule finalizes our proposals to update Medicare payments under the HH PPS for CY 2024. The net transfer impact related to the changes in payments under the HH PPS for CY 2024 is estimated to be $140 million (0.8 percent). The $140 million increase in estimated payments for CY 2024 reflects the effects of the final CY 2024 home health payment update percentage of 3.0 percent ($525 million increase), an estimated 2.6 percent decrease that reflects the effects of the permanent behavior adjustment ($455 million decrease), and an estimated 0.4 percent increase that reflects the effects of an updated FDL ($70 million increase).

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, 2022. 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 GG 1 represents how HHA revenues are likely to be affected by the finalized policy changes for CY 2024. For this analysis, we used an analytic file with linked CY 2022 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2022. The first column of Table GG 1 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 agencies in the impact analysis. The third column shows the payment effects of the permanent behavior assumption adjustment on all payments. The aggregate impact of the CY 2024 permanent BA adjustment reflected in the third column does not equal the final −2.890 percent permanent BA 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 2024 wage index with a 5-percent cap on wage index decreases. The sixth column shows the effect of the final CY 2024 labor-related share. The aggregate impact of the changes in the fifth and sixth columns is zero percent, due to the wage index budget neutrality factor and the labor-related share budget neutrality factor. The seventh column shows the payment effects of the final CY 2024 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 2024 would increase by 0.8 percent which reflects the 2.6 percent decrease from the permanent behavior adjustment, the 3.0 payment update percentage increase, and the 0.4 percent increase from decreasing the FDL. As illustrated in Table GG 1, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2024 wage index, the percentage of total HH PPS payments that were subject to the LUPA or paid as outlier payments, and the degree of Medicare utilization.

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TABLE GG 1: HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2024

	Number of Agencies	CY 2024 Permanent BA Adjustment	CY 2024 Case-Mix Weights Recalibration Neutrality Factor	CY 2024 Updated Wage Index	CY 2024 Updated Labor-Related Share	CY 2024 Final HH Payment Update Percentage	CY 2024 Fixed-Dollar Loss (FDL) Update	Total
All Agencies	**9,627**	**-2.6%**	**0.0%**	**0.0%**	**0.0%**	**3.0%**	**0.4%**	**0.8%**
Facility Type and Control								
Free-Standing/Other Vol/NP	909	-2.6%	-0.2%	-0.1%	0.0%	3.0%	0.5%	0.6%
Free-Standing/Other Proprietary	7,405	-2.7%	0.0%	0.0%	0.0%	3.0%	0.3%	0.6%
Free-Standing/Other Government	157	-2.6%	0.3%	-0.6%	0.1%	3.0%	0.4%	0.6%
Facility-Based Vol/NP	448	-2.5%	-0.1%	0.2%	0.0%	3.0%	0.6%	1.2%
Facility-Based Proprietary	48	-2.6%	0.0%	0.0%	0.1%	3.0%	0.5%	1.0%
Facility-Based Government	140	-2.6%	0.1%	-0.7%	0.1%	3.0%	0.5%	0.4%
Subtotal: Freestanding	8,471	-2.6%	0.0%	0.0%	0.0%	3.0%	0.4%	0.8%
Subtotal: Facility-based	636	-2.5%	-0.1%	0.1%	0.0%	3.0%	0.6%	1.1%
Subtotal: Vol/NP	1,357	-2.5%	-0.2%	0.0%	0.0%	3.0%	0.5%	0.8%
Subtotal: Proprietary	7,453	-2.7%	0.0%	0.0%	0.0%	3.0%	0.3%	0.6%
Subtotal: Government	297	-2.6%	0.2%	-0.7%	0.1%	3.0%	0.5%	0.5%
Facility Type and Control: Rural								
Free-Standing/Other Vol/NP	217	-2.6%	0.0%	-0.7%	0.2%	3.0%	0.5%	0.4%
Free-Standing/Other Proprietary	759	-2.7%	0.0%	-0.4%	0.3%	3.0%	0.3%	0.5%
Free-Standing/Other Government	105	-2.5%	0.1%	-0.6%	0.2%	3.0%	0.6%	0.8%
Facility-Based Vol/NP	195	-2.5%	0.1%	-0.6%	0.2%	3.0%	0.6%	0.8%
Facility-Based Proprietary	16	-2.6%	0.2%	-0.5%	0.2%	3.0%	0.5%	0.8%
Facility-Based Government	103	-2.5%	0.3%	-1.1%	0.2%	3.0%	0.6%	0.5%
Facility Type and Control: Urban								
Free-Standing/Other Vol/NP	692	-2.6%	-0.2%	0.0%	-0.1%	3.0%	0.5%	0.6%
Free-Standing/Other Proprietary	6,638	-2.7%	0.0%	0.1%	0.0%	3.0%	0.4%	0.8%
Free-Standing/Other Government	52	-2.6%	0.4%	-0.7%	0.0%	3.0%	0.4%	0.5%
Facility-Based Vol/NP	253	-2.5%	-0.2%	0.4%	-0.1%	3.0%	0.6%	1.2%
Facility-Based Proprietary	32	-2.6%	-0.1%	0.2%	0.1%	3.0%	0.4%	1.0%
Facility-Based Government	37	-2.6%	0.0%	-0.4%	0.0%	3.0%	0.4%	0.4%
Facility Location: Urban or Rural								
Rural	1,395	-2.7%	0.0%	-0.5%	0.2%	3.0%	0.4%	0.4%
Urban	7,704	-2.6%	0.0%	0.1%	0.0%	3.0%	0.4%	0.9%
Facility Location: Region of the Country (Census Region)								
New England	318	-2.6%	-0.1%	-0.8%	-0.1%	3.0%	0.5%	-0.1%
Mid Atlantic	400	-2.6%	-0.2%	1.0%	-0.1%	3.0%	0.4%	1.5%
East North Central	1,492	-2.6%	0.0%	-0.5%	0.1%	3.0%	0.4%	0.4%
West North Central	587	-2.6%	0.0%	-0.5%	0.1%	3.0%	0.5%	0.5%
South Atlantic	1,584	-2.6%	-0.2%	0.3%	0.1%	3.0%	0.3%	0.9%
East South Central	360	-2.7%	-0.2%	-0.3%	0.3%	3.0%	0.2%	0.3%

West South Central	2,061	-2.7%	0.2%	0.1%	0.2%	3.0%	0.4%	1.2%
Mountain	711	-2.6%	0.2%	-1.1%	0.0%	3.0%	0.4%	-0.1%
Pacific	2,071	-2.6%	0.3%	0.1%	-0.4%	3.0%	0.4%	0.8%
Outlying	43	-2.7%	0.3%	-1.2%	0.9%	3.0%	0.3%	0.6%
Facility Size (Number of 30-day Periods)								
< 100 periods	2,190	-2.6%	0.6%	0.0%	0.0%	2.7%	0.5%	1.2%
100 to 249	1,475	-2.6%	0.5%	-0.1%	0.0%	2.7%	0.5%	1.0%
250 to 499	1,648	-2.6%	0.4%	-0.1%	0.0%	2.7%	0.5%	0.9%
500 to 999	1,945	-2.6%	0.3%	-0.1%	0.0%	2.7%	0.4%	0.7%
1,000 or More	2,369	-2.6%	-0.1%	0.0%	0.0%	2.7%	0.4%	0.4%

Source: CY 2022 Medicare claims data for periods with matched OASIS records ending in CY 2022 (as of July 13, 2023). In the CY 2024 HH PPS proposed rule we inadvertently stated that the source of the impacts was from March 17, 2022. The correct date should have been March 17, 2023.

Notes:
1.The permanent BA adjustment reflected in the third column does not equal the final -2.890 percent permanent BA adjustment. The -2.6 percent reflected in column 3 includes all payments while the final -2.890 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.
2.The CY 2024 home health payment update percentage reflects the final home health productivity-adjusted market basket percentage update of 3.0 percent as described in section II.C.4.e. of this final rule.
3. The "Fixed Dollar Loss (FDL) Update" column reflects a change in the FDL from 0.35 to 0.27.
4. 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 9,627): totals involving facility type or control only add up to 9,099 and totals involving urban/rural locations (also) only add up to 9,099.

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

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2. Effects of the Changes for the HH QRP for CY 2024

Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year results in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. For the CY 2023 program year, 820 of the 11,549 active Medicare-certified HHAs, or approximately 7.1 percent, did not receive the full annual percentage increase because they did not meet assessment submission requirements. The 820 HHAs that did not satisfy the reporting requirements of the HH QRP for the CY 2023 program year represent $149 million in home health claims payment dollars during the reporting period out of a total $16.4 billion for all HHAs.

This final rule finalizes the adoption of the ''COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date'' (Patient/Resident COVID–19 Vaccine) measure to the HH QRP beginning with the CY 2025 HH QRP. CMS also proposed to adopt the ''Functional Discharge Score'' (DC Function) measure for the HH QRP beginning with the CY 2025 HH QRP. Along with the addition of the Discharge Function measure, we proposed to remove the ''Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function'' (Application of Functional Assessment/Care Plan) measure from the HH QRP beginning with the CY 2025 HH QRP. We additionally proposed the removal of two OASIS items no longer necessary for collection, the M0110—''Episode Timing'' and M2200—''Therapy Need'' items. The net effect of the finalization these proposals is a reduction of four data elements across all OASIS data collection time points and a net reduction in burden.

Section IX.B.1. of this final rule provides a detailed description of the net decrease in burdens associated with the final changes. We proposed that additions and removal of data elements associated with the HH QRP proposals would begin with January 1, 2025 discharges. The cost impact of these proposed changes was estimated to be a net decrease of $5,123,430 in annualized cost to HHAs, discounted at 7 percent relative to year 2021, over a perpetual time horizon beginning in CY 2025. We described the estimated burden and cost reductions for these measures in section IX of this final rule. In summary, the implementation of the proposals outlined in this final rule for the HH QRP is estimated to decrease the burden on HHAs by $437 per HHA annually, or $5,123,430 for all HHAs annually.

We received no comments on the burden calculations related to the HH QRP proposals and therefore are finalizing this provision without modification.

3. Effects of the Changes for the Expanded HHVBP Model

In the CY 2023 HH PPS final rule (87 FR 66883), we estimated that the expanded HHVBP Model would generate a total projected 5-year gross FFS savings for CYs 2023 through 2027 of $3,376,000,000. Finalization of the changes to the applicable measure set and the Model baseline year in this rule will not change those estimates because they do not change the number of HHAs in the Model or the payment methodology.

Based on policies discussed in this final rule, Tables GG 2A and GG 2B display the distribution of possible payment adjustments using CY 2021 data as the performance year and CY 2019 for the baseline year. Note that due to limited data availability, this impact analysis does not account for improvement points for the PPH measure because this measure is not available based on CY 2022 data at the time of the release of this final rule.

Table GG 2A and GG 2B shows the value-based incentive payment adjustments for the estimated 6,750 HHAs that would qualify to compete in the expanded Model based on CY 2021 performance data stratified by volume-based cohort, as defined in section III.F. of the CY 2022 HH PPS final rule (86 FR 62312). This impact analysis used CY 2019 to determine HHA size instead of the calendar year prior to the performance year (that is, CY 2020) to avoid using data impacted by the Public Health Emergency (PHE). Using CY 2021 performance year data and the finalized payment adjustment of 5 percent, based on the 10 final quality measures, the 6,504 HHAs in the larger-volume cohort would have an average payment adjustment of positive 0.164 percent (+0.164 percent). Furthermore, 246 HHAs have fewer than 60 unique beneficiaries in CY 2019 and are, therefore, included in the smaller-volume cohort. Overall, smaller-volume HHAs would have an average payment adjustment of negative 0.114 percent (−0.114 percent). Twenty-four states/territories do not have any HHAs in the smaller-volume cohort, including Alabama, District of Columbia, and Georgia. The remaining states/territories have HHAs in both volume-based cohorts. Florida, for example, has 622 HHAs in the larger-volume cohort with an average payment adjustment of positive 1.154 percent (+1.154 percent) and 17 HHAs in the smaller-volume cohort with an average payment adjustment of positive 0.102 percent (+0.102 percent). The next columns provide the distribution of payment adjustment by percentile. Specifically, 10 percent of HHAs in the larger-volume cohort would receive payment adjustments of more than negative 3.851 percent (−3.851 percent). Among smaller-volume HHAs, 10 percent of HHAs would receive payment adjustments of more than negative 4.120 percent (−4.120 percent). For larger-volume HHAs in Florida, the payment adjustments range from negative 3.161 percent (−3.161 percent) at the 10th percentile to positive 5.000 percent (+5.000 percent) at the 90th percentile, while the median (50th percentile) payment adjustment is positive 1.160 percent (+1.160 percent).

Table GG 3 provides the payment adjustment distribution based on the proportion of dual-eligible beneficiaries, average case mix using Hierarchical Condition Category (HCC) scores, proportion of beneficiaries that reside in rural areas, and HHA organizational status. To define cutoffs for the ''percentage of dual eligible beneficiaries,'' low through high percentage dual-eligible are based on the 20th, 40th, 60th, and 80th percentiles of percent dual eligible beneficiaries, respectively, across HHAs in CY 2021. To define case mix cutoffs, low, medium, or high acuity are based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of average HCC scores, respectively, across HHAs in CY 2021. To define cutoffs for percentage of rural beneficiaries, all non-rural, up to 50 percent rural, and over 50 percent rural are based on the home health beneficiaries' core-based statistical area (CBSA) urban versus rural designation. Based on CY 2021 data, HHAs with the highest proportion of dual-eligible beneficiaries served have a positive average payment adjustment (+0.035 percent). In addition, a higher proportion of rural beneficiaries served is associated with better performance. Specifically, HHAs serving over 50 percent rural beneficiaries have an average payment adjustment of positive 0.728 percent (+0.728 percent), compared to HHAs

TABLE GG 2A: PAYMENT ADJUSTMENT DISTRIBUTION BY VOLUME-BASED COHORT: LARGE-VOLUME COHORT

Larger-volume Cohort										
State	Number of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	11	(1.059)	(3.247)	(2.196)	(1.961)	(1.313)	(0.425)	(0.412)	0.103	0.159	0.381
AL	112	1.078	(1.926)	(0.938)	(0.051)	0.278	1.004	1.579	2.428	3.218	4.888
AR	90	0.567	(2.550)	(1.630)	(0.661)	(0.150)	0.885	1.235	1.872	2.321	3.702
AZ	104	(0.215)	(3.943)	(3.307)	(2.171)	(1.241)	(0.249)	0.671	1.436	2.362	3.603
CA	924	0.066	(4.450)	(3.378)	(2.261)	(1.401)	(0.293)	0.821	2.388	4.333	5.000
CO	102	0.405	(3.134)	(2.313)	(1.513)	(0.910)	0.189	0.930	1.960	3.996	5.000
CT	64	(1.171)	(4.176)	(3.695)	(2.811)	(2.380)	(1.973)	(1.376)	(0.518)	1.021	3.985
DC	6	1.525	(2.334)	(0.057)	(0.057)	1.519	2.113	2.707	3.528	3.528	3.787
DE	12	0.783	(2.652)	(0.709)	(0.071)	0.106	0.575	1.147	1.913	2.116	5.000
FL	622	1.154	(3.161)	(1.977)	(0.942)	0.037	1.160	2.386	3.774	5.000	5.000
GA	98	0.065	(3.169)	(2.312)	(1.574)	(1.058)	(0.270)	0.186	1.266	3.035	4.362
GU	2	(4.087)	(4.301)	(4.301)	(4.301)	(4.301)	(4.087)	(3.874)	(3.874)	(3.874)	(3.874)
HI	13	0.888	(2.573)	(1.652)	(1.636)	1.298	1.493	1.892	2.780	2.897	4.267
IA	88	1.648	(2.620)	(0.756)	(0.100)	0.923	2.066	3.128	3.916	4.732	5.000
ID	43	0.972	(3.269)	(2.017)	(1.566)	0.114	1.568	2.635	3.579	4.032	5.000
IL	356	(0.103)	(4.434)	(3.242)	(2.270)	(1.220)	(0.404)	0.699	2.008	3.139	4.955
IN	126	(0.383)	(4.318)	(2.731)	(1.975)	(1.248)	(0.437)	0.247	0.973	2.031	3.476
KS	80	0.531	(3.881)	(2.400)	(1.234)	(0.242)	0.850	1.393	2.244	3.810	5.000
KY	87	0.878	(2.134)	(1.004)	(0.243)	0.292	0.897	1.354	1.767	3.128	4.036
LA	165	0.484	(3.009)	(2.249)	(1.528)	(0.541)	0.536	1.208	2.215	3.375	4.468
MA	101	(0.090)	(3.418)	(2.291)	(1.342)	(1.061)	(0.476)	(0.036)	1.113	1.929	4.649
MD	48	1.343	(1.697)	(1.470)	(0.328)	0.299	1.113	1.761	2.691	4.484	5.000
ME	19	1.084	(2.414)	(1.110)	(0.549)	0.627	1.017	2.000	2.598	2.912	5.000
MI	282	1.150	(3.159)	(1.766)	(0.904)	0.099	1.340	2.262	3.355	5.000	5.000
MN	89	0.470	(2.178)	(1.724)	(0.594)	(0.019)	0.411	0.984	1.581	2.678	3.932
MO	116	0.874	(3.578)	(2.593)	(1.273)	(0.067)	1.152	2.175	3.438	4.615	5.000
MS	43	1.104	(0.394)	(0.160)	0.209	0.592	0.825	1.609	1.970	2.386	3.513
MT	20	0.185	(2.906)	(1.573)	(1.188)	(0.814)	(0.103)	0.566	1.473	2.503	2.981
NC	152	0.541	(2.925)	(1.801)	(1.023)	(0.414)	0.089	1.062	2.315	3.120	4.720
ND	13	1.342	(1.963)	(0.817)	(0.751)	0.374	0.696	2.716	2.848	5.000	5.000
NE	44	1.172	(3.509)	(2.051)	(0.108)	1.075	1.542	2.408	3.038	4.257	5.000
NH	20	0.493	(2.620)	(1.468)	(0.300)	0.273	0.493	0.945	1.324	2.573	3.405
NJ	41	0.446	(2.132)	(1.482)	(0.928)	(0.352)	(0.105)	0.424	1.202	2.302	4.127
NM	56	(0.601)	(4.428)	(3.181)	(2.494)	(1.795)	(0.995)	(0.310)	1.434	2.155	3.513

serving only rural beneficiaries or HHAs serving up to 50 percent rural beneficiaries. Among organizational type, proprietary HHAs have a slightly negative average payment adjustment of 0.092, whereas HHAs in other organizational type categories have a positive average payment adjustment.

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Larger-volume Cohort											
State	Number of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
NV	95	(1.722)	(4.897)	(4.479)	(3.918)	(2.915)	(1.933)	(1.264)	(0.555)	0.277	2.540
NY	98	0.637	(2.517)	(1.731)	(0.836)	(0.109)	0.300	0.806	1.950	3.375	4.604
OH	248	(0.065)	(4.290)	(2.925)	(2.158)	(1.563)	(0.476)	0.681	1.966	3.123	5.000
OK	174	(1.016)	(4.142)	(3.485)	(2.695)	(2.166)	(1.578)	(0.633)	0.058	1.373	2.847
OR	42	(0.223)	(3.417)	(2.686)	(2.079)	(1.310)	(0.568)	0.407	1.611	2.453	3.013
PA	198	0.858	(3.014)	(1.804)	(0.987)	(0.139)	0.623	1.826	2.847	4.181	5.000
PR	32	(1.760)	(3.603)	(3.454)	(2.960)	(2.530)	(2.398)	(1.416)	(0.833)	0.074	0.631
RI	19	1.069	(3.533)	(1.920)	(1.347)	(0.267)	0.986	2.164	3.078	5.000	5.000
SC	65	0.654	(2.618)	(1.604)	(0.779)	(0.103)	0.452	1.601	2.025	2.653	3.889
SD	17	2.122	(3.764)	0.075	1.752	1.792	2.543	3.698	4.187	5.000	5.000
TN	109	0.289	(2.659)	(1.776)	(1.073)	(0.640)	(0.014)	0.655	1.353	2.422	3.824
TX	824	(1.233)	(4.536)	(3.700)	(2.943)	(2.152)	(1.534)	(0.801)	(0.026)	1.104	2.370
UT	62	1.291	(2.113)	(1.758)	(0.892)	0.112	0.881	2.928	3.746	4.758	5.000
VA	171	0.144	(3.732)	(2.615)	(1.853)	(0.887)	(0.222)	1.062	2.099	2.616	5.000
VI	2	2.815	0.631	0.631	0.631	0.631	2.815	5.000	5.000	5.000	5.000
VT	10	(2.293)	(4.134)	(4.105)	(3.751)	(2.960)	(2.229)	(1.849)	(1.095)	(0.365)	(0.255)
WA	54	0.430	(2.423)	(1.958)	(0.908)	(0.524)	(0.089)	1.087	1.892	2.911	3.644
WI	69	0.733	(3.547)	(1.980)	(1.218)	(0.311)	1.019	1.548	2.951	3.603	5.000
WV	47	0.828	(1.905)	(1.303)	(0.825)	(0.159)	0.440	1.530	2.014	3.365	4.681
WY	19	(0.389)	(4.210)	(2.721)	(2.083)	(1.582)	(0.297)	0.003	0.911	2.412	3.607
ALL	**6,504**	**0.164**	**(3.851)**	**(2.658)**	**(1.789)**	**(0.931)**	**(0.079)**	**0.876**	**1.938**	**3.251**	**5.000**

TABLE GG 2B: PAYMENT ADJUSTMENT DISTRIBUTION BY VOLUME-BASED COHORT: SMALL-VOLUME COHORT

Smaller-volume Cohort											
State	Number of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	1	(1.697)	(1.697)	(1.697)	(1.697)	(1.697)	(1.697)	(1.697)	(1.697)	(1.697)	(1.697)
AL	0	-	-	-	-	-	-	-	-	-	-
AR	1	(0.995)	(0.995)	(0.995)	(0.995)	(0.995)	(0.995)	(0.995)	(0.995)	(0.995)	(0.995)
AZ	3	0.779	(0.578)	(0.578)	(0.578)	0.418	0.418	0.418	2.496	2.496	2.496
CA	63	1.032	(3.748)	(2.655)	(1.570)	(0.175)	2.283	3.005	3.592	4.888	5.000
CO	1	(1.931)	(1.931)	(1.931)	(1.931)	(1.931)	(1.931)	(1.931)	(1.931)	(1.931)	(1.931)
CT	2	(0.745)	(2.244)	(2.244)	(2.244)	(2.244)	(0.745)	0.754	0.754	0.754	0.754

Smaller-volume Cohort											
State	Number of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
DC	0	-	-	-	-	-	-	-	-	-	-
DE	0	-	-	-	-	-	-	-	-	-	-
FL	17	0.102	(3.200)	(2.957)	(2.678)	(2.604)	(1.370)	0.442	1.995	4.974	5.000
GA	0	-	-	-	-	-	-	-	-	-	-
GU	0	-	-	-	-	-	-	-	-	-	-
HI	0	-	-	-	-	-	-	-	-	-	-
IA	5	1.278	(0.889)	(0.435)	0.018	0.194	0.370	1.512	2.654	3.446	4.238
ID	0	-	-	-	-	-	-	-	-	-	-
IL	33	0.066	(4.435)	(2.972)	(2.331)	(1.212)	0.377	0.871	2.735	3.387	4.242
IN	4	(2.732)	(4.509)	(4.509)	(2.976)	(2.976)	(2.457)	(1.937)	(1.937)	(1.507)	(1.507)
KS	2	(0.517)	(2.109)	(2.109)	(2.109)	(2.109)	(0.517)	1.075	1.075	1.075	1.075
KY	0	-	-	-	-	-	-	-	-	-	-
LA	0	-	-	-	-	-	-	-	-	-	-
MA	5	(1.726)	(5.000)	(3.151)	(1.302)	(1.185)	(1.068)	(0.992)	(0.915)	(0.630)	(0.345)
MD	0	-	-	-	-	-	-	-	-	-	-
ME	0	-	-	-	-	-	-	-	-	-	-
MI	21	1.110	(2.837)	(2.223)	(1.397)	(1.291)	2.307	3.044	4.086	4.365	5.000
MN	5	1.750	(1.605)	(1.401)	(1.196)	0.511	2.219	3.276	4.333	4.666	5.000
MO	4	1.116	(0.627)	(0.627)	0.205	0.205	1.247	2.289	2.289	2.598	2.598
MS	0	-	-	-	-	-	-	-	-	-	-
MT	2	(0.419)	(3.359)	(3.359)	(3.359)	(3.359)	(0.419)	2.520	2.520	2.520	2.520
NC	1	2.597	2.597	2.597	2.597	2.597	2.597	2.597	2.597	2.597	2.597
ND	1	2.817	2.817	2.817	2.817	2.817	2.817	2.817	2.817	2.817	2.817
NE	6	0.167	(4.555)	(1.213)	(1.213)	(0.954)	(0.569)	(0.184)	2.908	2.908	5.000
NH	0	-	-	-	-	-	-	-	-	-	-
NJ	0	-	-	-	-	-	-	-	-	-	-
NM	0	-	-	-	-	-	-	-	-	-	-
NV	4	(3.419)	(5.000)	(5.000)	(4.261)	(4.261)	(3.881)	(3.502)	(3.502)	(0.915)	(0.915)
NY	0	-	-	-	-	-	-	-	-	-	-
OH	2	3.690	2.381	2.381	2.381	2.381	3.690	5.000	5.000	5.000	5.000
OK	7	(2.967)	(5.000)	(4.600)	(4.083)	(4.083)	(3.335)	(2.264)	(2.264)	(0.965)	(0.526)
OR	1	(1.623)	(1.623)	(1.623)	(1.623)	(1.623)	(1.623)	(1.623)	(1.623)	(1.623)	(1.623)
PA	6	1.596	(2.246)	(1.211)	(1.211)	2.032	2.147	2.263	3.736	3.736	5.000
PR	0	-	-	-	-	-	-	-	-	-	-
RI	0	-	-	-	-	-	-	-	-	-	-
SC	0	-	-	-	-	-	-	-	-	-	-
SD	2	3.553	2.106	2.106	2.106	2.106	3.553	5.000	5.000	5.000	5.000
TN	1	(1.067)	(1.067)	(1.067)	(1.067)	(1.067)	(1.067)	(1.067)	(1.067)	(1.067)	(1.067)
TX	35	(2.851)	(4.798)	(4.494)	(3.973)	(3.848)	(3.276)	(2.926)	(1.646)	(0.939)	(0.471)

Smaller-volume Cohort											
State	Number of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
UT	6	(0.020)	(3.317)	(1.115)	(1.115)	(1.097)	(0.500)	0.096	1.419	1.419	3.894
VA	3	(1.854)	(4.103)	(4.103)	(4.103)	(3.651)	(3.651)	(3.651)	2.192	2.192	2.192
VI	0	-	-	-	-	-	-	-	-	-	-
VT	0	-	-	-	-	-	-	-	-	-	-
WA	0	-	-	-	-	-	-	-	-	-	-
WI	2	(1.218)	(4.023)	(4.023)	(4.023)	(4.023)	(1.218)	1.587	1.587	1.587	1.587
WV	0	-	-	-	-	-	-	-	-	-	-
WY	0	-	-	-	-	-	-	-	-	-	-
ALL	**246**	**(0.114)**	**(4.120)**	**(3.266)**	**(2.298)**	**(1.507)**	**(0.904)**	**0.377**	**2.307**	**3.475**	**5.000**

TABLE GG 3: PAYMENT ADJUSTMENT DISTRIBUTION BY HHA CHARACTERISTICS

HHA Characteristics	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
Percentage Dual-eligible											
1st Quintile: % Dual-eligible	1,344	0.781	(3.242)	(2.080)	(1.160)	(0.216)	0.730	1.662	2.592	4.241	5.000
2nd Quintile: % Dual-eligible	1,343	0.377	(3.128)	(2.100)	(1.344)	(0.610)	0.173	1.081	1.966	3.025	4.678
3rd Quintile: % Dual-eligible	1,344	0.176	(3.418)	(2.365)	(1.563)	(0.836)	(0.045)	0.746	1.709	2.908	4.408
4th Quintile: % Dual-eligible	1,343	(0.565)	(4.232)	(3.276)	(2.370)	(1.754)	(0.882)	(0.071)	0.859	2.096	3.887
5th Quintile: % Dual-eligible	1,343	0.035	(4.588)	(3.667)	(2.655)	(1.554)	(0.392)	0.953	2.668	4.672	5.000
Acuity (HCC)											
1-Lowest Acuity	1,678	0.599	(4.046)	(2.775)	(1.586)	(0.591)	0.495	1.764	3.075	4.846	5.000
2-Medium Acuity	3,354	0.095	(3.743)	(2.646)	(1.823)	(0.995)	(0.145)	0.782	1.717	2.988	4.884
3-Highest Acuity	1,677	(0.145)	(3.843)	(2.650)	(1.878)	(1.178)	(0.406)	0.419	1.361	2.494	4.224
% Rural Beneficiaries											
1-All non-rural	3,448	0.114	(4.164)	(2.938)	(2.004)	(1.095)	(0.195)	0.863	2.114	3.591	5.000
2-Up to 50% rural	1,998	(0.118)	(3.675)	(2.651)	(1.896)	(1.180)	(0.405)	0.425	1.361	2.549	4.220
3-Over 50% rural	1,266	0.728	(3.078)	(1.916)	(0.976)	(0.086)	0.664	1.523	2.461	3.595	5.000
Organizational Type											
1-Vol Non-Profit-Religious	273	1.309	(2.449)	(0.989)	(0.327)	0.509	1.444	2.096	3.058	3.918	5.000
2-Vol Non-Profit-Private	548	0.878	(3.078)	(1.944)	(1.051)	(0.068)	0.822	1.675	2.908	4.206	5.000
3-Vol Non-Profit-Other	447	0.909	(2.811)	(1.684)	(0.680)	0.106	0.846	1.738	2.709	3.785	5.000
4-Proprietary	5,233	(0.092)	(4.086)	(2.943)	(2.060)	(1.273)	(0.436)	0.485	1.609	2.956	5.000
5-Govt-State/County	149	1.043	(2.682)	(1.719)	(0.654)	0.255	1.142	2.074	3.080	3.918	4.796
6-Govt-Govt & Voluntary	10	2.227	(0.890)	0.488	1.133	1.762	2.424	2.853	3.491	4.498	4.977
7-Govt-Local	90	1.096	(2.591)	(1.275)	(0.699)	0.320	1.059	1.810	2.872	4.096	5.000

Notes:

- Dual: Based on 20th, 40th, 60th, and 80th percentiles of the percent of beneficiaries with any dual indicated across all HHAs in 2021.
- HCC Score Acuity: low, medium, high are based on 25th and 75th percentiles of the average HCC of beneficiaries across all HHAs in 2021.
- Percentage rural beneficiaries: based on CBSA of beneficiaries' ZIP code aggregated to the HHA level in 2021.

The total number of HHAs differ by category due to missing HHAs in some data sources.

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We did received comments on this impact analysis and therefore are finalizing this without modification.

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 rule as added by section 4134 of the CAA, 2023 and accordingly, describes the impact for CY 2024 only. Table GG 4 represents the estimated costs of home IVIG users for CY 2024. We used CY 2022 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 2024 active enrollees in the new benefit, which are shown in column 2. In column 3, CY 2022 claims for IVIG visits under the Demonstration were again used to estimate potential utilization under the new benefit in CY 2024. Column 4 shows the final CY 2024 home IVIG items and services rate. The fifth column estimates the cost to Medicare for CY 2024 ($8,661,888). The estimated cost for CY 2023 under the Demonstration is $8,409,538 (not shown in chart) resulting in an increase of $252,350 in payments to providers under the permanent benefit. Table GG 5 represents the estimated impacts of the home IVIG items and services payment for CY 2024 by census region.

TABLE GG 4: ESTIMATED COSTS OF COVERED IVIG ITEMS AND SERVICES, CY 2024

Year	Number of Active Enrollees[1]	Number of IVIG Visits[1]	Nationwide Rate	Estimated Cost
CY 2024	1,853	20,600	$420.48	$8,661,888

[1]The number of active enrollees and IVIG visits in CY 2022 was used to estimate utilization in CY 2023 and CY 2024. Claims data were extracted on August 24, 2023.

TABLE GG 5—ESTIMATED IMPACTS OF THE HOME IVIG ITEMS AND SERVICES PAYMENT BY REGION, CY 2024

Census Region	States	Number of Active Enrollees[1]	Number of IVIG Visits[1]	Estimated CY 2024 Cost
New England	CT, ME, MA, NH, RI, VT	172	1,967	$ 827,084
Middle Atlantic	NJ, NY, PA	205	2,391	$ 1,005,368
South Atlantic	DE, DC, FL, GA, MD, NC, SC, VA, WV	467	5,053	$ 2,124,685
East North Central	IL, IN, MI, OH, WI	163	1,720	$ 723,226
East South Central	AL, KY, MS, TN	183	1,934	$ 813,208
West North Central	IA, KS, MN, MO, NE, ND, SD	128	1,497	$ 629,459
West South Central	AR, LA, OK, TX	176	1,920	$ 807,322
Mountain	AZ, CO, ID, MT, NV, NM, UT, WY	149	1,616	$ 679,496
Pacific	AK, CA, HI, OR, WA	210	2,502	$ 1,052,041
Other	GU, PR, VI	0	0	$ -

[1]The number of active enrollees and IVIG visits in CY 2022 was used to estimate utilization in CY 2024. Claims data were extracted on August 24, 2023.

5. Effects of the Changes for Hospice IDR and SFP

The hospice IDR is an administrative process to be conducted by CMS, SAs, or AOs as part of their survey activities, and is separate from the SFP. SAs and AOs may already have existing IDR processes in place for the HHA IDR requirements. The hospice IDR requirements will align with HHA. the IDR process currently in place for HHAs. The Congress has already allocated $10 million annually to CMS to implement the CAA, 2021 hospice survey and enforcement provisions, which includes the SFP. Additionally, CMS obligates monies to the SAs to carry out survey and certification responsibilities under their agreement with the Secretary under section 1864 of the Act. Therefore, no additional burden will be incurred by CMS, SAs, or AOs.

We did not receive comments on our burden estimate and are therefore finalizing without this without modification.

6. Effects of the Changes for DMEPOS CAA, 2023-Related Provisions

a. Conforming Changes to Regulations To Codify Change Mandated by Section 4139 of the Consolidated Appropriations Act, 2023

One benefit of this provision is that it provides additional revenue to DMEPOS suppliers. One cost of this provision is that it increases the copayments of the Medicare beneficiaries. The transfer from the Medicare program to the DMEPOS suppliers of $100 million for CY 2023 will be paid in CY 2023 and CY 2024. The amount of copayments from Medicare beneficiaries over the same period is expected to be $30 million. The Federal share of Medicaid for the copayments for dual eligibles is expected to be $5 million and the State share of the Medicare payments for this populations is expected to be $4 million.

We received no comments on the impact analysis of this provision.

b. Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

The benefits of this provision are that Medicare enrollees suffering from lymphedema will have Medicare pay 80 percent of the cost of the lymphedema compression treatment items. This

Medicare payment should enable more Medicare enrollees suffering from lymphedema to access treatment items in the home, reducing both the financial burden of lymphedema and, by encouraging earlier treatment, the frequency of institutional care for infections or other complications of lymphedema. The transfer from the Medicare program to the lymphedema compression treatment suppliers is estimated to be $150 million from CY 2024 to CY 2028. The amount of copayments from Medicare beneficiaries over the same period is expected to be $30 million. The Federal share of Medicaid expenditures for the copayments of dual eligibles is expected to be $5 million and the State share for this population is expected to be $4 million.

We received no comments on the impact analysis of this provision.

c. Definition of Brace

The benefit of this provision is to add the definition of brace in regulation to clearly identify what is included in the definition of a brace. This is purely an administrative effort with no impact on Medicare coverage or expenditure, and, for this reason, has no cost or transfer associated with it.

We did not received any comments on the impact analysis of this provision.

7. Effects of the Changes to the Requirements for Refillable DMEPOS

This rule codifies and clarifies our requirements for refillable DMEPOS items. The fiscal impact of these requirements cannot be estimated as claims often deny for multiple reasons, which may include non-compliance with our refill requirements; creating an inability for us to accurately demonstrate a causal relationship. In addition, to demonstrate impacts we would have to be able to predict behaviors and anticipated non-compliance in future claim submissions, which are unknown variables to us.

We did not receive any public comments regarding the financial impact of our proposals.

8. Effects of the Changes Regarding for Provider Enrollment Requirements

There are four principal impacts of the provider enrollment provisions outlined in section VIII. of this final rule.

The first was addressed in section IX. of this final rule. It involves the ICR burden associated with a hospice's completion of an initial Form CMS–855A application and Form CMS–1561 provider agreement per a § 424.550(b) change in majority ownership for which an exception does not apply. The combined annual burden was estimated to be 167 hours at a cost of $8,530.

The second involves moving hospices from the ''moderate'' screening category to the ''high'' screening level.

The third involves incorporating within the high screening category revalidating DMEPOS suppliers, HHAs, OTPs, MDPP suppliers, and SNFs for which CMS waived the fingerprint-based criminal background check requirement when they initially enrolled in Medicare.

The fourth pertains to the fingerprinting and application fee requirements (referenced in section IX. of this final rule) associated with a § 424.550(b) change in majority ownership.

We address the second, third, and fourth impacts as follows:

a. Moving Hospices to High-Risk

With this change to § 424.518, hospices that are initially enrolling in Medicare or reporting any new owner would have to submit the fingerprints of their 5 percent or greater direct or indirect owners for a Federal Bureau of Investigation criminal background check. Based on enrollment statistics and our experience, we projected in the proposed rule that 1,782 hospices per year (425 initially enrolling + 1,357 reporting a new 5 percent or greater owner) would be required to submit these fingerprints. (This figure does not include hospices initially enrolling pursuant to § 424.550(b); this matter is addressed in section X.C.8.c. of this final rule). Using an estimate of one owner per hospice (which aligns with previous fingerprinting projections we have made), 1,782 sets of fingerprints per year would be submitted.

Consistent with prior burden estimates, we projected that it would take each owner approximately 2 hours to be fingerprinted. According to the most recent BLS wage data for May 2022, the mean hourly wage for the general category of ''Top Executives'' (the most appropriate BLS category for owners) is $62.04. With fringe benefits and overhead, the figure is $124.08. This would result in an estimated annual burden of this final change of 3,564 hours (1,782 × 2) at a cost of $442,221 (3,564 × $124.08).

b. Providers and Suppliers Previously Waived From Fingerprinting

Approximately 6,388 high-risk level providers and suppliers were waived from fingerprinting when they initially enrolled in Medicare during the PHE. We proposed that these providers and suppliers, upon their revalidation, would be subject to the ''high'' level of screening and, consequently, fingerprinting. Using the fingerprinting burden estimates from section X.C.8.a. of this final rule, we project the total burden of this proposal to be 12,776 hours (6,388 × 2 hr) and $1,585,246 (12,776 × $124.08). Calculated as annual figures over a 3-year period, this results in a burden of 4,259 hours and $528,415.

c. Hospice Changes in Majority Ownership

Hospices that are initially enrolling in Medicare due to a change in majority ownership under § 424.550(b) will be subject to fingerprinting and must pay an application fee in accordance with § 424.514. Using the fingerprinting estimates already referenced in section X.C.8. of this final rule, we estimate an annual fingerprinting burden to hospices per § 424.550(b) of 200 hours (100 × 2 hr) at a cost of $24,816 (200 hr × $124.08).

The application fees for each of the past 3 calendar years were or are $599 (CY 2021), $631 (CY 2022), and $688 (CY 2023). Consistent with § 424.514, the differing fee amounts were predicated on changes/increases in the CPI for all urban consumers (all items; United States city average, CPI–U) for the 12-month period ending on June 30 of the previous year. While we cannot predict future changes to the CPI, the fee amounts between 2021 and 2023 increased by an average of $45 per year. As stated in the proposed rule, we believe this is a reasonable barometer with which to establish estimates (strictly for purposes of this final rule) of the fee amounts in the first 3 calendar years of the final provision (that is, 2024, 2025, and 2026). Thus, we project a fee amount of $733 in 2024, $778 for 2025, and $823 for 2026.

Applying these prospective fee amounts to the annual number of projected hospices impacted by our change in majority ownership proposal, this results in a cost of $73,300 (or 100 × $733) in the first year, $77,800 in the second year, and $82,300 in the third year.

d. Totals

The following table outlines the total annual costs associated with our enrollment provisions addressed in section X.C.8. of this final rule for each of the first 3 years.

TABLE GG 7—ESTIMATED COSTS OF HIGH-RISK SCREENING AND CHANGE IN MAJORITY OWNERSHIP PROVISIONS

Requirement	Year 1	Year 2	Year 3
Hospice Completion of Initial Form CMS-855A and Provider Agreement Per § 424.550(b)	8,530	8,530	8,530
Hospice High-Risk Screening (Fingerprinting)	442,221	442,221	442,221
Providers and Suppliers Previously Waived from Fingerprinting	528,415	528,415	528,415
Hospice Fingerprinting for Change in Majority Ownership	24,816	24,816	24,816
Hospice Application Fee for Change in Majority Ownership	73,300	77,800	82,300
Total	1,077,282	1,081,782	1,086,282

We solicited comment from stakeholders, including hospices, regarding any other RIA costs that may be associated with our proposed expansion of the 36-month rule to incorporate hospices. This could include costs incurred during the survey, accreditation, and/or certification processes.

e. Comments Received

We did not receive comments on our RIA estimates and are accordingly finalizing them as proposed.

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 $123.06 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 5.76 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $708.83 (5.76 hours × $123.06). Therefore, we estimate that the total cost of reviewing this regulation is $671,971 ($708.83 × 948) [948 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 2024 HH PPS final rule, we considered alternatives to the provisions articulated in section II.C.1. of this final rule. As described in section II.C.1. of this rule, to help prevent future over or underpayments, we calculated a permanent prospective adjustment by determining what the 30-day base payment amount should have been in CYs 2020, 2021, and 2022 in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes. One alternative to the final –2.890 percent permanent payment adjustment included taking the full adjustment of −5.779. Another alternative would be to take the remaining permanent adjustment not taken in the CY 2023 HH PPS final rule, which resulted in −4.085 percent. Another alternative would be a phase-in approach, where we could reduce the permanent adjustment, by spreading out the CY 2024 permanent adjustment over a specified period of years, rather than halving the adjustment in CY 2024 and adjusting the CY 2025 rate by the rest of that amount. Another alternative would be to delay the permanent adjustment to a future year. However, we believe that the full permanent reduction in a single year may be too burdensome for certain HHA providers at this time. Additionally, we believe that a phase-in approach or delay in 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 −2.890 percent (half of the permanent −5.779 adjustment) permanent adjustment to the CY 2024 30-day payment rate.

Additionally, we considered alternatives to rebasing and revising the home health market basket to reflect a 2021 base year. We considered continuing to use the 2016-based home health market basket without rebasing to determine the market basket increase factor for CY 2024. However, we typically rebase and revise the market baskets for the various PPS every 4 to 5 years so that the cost weights and price proxies reflect more recent data. Therefore, we believe it is more technically appropriate to use a 2021-based home health market basket and labor-related share since it allows for the CY 2024 market basket increase factor to reflect a more up-to-date cost structure experienced by HHAs.

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 mandates several amendments to the Medicare separate payment for dNPWT devices beginning in CY 2024. Therefore, we do not have the discretion to delay or eliminate the implementation of the changes to the separate payment amount for dNPWT and thus we did not consider any alternatives regarding this policy.

2. HH QRP

We considered alternative measures to the Discharge Function measure and determined this measure was the strongest. No appropriate alternative was available for the COVID–19 Patient Vaccination measure.

3. Expanded HHVBP Model

We discuss the alternatives we considered to the final weights of the individual measures within the OASIS-based measure category and within the claims-based measure category starting in the CY 2025 performance year for the expanded HHVBP Model in section IV.B.2. of this final rule.

4. Home IVIG Items and Services

For the CY 2024 HH PPS final rule, we did not consider alternatives to implementing the home IVIG items and services payment for CY 2024 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. We did consider alternatives to annually updating this payment rate, as articulated in section II.V.D. of this final rule. We considered updating the annual rate using the LUPA rate for skilled nursing in accordance with the demonstration program update. However, as the IVIG services payment is not geographically wage adjusted, and the LUPA rate incorporates a wage index budget neutrality factor, we believe it is more appropriate to annually adjust the IVIG items and services payment rate only by the home health payment update percentage. We also considered annually updating the rate by the CPI–U percentage increase in accordance with the annual update to the home infusion therapy services payment rate. However, the Demonstration has never used the CPI–U percentage increase to update the payment rate, and we believe it is more beneficial to keep the permanent payment as closely aligned with the Demonstration rate as possible. Therefore, we are finalizing these policies as proposed.

5. IDR and Hospice SFP

We did not consider any alternatives in this final rule for either proposal. An initial alternative proposal was published in CY 22 Home Health PPS final rule (86 FR 35874) but was not finalized due to public comments and requests that CMS establish a Technical Expert Panel (TEP) to inform the development of the SFP. We believe the new final methodology, based on feedback provided by the TEP, is the best way to identify and remedy the issue of poor -performing hospices. We received no comments on the consideration of no alternatives proposed.

6. DMEPOS CAA, 2023-Related Provisions

a. Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

As this provision is statutorily mandated, CMS needed to consider no alternatives for implementation. Similarly, the statutory language provided a definition for the lymphedema compression treatment items to be covered by this benefit, so CMS did not consider any alternative to coverage of a list of items meeting the statutory requirements. Regarding the payment methodology, CMS considered numerous sources for prices as suggested in statute. Different combinations of internet and insurer prices were alternatives considered. Ultimately, CMS decided on a payment methodology that CMS considered reasonable given the market for these items.

We received no comments on the consideration of no alternatives to regulatory action to implement the Lymphedema Compression Treatment Item benefit required by the CAA, 2023.

b. Conforming Changes to Regulations To Codify Change Mandated by Section 4139 of the Consolidated Appropriations Act, 2023

This is a conforming change to a statutory mandate and therefore required no alternatives be considered.

We did not receive comments about this provision's impact. We are finalizing our proposed conforming changes to § 414.210(g)(9), consistent with requirements in section 4139(a) and 4139(b) of the CAA, 2023.

c. Definition of Brace

This is a codification of an existing definition and therefore required no alternatives be considered.

We received no comments on the consideration of no alternatives to codifying the definition in regulation.

7. Refillable DMEPOS

We did not consider alternatives as this is existing policy that is being codified with additional leniencies based on prior experiences. We welcomed but did not receive any comments.

8. Provider Enrollment Provisions

We considered several alternatives for addressing our provider enrollment-related concerns regarding hospice program integrity and quality of care. We concluded that moving hospices to the high-risk screening category and expanding § 424.550(b) to include hospices were the most appropriate provider enrollment regulatory means of addressing these issues.

Except as discussed in section VIII. of this final rule, we received no comments on possible alternatives to our hospice provisions.

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 GG 8, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2024 HH PPS provisions of this rule.

TABLE GG 8: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2023 TO 2024

Category	Transfers
Annualized Monetized Transfers	$140 million
From Whom to Whom?	Federal Government to HHAs

2. HH QRP

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table GG 9, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule as they relate to HHAs. Table GG 9 provides our best estimate of the increase in burden for OASIS submission.

TABLE GG 9: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS OF OASIS ITEM COLLECTION, FROM CY 2023 TO CY 2025

Category	Costs
The net impact of the COVID-19 QM, Removal of the Application of Functional Assessment/Care Plan QM, and removal of the M0110 – Episode Timing and M2200-Therapy Need items	$5,123,430

3. Expanded HHVBP Model

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table GG 10 we have prepared an accounting statement Table GG 10 provides our best estimate of the decrease in Medicare payments under the expanded HHVBP Model.

TABLE GG 10: ACCOUNTING STATEMENT: EXPANDED HHVBP MODEL CLASSIFICATION OF ESTIMATED TRANSFERS FOR CYs 2023 – 2027

Category	Transfers	Discount Rate	Period Covered
Annualized Monetized Transfers	-$662.4 Million	7%	CYs 2023-2027
Annualized Monetized Transfers	-$669.7 Million	3%	CYs 2023-2027
From Whom to Whom?	Federal Government to Hospitals and SNFs		

4. 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 GG 11, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2024 IVIG provisions of this rule.

TABLE GG 11: ACCOUNTING STATEMENT: IVIG CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2023 TO 2024

Category	Transfers
Annualized Monetized Transfers	$8.7 million
From Whom to Whom?	Federal Government to DMEPOS suppliers

5. DMEPOS

a. Conforming Changes to Regulations To Codify Change Mandated by Section 4139 of the Consolidated Appropriations Act, 2023

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table GG 12, we have prepared an accounting statement showing the classification of the expenditures associated with this provision. Table GG 12 provides our best estimate of the transfers.

TABLE GG 12: ACCOUNTING STATEMENT: RELATED TO CODIFICATION OF CHANGES MANDATED BY SECTION 4139 OF THE CAA, 2023

Category	Transfers	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized	$53 million	2023	7%	CY 2023 – CY 2024
	$53 million	2023	3%	CY 2023 – CY 2024
From Whom to Whom	**Transfers from Federal Government to DME Suppliers**			
Annualized Monetized	$15 million	2023	7%	CY 2023 – CY 2024
	$15 million	2023	3%	CY 2023 – CY 2024
From Whom to Whom	**Transfers from Federal Government to Medicare Beneficiaries**			
Annualized Monetized	$2 million	2023	7%	CY 2023- CY 2024
	$2 million	2023	3%	CY 2023 – CY 2024
From Whom to Whom	**Transfers from State Government to Medicare Beneficiaries**			

b. Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table GG 13, we have prepared an accounting statement showing the classification of the expenditures associated with this provision. Table GG 13 provides our best estimate of the transfers.

TABLE GG 13: ACCOUNTING STATEMENT: RELATED TO LYMPHEDEMA COMPRESSION TREATMENT ITEM PROVISION

Category	Transfers	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized	$47 million	2023	7%	CY 2024 – CY 2028
	$50 million	2023	3%	CY 2024 – CY 2028
From Whom to Whom	Transfers from Federal Government to DME Suppliers			
Annualized Monetized	$1 million	2023	7%	CY 2024 – CY 2028
	$1 million	2023	3%	CY 2024 – CY 2028
From Whom to Whom	Transfers from Federal Government to Medicare Beneficiaries			
Annualized Monetized	$1 million	2023	7%	CY 2024- CY 2028
	$1 million	2023	3%	CY 2024 – CY 2028
From Whom to Whom	Transfers from State Government to Medicare Beneficiaries			

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 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 [222] and approximately 96 percent of HHAs are considered small entities. Table GG 14 shows the number of firms, revenue, and estimated impact per home health care service category.

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

TABLE GG 14: NUMBER OF FIRMS, REVENUE, AND ESTIMATED IMPACT OF HOME HEALTH CARE SERVICES BY NAICS CODE 621610

NAICS Code	NAICS Description	Enterprise Size	Number of Firms	Receipts ($1,000)	Estimated Impact ($1,000) per Enterprise Size
621610	Home Health Care Services	<100	5,861	210,697	$35.95
621610	Home Health Care Services	100-499	5,687	1,504,668	$264.58
621610	Home Health Care Services	500-999	3,342	2,430,807	$727.35
621610	Home Health Care Services	1,000-2,499	4,434	7,040,174	$1,587.77
621610	Home Health Care Services	2,500-4,999	1,951	6,657,387	$3,412.29
621610	Home Health Care Services	5,000-7,499	672	3,912,082	$5,821.55
621610	Home Health Care Services	7,500-9,999	356	2,910,943	$8,176.81
621610	Home Health Care Services	10,000-14,999	346	3,767,710	$10,889.34
621610	Home Health Care Services	15,000-19,999	191	2,750,180	$14,398.85
621610	Home Health Care Services	≥20,000	961	51,776,636	$53,877.87
621610	Home Health Care Services	Total	23,801	82,961,284	$3,485.62

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_2017" (SOURCE: 2017 County Business Patterns and Economic Census) Release Date: 5/28/2021: https://www2.census.gov/programs-surveys/susb/tables/2017/
Notes: Estimated impact is calculated as Receipts ($1,000)/Number of firms.

The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies finalized in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS final rule would have significant economic impact on a substantial number of small entities. We estimate that the net impact of the policies in this rule is approximately $140 million in increased payments to HHAs in CY 2024. The $140 million in increased payments are reflected in the last column of the first row in Table GG 14 as a 0.8 percent increase in expenditures when comparing CY 2024 payments to estimated CY 2023 payments. The 0.8 percent increase is mostly driven by the impact of the permanent behavior assumption adjustment reflected in the third column of Table GG 1. Further detail is presented in Table GG 1, by HHA type and location.

With regards to options for regulatory relief, we note that section 1895(b)(3)(D)(i) of the Act requires CMS to annually determine the impact of differences between the assumed behavior changes finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56455) and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Additionally, section 1895(b)(3)(D)(ii) and (iii) of the Act requires us to make permanent and temporary adjustments to the payment rate to offset for such increases or decreases in estimated aggregate expenditures through notice and comment rulemaking. While we find that the −2.890 percent permanent payment adjustment, described in section II.C.1.g. of this final rule, is necessary to offset the increase in estimated aggregate expenditures for CYs 2020 through 2022 based on the impact of the differences between assumed behavior changes and actual behavior changes, we would also continue to reprice claims, per the finalized methodology, and make any additional adjustments at a time and manner deemed appropriate in future rulemaking. We solicited comments on the overall HH PPS RFA analysis and received no comments.

Guidance issued by HHS interpreting the Regulatory Flexibility Act considers the effects economically 'significant' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. Among the over 7,500 HHAs that are estimated to qualify to compete in the expanded HHVBP Model, we estimate that the percent payment adjustment resulting from this rule would be larger than 3 percent, in magnitude, for about 28 percent of competing HHAs (estimated by applying the final 5-percent maximum payment adjustment under the expanded Model to CY 2019 data). As a result, more than the RFA threshold of 5-percent of HHA providers nationally would be significantly impacted. We refer readers to Tables 43 and 44 in the CY 2022 HH PPS final rule (86 FR 62407 through 62410) for our analysis of payment adjustment distributions by State, HHA characteristics, HHA size, and percentiles.

Thus, the Secretary has certified that this final rule would have a significant economic impact on a substantial number of small entities. Though the RFA requires consideration of alternatives to avoid economic impacts on small entities, the intent of the rule, itself, is to encourage quality improvement by HHAs through the use of economic incentives. As a result, alternatives to mitigate the payment reductions would be contrary to the intent of the rule, which is to test the effect on quality and costs of care of applying payment adjustments based on HHAs' performance on quality measures.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This 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 2023, that threshold is approximately $177 million. This final rule would not impose a mandate that would result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $177 million in any one year.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final 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 estimate that the provisions in this final rule would result in an estimated net increase in home health payments of 0.8 percent for CY 2024 ($140 million). The $140 million increase in estimated payments for CY 2024 reflects the effects of the CY 2024 home health payment update percentage increase of 3.0 percent ($525 million increase), a 0.4 percent increase in payments due to the new lower FDL ratio, which would increase outlier payments in order to target to pay no more than 2.5 percent of total payments as outlier payments ($70 million increase) and an estimated 2.6 percent decrease in payments that reflects the effects of the permanent behavior adjustment ($455 million decrease).

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 25, 2023.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Administrative practice and procedure, Grant programs-health, Health facilities, Health professions, Home health care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 409.50 [Amended]

■ 2. In § 409.50 amend paragraph (b) by removing the phrase ''for furnishing the Negative Pressure Wound Therapy (NPWT) using a disposable device'' and adding in its place the phrase ''for the disposable Negative Pressure Wound Therapy (NPWT) device''.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 3. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 4. Amend § 410.2 by adding the definitions of ''Brace'', ''Custom fitted gradient compression garment'', ''Gradient compression'', and ''Lymphedema compression treatment item'' in alphabetical order to read as follows:

§ 410.2 Definitions.

* * * * *

Brace means a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

* * * * *

Custom fitted gradient compression garment means a garment that is uniquely sized and shaped to fit the exact dimensions of the affected extremity or part of the body, of an individual to provide accurate gradient compression to treat lymphedema.

* * * * *

Gradient compression means the ability to apply a higher level of compression or pressure to the distal (farther) end of the limb or body part affected by lymphedema with lower, decreasing compression or pressure at the proximal (closer) end of the limb or body part affected by lymphedema.

Lymphedema compression treatment item means standard and custom fitted gradient compression garments and other items specified under § 410.36(a)(4) that are—

(1) Furnished on or after January 1, 2024, to an individual with a diagnosis of lymphedema for treatment of such condition;

(2) Primarily and customarily used to serve a medical purpose and for the treatment of lymphedema; and

(3) Prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act)) to the extent authorized under State law.

* * * * *

§ 410.10 [Amended]

■ 5. In § 410.10 amend paragraph (y) by removing the phrase ''globulin administered'' and adding in its place the phrase ''globulin, including items and services, administered''.

■ 6. Amend § 410.36 by revising paragraph (a)(3) and adding paragraph (a)(4) to read as follows:

§ 410.36 Medical supplies, appliances, and devices: Scope.

* * * * *

(a) * * *

(3)(i) Leg, arm, back, and neck braces.

(A) A leg brace may include a shoe if it is an integral part of the brace (necessary for the leg brace to function properly) and its expense is included as part of the cost of the brace.

(ii) Artificial legs, arms, and eyes; and

(iii) Replacements for the devices specified in paragraphs (a)(3)(i) and (ii) if required because of a change in the individual's physical condition.

(4) Lymphedema compression treatment items, including the following:

(i) Standard and custom fitted gradient compression garments.

(ii) Gradient compression wraps with adjustable straps.

(iii) Compression bandaging systems.

(iv) Other items determined to be lymphedema compression treatment items under the process established under § 414.1670.

(v) For the purposes of paragraphs (i) and (ii) of this paragraph, the scope of the benefit for lymphedema compression treatment items includes accessories such as zippers in garments, liners worn under garments or wraps with adjustable straps, and padding or fillers that are necessary for the effective use of a gradient compression garment or wrap with adjustable straps.

* * * * *

■ 7. Section 410.38 is amended by adding paragraph (d)(4) to read as follows:

§ 410.38 Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS): Scope and conditions.

* * * * *

(d) * * *

(4) *Refills*—(i) *Definitions.* As used in this paragraph (d):

Date of service (for refilled items) means either—

(*1*) The date of delivery for the DMEPOS item; or

(*2*) For items rendered via delivery or shipping service, the shipping date.

Refills mean DMEPOS products that are provided on a recurring basis secondary to a medically necessary DMEPOS order.

Shipping date means—

(*1*) The date the delivery/shipping service label is created; or

(*2*) The date that the item is retrieved for delivery. These dates must not demonstrate significant variation.

(ii) *Documentation.* The DMEPOS supplier must document contact with the beneficiary or their representative to verify the refill is needed. This documentation must include both of the following:

(A) Evidence of the beneficiary or their representative's affirmative response of the need for supplies, which should be obtained as close to the expected end of the current supply as possible. Contact and affirmative response must be within 30 calendar days from the expected end of the current supply.

(B)(*1*) For shipped items, the beneficiary name, date of contact, the item requested, and an affirmative response from the beneficiary, indicative of the need for refill, prior to dispensing the product; or

(*2*) For items obtained in-person from a retail store, the delivery slip signed by the beneficiary or their representative or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

(iii) *Delivery of DMEPOS items provided on a recurring basis.* The date of service for DMEPOS items provided on a recurring basis must be no earlier than 10 calendar days before the expected end of the current supply.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 8. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 9. Section 414.210 is amended by—

■ a. In paragraph (g)(2)(ii) introductory text, removing the phrase ''(42 U.S.C. 1320b–5(g)(1)(B)), whichever is later'' and adding in its place the phrase ''(42 U.S.C. 1320b–5(g)(1)(B)), or December 31, 2023, whichever is later'';

■ b. In paragraph (g)(2)(iii) introductory text, removing the phrase ''(42 U.S.C. 1320b–5(g)(1)(B)), whichever is later'' and adding in its place the phrase ''(42 U.S.C. 1320b–5(g)(1)(B)), or December 31, 2023, whichever is later'';

■ c. In paragraph (g)(9)(iii) removing the phrase ''from June 1, 2018 through December 31, 2020 or through the duration'' and adding in its place the phrase ''from June 1, 2018 through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) or December 31, 2023'';

■ d. Revising paragraph (g)(9)(v); and

■ e. In paragraph (g)(9)(vi), removing the date ''February 28, 2022'' and adding in its place the date ''January 1, 2024''.

The revision reads as follows:

§ 414.210 General payment rules.

* * * * *

(g) * * *

(9) * * *

(v) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) or December 31, 2023, whichever is later, based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under this section and 25 percent of the unadjusted fee schedule amount.

* * * * *

■ 10. Amend § 414.402 by revising the definition of ''Item'' to read as follows:

§ 414.402 Definitions.

* * * * *

Item means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes with or without modifiers, and includes the services directly related to the furnishing of that product to the beneficiary. Items that may be included in a competitive bidding program are as follows:

(1) DME other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.402, group 3 complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such wheelchairs, and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a).

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a).

(iii) Oxygen and oxygen equipment, as specified in § 414.226(c)(1).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME other than inhalation and infusion drugs.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

(5) Lymphedema compression treatment items.

* * * * *

■ 11. Amend § 414.408 by adding paragraph (g)(5) to read as follows:

§ 414.408 Payment rules.

* * * * *

(g) * * *

(5) Lymphedema compression treatment items.

* * * * *

■ 12. Amend § 414.412 by revising paragraph (b)(2) to read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * * *

(b) * * *

(2) The bid submitted for each lead item and product category cannot exceed the payment amount that would otherwise apply to the lead item under—

(i) Subpart C of this part, without the application of § 414.210(g);

(ii) Subpart D of this part, without the application of § 414.105; or

(iii) Subpart Q of this part, without the application of § 414.1690.

* * * * *

■ 13. Add subpart Q, consisting of §§ 414.1600 through 414.1690, to read as follows:

Subpart Q—Payment for Lymphedema Compression Treatment Items

Sec.

Subpart Q—Payment for Lymphedema Compression Treatment Items

§ 414.1600 Purpose and definitions.

(a) *Purpose.* This subpart implements section 1834(z) of the Act and establishes procedures for making benefit category determinations and payment determinations for lymphedema compression treatment items.

(b) *Definitions.* For purposes of this subpart the following definitions apply:

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of lymphedema compression treatment item at section 1861(mmm) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

Lymphedema compression treatment item means an item as described in § 410.2.

§ 414.1650 Payment basis for lymphedema compression treatment items.

(a) *General payment rule.* For items furnished on or after January 1, 2024, Medicare pays for lymphedema compression treatment items on the basis of 80 percent of the lesser of—

(1) The actual charge for the item; or

(2) The payment amount for the item, as determined in accordance with paragraph (b) of this section.

(b) *Payment amounts.* The payment amounts for covered lymphedema compression treatment items paid for under this subpart are established based on one of the following:

(1) If payment amounts are available from Medicaid state plans, then 120 percent of the average of the Medicaid payment amounts.

(2) If payment amounts are not available from Medicaid state plans, then 100 percent of the average of average internet retail prices and payment amounts from TRICARE (Department of Defense).

(3) If payment amounts are not available from Medicaid state plans or TRICARE, then 100 percent of average internet retail prices.

(c) *Updates to payment amounts.* The payment amounts for covered lymphedema compression treatment items established in accordance with paragraph (b) of this section are increased on an annual basis beginning on January 1 of the year subsequent to the year in which the payment amounts are initially established based on the percent change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending with June of the previous year.

§ 414.1660 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General rule.* If HCPCS codes for lymphedema compression treatment items are divided or combined, the payment amounts for the old codes are mapped to the new codes to ensure continuity of pricing.

(b) *Mapping of payment amounts.* (1) If there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, then the payment amounts that applied to the single code continue to apply to each of the items described by the new codes.

(2) If the codes for several different items are combined into a single code, then the payment amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the payment amounts for the formerly separate codes.

§ 414.1670 Procedures for making benefit category determinations and payment determinations for new lymphedema compression treatment items.

The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services paid for in accordance with this subpart are as follows:

(a) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item is statutorily excluded from coverage under Medicare under section 1862 of the Act.

(1) If not excluded by statute, then CMS determines whether the item is a lymphedema compression treatment item as defined under section 1861(mmm) of the Act.

(2) If excluded by statute, the analysis is concluded.

(b) If a preliminary determination is made that the item is a lymphedema compression treatment item, CMS makes a preliminary payment determination for the item or service.

(c) CMS posts preliminary benefit category determinations and payment determinations on *CMS.gov* approximately 2 weeks prior to a public meeting.

(d) After consideration of public consultation provided at a public meeting on preliminary benefit category determinations and payment determinations for items, CMS establishes the benefit category determinations and payment determinations for items through program instructions.

§ 414.1680 Frequency limitations.

(a) *General rule.* With the exception of replacements of items that are lost, stolen, or irreparably damaged, or if needed due to a change in the patient's medical or physical condition, no payment may be made for gradient compression garments or wraps with adjustable straps furnished other than at the frequencies established in paragraphs (b) and (c) of this section.

(b) *Initial furnishing of lymphedema compression treatment items.* The following frequency limitations apply to items initially furnished to the beneficiary if determined to be reasonable and necessary for the treatment of lymphedema:

(1) Three units of daytime gradient compression garments or wraps with adjustable straps per affected extremity or part of the body.

(2) Two garments for nighttime use per affected extremity or part of the body.

(c) *Replacements of lymphedema compression treatment items.* The

following frequency limitations apply to replacements of lymphedema compression treatment items if determined to be reasonable and necessary for the treatment of lymphedema:

(1) Payment for the replacement of gradient compression garments or wraps with adjustable straps per each affected extremity or part of the body can be made once every 6 months.

(2) Payment for the replacement of nighttime garments per each affected extremity or part of the body can be made once every 2 years.

(d) *Replacements of lymphedema compression bandaging systems or supplies.* Specific frequency limitations are not established for these items. Determinations regarding the quantity of compression bandaging supplies needed by each beneficiary are made by the DME MAC that processes the claims for the supplies.

§ 414.1690 Application of competitive bidding information.

The payment amounts for lymphedema compression treatment items under § 414.1650(b) may be adjusted using information on the payment determined as part of implementation of the programs under subpart F using the methodologies set forth at § 414.210(g).

■ 14. Add subpart R, consisting of § 414.1700, to read as follows:

Subpart R—Home Intravenous Immunoglobulin (IVIG) Items and Services Payment

§ 414.1700 Basis of payment.

(a) *General rule.* For home intravenous immunoglobulin (IVIG) items or services furnished on or after January 1, 2024, Medicare payment is made on the basis of 80 percent of the lesser of the following:

(1) The actual charge for the item or service.

(2) The fee schedule amount for the items and services, as determined in accordance with the provisions of this section.

(b) *Per visit amount.* A single payment amount is made for items and services furnished by a DME supplier per visit.

(c) *Initial establishment of the payment amount.* In establishing the initial per visit IVIG items and services payment amount for CY 2024, CMS used the CY 2023 bundled payment rate under the IVIG Demonstration updated by the home health payment percentage update for CY 2024.

(d) *Annual payment adjustment.* The per visit payment amount represents payment in full for all costs associated with the furnishing of home IVIG items and services and is subject to the following adjustment:

(1) Beginning in 2025, an annual increase in the per-visit payment amount from the prior year by the home health update percentage increase for the current calendar year.

(2) [Reserved]

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 15. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

■ 16. Amend § 424.502 by—

■ a. In the definition of ''Change in majority ownership''—

■ (i) Removing the term ''HHA'' and in its place adding the phrase ''HHA or hospice'' wherever it appears; and

■ (ii) Removing the term ''HHA's'' and in its place adding the phrase ''HHA's or hospice's'' wherever it appears.

■ b. Revising the definition of ''Managing employee''.

The revision reads as follows:

§ 424.502 Definitions.

* * * * *

Managing employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W–2 employee of the provider or supplier. For purposes of this definition, this includes, but is not limited to, a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director.

* * * * *

■ 17. Amend § 424.518 by—

■ a. Removing paragraph (b)(1)(iv);

■ b. Redesignating paragraphs (b)(1)(v) through (b)(1)(viii) as paragraphs (b)(1)(iv) through (b)(1)(vii);

■ c. Redesignating paragraph (b)(1)(xii) as paragraph (b)(1)(viii);

■ d. Revising newly redesignated paragraphs (b)(1)(viii) and (b)(1)(ix);

■ e. Removing paragraphs (b)(1)(x) through (b)(1)(xiv);

■ f. Revising (c)(1)(vi); and

■ g. Adding paragraphs (c)(1)(vii) and (viii).

The revisions and additions read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(b) * * *

(1) * * *

(viii) Prospective (newly enrolling) and revalidating opioid treatment programs that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since October 23, 2018.

(ix) Revalidating opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices to which CMS applied the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section upon the provider's or supplier's—

(A) New/initial enrollment; or

(B) Revalidation after CMS waived the fingerprinting requirements, under the circumstances described in paragraph (c)(1)(viii) of this section, when the provider or supplier initially enrolled in Medicare.

* * * * *

(c) * * *

(1) * * *

(vi) Prospective (newly enrolling) hospices.

(vii) Enrolled opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, DMEPOS suppliers, MDPP suppliers, HHAs, SNFs, and hospices that are submitting a change of ownership application pursuant to 42 CFR 489.18 or reporting any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42.

(viii) Except as stated in paragraph (b)(1)(ix) of this section, revalidating opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices for which, upon their new/initial enrollment, CMS waived the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section in accordance with applicable legal authority due to a national, state, or local emergency declared under existing law.

* * * * *

■ 18. Add § 424.527 to read as follows:

§ 424.527 Provisional period of enhanced oversight.

(a) *New provider or supplier.* Exclusively for purposes of both section 1866(j)(3) of the Act and this § 424.527, the term ''new provider or supplier'' is defined as any of the following:

(1) A newly enrolling Medicare provider or supplier. (This includes providers that are required to enroll as a new provider in accordance with the change in majority ownership provisions in § 424.550(b).)

(2) 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).

(3) 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.

(b) *Effective date.* The effective date of a provisional period of enhanced oversight that is commenced under section 1866(j)(3) of the Act is the date on which the new provider or supplier submits its first claim.

■ 19. Amend § 424.530 by—

■ a. In paragraph (f) introductory text removing the phrase ''3 years'' and adding in its place ''10 years''.

■ b. Adding paragraph (f)(3).

The revision and additions read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

* * * * *

(f) * * *

(3)(i) A provider or supplier that is currently subject to a reapplication bar under paragraph (f) of this section may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs.

(ii) Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a provider or supplier that is currently under a reapplication bar.

§ 424.540 [Amended]

■ 20. Section 424.540(a)(1) is amended by removing the number ''12'' and adding in its place the number ''6'' wherever it appears.

■ 21. Add § 424.542 to read as follows:

§ 424.542 Prohibition on ordering, certifying, referring, or prescribing based on felony conviction.

(a) *General prohibition.* A physician or other eligible professional (regardless of whether he or she is or was enrolled in Medicare) who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs.

(b) *Payment.* Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a physician or other eligible professional (as that term is defined in section 1848(k)(3)(B) of the Act) who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

■ 22. Amend § 424.550 by—

■ a. Revising paragraph (b)(1) introductory text;

■ b. In paragraph (b)(1)(i) removing the term ''HHA'' and adding in its place the phrase ''HHA or hospice'';

■ c. In paragraph (b)(2)(i) removing the phrase ''The HHA submitted two consecutive years'' and adding in its place the phrase ''The HHA or hospice submitted 2 consecutive years'';

■ d. In paragraph (b)(2)(ii), removing the term ''HHA's'' and adding in its place the phrase ''HHA's or hospice's'';

■ e. In paragraph (b)(2)(iii), removing the phrase ''The owners of an existing HHA are changing the HHA's'' and adding in its place the phrase ''The owners of an existing HHA or hospice are changing the HHA's or hospice's'';

■ f. In paragraph (b)(2)(iv) removing the term ''HHA'' and adding in its place the phrase ''HHA or hospice''.

The revision reads as follows:

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

* * * * *

(b) * * *

(1) Unless an exception in paragraph (b)(2) of this section applies, if there is a change in majority ownership of a home health agency (HHA) or hospice by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's or hospice's initial enrollment in Medicare or within 36 months after the HHA's or hospice's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA or hospice must instead do both of the following:

* * * * *

PART 484—HOME HEALTH SERVICES

■ 23. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 24. Section 484.202 is amended by revising the definition of ''Furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device'' to read as follows:

§ 484.202 Definitions.

* * * * *

Furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device means the device is paid separately (specified by the assigned CPT® code) and does not include payment for the professional services. The nursing and therapy services are to be included as part of the payment under the home health prospective payment system.

* * * * *

■ 25. Section 484.245 is amended by—

■ a. Redesignating paragraph (b)(2) as paragraph (b)(2)(i);

■ b. In newly redesignated paragraph (b)(2)(i), removing the phrase ''The data submitted'' and adding in its place the phrase ''*Data submission requirements.* The data submitted''; and

■ c. Adding paragraph (b)(2)(ii).

The addition reads as follows:

§ 484.245 Data submission requirements under the home health quality reporting program

* * * * *

(b) * * *

(2) * * *

(ii) *Data completion thresholds.* (A) A home health agency must meet or exceed the data submission threshold for each submission year (July 1 through June 30) set at 90 percent of all required OASIS or successor instrument records submitted through the CMS designated data submission systems.

(B) A home health agency must meet or exceed the data submission compliance threshold described in paragraph (b)(2)(ii)(A) of this section to avoid receiving a 2-percentage point reduction to its annual payment update for a given fiscal year described under § 484.225(b).

* * * * *

■ 26. Add § 484.358 to read as follows:

§ 484.358 HHVBP Measure removal factors.

CMS may remove a quality measure from the expanded HHVBP Model based on one or more of the following factors:

(a) Measure performance among HHAs is so high and unvarying that meaningful distinctions in

improvements in performance can no longer be made (that is, topped out).

(b) Performance or improvement on a measure does not result in better patient outcomes.

(c) A measure does not align with current clinical guidelines or practice.

(d) A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

(e) A measure that is more proximal in time to desired patient outcomes for the particular topic is available.

(f) A measure that is more strongly associated with desired patient outcomes for the particular topic is available.

(g) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(h) The costs associated with a measure outweigh the benefit of its continued use in the program.

■ 27. Amend § 484.375 by revising paragraph (b)(5) to read as follows:

§ 484.375 Appeals process for the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

* * * * *

(b) * * *

(5) *Reconsideration decision.* (i) CMS reconsideration officials issue a written decision that is final and binding upon issuance unless the CMS Administrator—

(A) Renders a final determination reversing or modifying the reconsideration decision; or

(B) Does not review the reconsideration decision within 14 days of the request.

(ii) An HHA may request that the CMS Administrator review the reconsideration decision within 7 calendar days of the decision.

(iii) If the CMS Administrator receives a request to review, the CMS Administrator must do one of the following:

(A) Render a final determination based on his or her review of the reconsideration decision.

(B) Decline to review a reconsideration decision made by CMS.

(C) Choose to take no action.

(iv) If the CMS Administrator does not review an HHA's request within 14 days (as described in paragraph (b)(5)(iii)(B) or (C) of this section), the reconsideration official's written reconsideration decision is final.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 28. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

Subpart M—Survey and Certification of Hospice Programs

■ 29. Amend § 488.1105 by adding the definitions of ''Hospice Special Focus Program (SFP)'', ''IDR'', ''SFP status'', and ''SFP survey'' in alphabetical order to read as follows:

§ 488.1105 Definitions.

* * * * *

Hospice Special Focus Program (SFP) means a program conducted by CMS to identify hospices as poor performers, based on defined quality indicators, in which CMS selects hospices for increased oversight to ensure that they meet Medicare requirements. Selected hospices either successfully complete the SFP program or are terminated from the Medicare program.

IDR stands for informal dispute resolution.

* * * * *

SFP status means the status of a hospice provider in the SFP with respect to the provider's progress in the SFP, which is indicated by one of the following status levels:

(1) Level 1—in progress.

(2) Level 2—completed successfully.

(3) Level 3—terminated from the Medicare program.

SFP survey means a standard survey as defined in this section and is performed after a hospice is selected for the SFP and is conducted every 6 months, up to 3 occurrences.

* * * * *

■ 30. Add § 488.1130 to read as follows:

§ 488.1130 Informal dispute resolution (IDR).

(a) *Opportunity to refute survey findings.* Upon the provider's receipt of an official statement of deficiencies, hospice programs can request an informal opportunity to dispute condition-level survey findings.

(b) *Failure to conduct IDR timely.* Failure of CMS, the State, or the AO, as appropriate, to complete IDR must not delay the effective date of any enforcement action.

(c) *Revised statement of deficiencies as a result of IDR.* If any findings are revised or removed by CMS, the State, or the AO based on IDR, the official statement of deficiencies is revised accordingly, and any enforcement actions imposed solely as a result of those cited deficiencies are adjusted accordingly.

(d) *Notification.* (1) If the survey findings indicate a condition-level deficiency, the hospice program is notified in writing of its opportunity for participating in an IDR process at the time the official statement of deficiencies is issued.

(2) The request for IDR must—

(i) Be submitted in writing;

(ii) Include the specific deficiencies that are disputed; and

(iii) Be made within the same 10 calendar day period that the hospice program has for submitting an acceptable plan of correction.

■ 31. Add § 488.1135 to read as follows:

§ 488.1135 Hospice Special Focus Program (SFP).

(a) *Applicability.* (1) The provisions of this section are effective on or after January 1, 2024. ; and

(2) SFP selection begins in CY 2024.

(b) *Selection criteria.* (1) Selection of hospices for the SFP is made based on the highest aggregate scores based on the algorithm used by CMS.

(2) Hospice programs with accrediting organization deemed status placed in the SFP—

(i) Do not retain deemed status; and

(ii) Are placed under CMS or State survey agency jurisdiction until completion of the SFP or termination.

(c) *Survey and enforcement criteria.* A hospice in the SFP—

(1) Is surveyed not less than once every 6 months by CMS or the State agency; and

(2) With condition level deficiencies on any survey is subject to standard enforcement actions and may be subject to progressive enforcement remedies at the discretion of CMS.

(d) *Completion criteria.* A hospice in the SFP that has two SFP surveys within 18 months with no condition-level deficiencies, and that has no pending complaint survey triaged at an immediate jeopardy or condition level, or that has returned to substantial compliance with all requirements may complete the SFP.

(e) *Termination criteria.* (1) A hospice in the SFP that does not meet the SFP completion requirements in paragraph (d) of this section is considered for termination from the Medicare program in accordance with 42 CFR 489.53.

(2) CMS may consider termination from the Medicare program in accordance with § 488.1225 if any survey results in an immediate jeopardy citation while the hospice is in the SFP.

(f) *Public reporting.* CMS posts all of the following at least annually on a CMS public-facing website:

(1) A subset of 10 percent of hospice programs based on the highest aggregate scores as determined by the algorithm used by CMS.

(2) Hospice SFP selection from the list in paragraph (f)(1) of this section as determined by CMS.

(3) SFP status as defined in § 488.1105.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 32. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

■ 33. Section 489.52 is amended by adding paragraph (b)(4) to read as follows:

§ 489.52 Termination by the provider.

* * * * *

(b) * * *

(4) A provider may request a retroactive termination date if no Medicare beneficiary received services from the facility on or after the requested termination date.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

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