Medicare Program; Calendar Year 2024 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health 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

(CMS-1780-F)

Summary of Final Rule

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I. Introduction

On November 1, 2023 the Centers for Medicare & Medicaid Services (CMS) placed the calendar year 2024[1] Home Health Prospective Payment System (HH PPS) on public display. The final rule will be published in the *Federal Register* on November 13, 2023. The final rule updates the payment rate for home health agencies (HHAs) for 2024 and also includes policies related to the hospice informal dispute resolution and special focus program; certain requirements for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); and provider and supplier requirements.

CMS finalizes a permanent, prospective adjustment to the 2024 home health payment rate to account for the impact of the implementation of the Patient-Driven Groupings Model (PDGM). Speifically, it finalized a -2.890 percent (half of the permanent -5.779 adjustment) permanent adjustment to the 2024 30-day payment rate as it believed that the full permanent reduction in a single year may be too burdensome for certain HHA providers. This adjustment accounts for any changes in aggregate expenditures resulting from the difference between assumed behavior changes and actual behavior changes, due to implementation of the PDGM and 30-day unit of payment.

CMS estimates that the net impact of the policies would increase Medicare payments to home health agencies (HHAs) in 2024 by 0.8 percent (+$140 million). This increase reflects the effects of the +3.0 percent home health payment update, an estimated 2.6 percent decrease from the prospective, permanent behavioral assumption adjustment of -2.890 percent,[2] and an estimated +0.4 percent from the update to the fixed-dollar loss ratio (FDL) used in determining outlier payments.

For the Home Health Quality Reporting Program (HH QRP), CMS finalizes adoption of two new measures, the removal of one measure and two OASIS items, and the public reporting of four measures. For the Expanded Home Health Value-Based Purchasing (HHVBP) Model, CMS finalizes the removal of five and addition of three quality measures as well as finalizes its proposals to update the Model baseline year to 2023 for all applicable measures in the measure set and to change the weights of individual measures in two of the measure categories.

[1] Henceforth in this document, a year is a calendar year unless otherwise specified.
[2] CMS finalizes a permanent behavior adjustment of -2.890 percent which applies only to the national, standardized 30-day period payments and does not impact payments for 30-day periods that are LUPAs. The estimated -2.6 percent includes all payments.

II. Home Health Prospective Payment System

A. Overview

CMS reviews the statutory and regulatory history of the HH PPS from 1997. Most recently, as required by the Bipartisan Budget Act of 2018 (BBA of 2018), on January 1, 2020, CMS implemented the home health Patient Driven Groupings Model (PDGM) and a 30-day unit of payment.

Medicare makes payment under the HH PPS based on a national, standardized 30-day period payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 30-day period rate includes 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), previously paid through a separate adjustment, is now part of the national, standardized 30-day period rate. Durable medical equipment provided as a home health service is not included in the national, standardized 30-day period payment. The 30-day period payment rate does not include payment for certain injectable osteoporosis drugs and negative pressure wound therapy (NPWT) using a disposable device; these drugs and services must be billed by the HHA while a patient is under a home health plan of care.

The PDGM is a patient case-mix adjustment methodology that shifts the focus from volume of services to a model that relies more on patient characteristics. It uses timing of episode, admission source, clinical groups based on principal diagnosis, level of functional impairment, and comorbidity to case-mix adjust payments resulting in 432 home health resource groups (HHRG). Patient characteristics and other clinical information are drawn from Medicare claims and the Outcome and Assessment Information Set (OASIS). Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care.

For low-utilization episodes, HHAs are paid national per-visit rates based on the discipline(s) providing the services; this payment adjustment is referred to as a low-utilization payment adjustment (LUPA). The national, standardized 30-day episode payment rate is also adjusted for certain intervening events that are subject to a partial episode payment (PEP) adjustment. In addition, an outlier adjustment may be available for certain cases that exceed a specific cost threshold.

B. Home Health Prospective Payment System

1. Monitoring the Effects of the Implementation of PDGM

Section 1895(b)(3)(D) of the Social Security Act (the Act) requires CMS to annually determine the impact of assumed versus actual behavioral changes on aggregate expenditures under the HH PPS for 2020 through 2026. Analysis for routine monitoring included analyzing: overall total 30-day periods of care and average periods of care per HHA user; the distribution of visits in a 30-day period of care; the percentage of periods that receive a LUPA; the percentage of 30-day

periods of care by clinical group, comorbidity adjustment, admission source, timing, and functional impairment level; and the proportion of 30-day periods of care with and without any therapy visits.

In the proposed rule, CMS examined simulated data for 2018 and 2019 and actual data for 2020, 2021, and 2022 for 30-day periods of care. One commenter stated there is a lack of data analysis and explanation by CMS indicating whether the appropriate level of care is being provided to beneficiaries. They also suggested that CMS should expand the data collected to include geographic, racial, ethnic, and other socioeconomic factors. CMS states in response to comments that it will continue to monitor and analyze home health tends and vulnerabilities with the HH PPS and will consider the additional monitoring suggested by the commenter.

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

Medicare covers intermittent/part-time personal care services and assistance with activities of daily living (ADL) provided by home health aides if a beneficiary is certified as needing a skilled service. CMS notes that as the population ages, the prevalence of chronic disease increases and the need for home-based dependent services increases.[3] CMS' monitoring, however, shows that home health aides visits have decreased in the past few years. In addition, CMS has heard that beneficiaries are having difficulty obtaining home health aide visits under the Medicare home health benefit.

To better understand the decline in utilization and improve the provision of the home health aide services under the home health benefit, CMS sought comment on home health agencies' recruitment and retention challenges, wage disparities, aide care impact and wage alignment, Medicare-Medicaid coordination, physicians' plans of care, and expected beneficiary outcomes, and how they might be interconnected.

CMS received a total of 85 comments where commenters highlighted a multitude of challenges and offered recommendations to improve the provision of home health aide services. Overall, commenters stated that the decline in the utilization in home health aide services is not indicative of a reduced need for such services. They stated that Medicare's current payment model, the PDGM, discourages HHAs from employing aides and providing necessary aide services. They state that this is particularly true for patients with high functional impairments and multiple comorbidities. Some commenters stated that HHAs engage in selective practices and strategic preference for serving lower acuity patients to maximize profits and 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.

For recruitment and retention challenges, commenters identified multiple barriers including low compensation, competition for labor in different job markets, inadequate/limited training opportunities, and demanding work conditions. Suggestions to overcome these barriers include

[3] Maresova P, Javanmardi E, Barakovic S, et al. Consequences of chronic diseases and other limitations associated with old age – a scoping review. BMC Public Health 19, 1431 (2019). https://doi.org/10.1186/s12889-019-7762-5.

improved compensation, including aide services more directly in care plans, providing advanced training, and establishing centralized systems for employee development.

Commenters stated that they believed a dual issue affected physicians' care plans for home health aide services including limited availability of aides to provide the aide services included on the care plans and that physicians were increasingly less likely to include home health aide services in care plans.

In reply, CMS states 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 HHS PPS, including how aides are paid, are more appropriately addressed to Congress. 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, CMS refers to the home health Conditions of Participation. Per the regulations, each patient is required to receive home health services as delineated in an individualized plan of care. It stresses that it is improper for an HHA to unduly influence a practitioner based on the HHA's service constraints. CMS states that the information provided may assist in policy development, addressing barriers, and fostering coordination under the home health benefit for future regulatory updates.

C. Provisions for Payment Under the HH PPS

1. Behavior Assumption Adjustments under the HH PPS

a. Background

As directed by section 1895(b)(2)(B) of the Act, beginning in 2020, CMS adopted a 30-day period of home health service in place of a 60-day period. Section 1895(b)(4)(B) of the Act further required CMS to eliminate use of therapy thresholds in assigning an episode to a case mix adjusted payment group. For 2020, section 1895(b)(3)(A)(iv) of the Act required CMS to adopt the change to a 30-day episode of care as budget neutral taking into account behavior changes from the new period of service and eliminating the use of therapy thresholds to assign a case to a payment group.

Section 1895(b)(3)(A)(iv) of the Act requires CMS to make a prospective adjustment for 2020 to maintain budget neutrality, while section 1895(b)(3)(D)(i) of the Act requires CMS to revisit the adjustment retrospectively for each year beginning with 2020 and ending with 2026. If CMS' retrospective review reveals that behavioral changes were different than assumed in the prospective adjustment, CMS is required to make both permanent and temporary adjustments to the home health rate to ensure aggregate spending neither increased or decreased as a result of the new unit of payment and elimination of therapy thresholds. The temporary adjustment is made to either recoup or repay past over or underspending, while the permanent adjustment ensures that future spending neither increased nor decreased relative to continuing the prior policies.

CMS applied a prospective budget neutrality adjustment including its behavior assumption of

-4.36 percent when setting the 2020 30-day payment rate of $1,864.03. CMS did not propose any changes for 2021 and 2022 relating to the behavior assumptions.

Section 4142(a) of the CAA, 2023 required CMS to present, to the extent practicable, a description of the actual behavior changes occurring under the HH PPS from CYs 2020-2026, the datasets underlying the simulated 60-day episodes, and provide for stakeholder input. It complied with these requirements by posting online the supplemental LDS and descriptive files and the description of actual behavior changes that affected the 2023 payment rate development. The agency also conducted a webinar on these issues on March 29, 2023.[4] It also notes that in the 2024 HH PPS proposed rule, it described the actual behavior changes identified through its analysis of 2020-2022 claims data, posted a descriptive statistics file, and made a file available for purchase that contained the simulated 60-day episodes and the actual 30-day periods.

b. Methodology

The final rule provides a detailed explanation of CMS' methodology and assumptions finalized in the 2023 HH PPS final rule to evaluate the differences between assumed and actual behavior changes on estimated aggregate expenditures. For 2020 through 2026, CMS will evaluate if the 30-day budget neutrality 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.

CMS provides an overview of the methodology and detailed instructions on each of the following steps.

- Create simulated 60-day episodes from 30-day periods;
- Price out the simulated 60-day episodes and determine aggregate expenditures;
- Price out only the 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; and
- Determine what the 30-day payment rate should have been to equal aggregate expenditures.

c. Calculating Permanent and Temporary Payment Adjustments

To calculate a permanent prospective adjustment, CMS determines what the 30-day base payment amount should have been in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes. This is the recalculated base payment rate. The percent change between the actual 30-day base payment rate and the recalculated 30-day base payment rate would be the permanent prospective adjustment.

To calculate a temporary retrospective adjustment for each year, CMS determines the dollar amount difference between the following:

[4] These materials can be found at https://www.cms.gov/medicare/medicare-fee-for-service-payment/homehealthpps/hh-pdgm

- Estimated aggregate expenditures from 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.

The temporary adjustment is applied on a prospective basis and applies only with respect to the year for which such temporary increase or decrease is made.

d. 2020 Results

This section discusses the final results CMS determined from 2020 claims data that was previously published in the 2023 HH PPS final rule (87 FR 66804 through 66805); it did not do any recalculations. Using its methodology, CMS simulated 60-day episodes using actual 2020 30-day periods to determine what the 2020 permanent and temporary payment adjustments should be to offset such increase or decreases in estimated aggregate expenditures. The final rule details the exclusions and assumptions that CMS needed to make to undertake this analysis. 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 2020.

CMS determined that a permanent prospective adjustment of -6.52 percent to the 2020 30-day payment rate would be required to offset such increases in estimated aggregate expenditures in future years. It also calculates that a temporary adjustment of $873 million would be required to achieve budget neutrality. Table B1 (reproduced below) details these results.

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: 2020 Home Health Claims Data. Periods that begin and end in 2020 accessed on the CCW July 12, 2021.
*This was the finalized 2020 base payment rate.
**This is what CMS determined the 2020 30-day base payment rate should have been.

e. 2021 Results

This section discusses the final results CMS determined from 2021 claims data that was previously published in the 2023 final rule (87 FR 66805 through 66806); CMS did not do any recalculations. It followed the same methodology described previously. 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 2021.

CMS determined that a permanent prospective adjustment of -1.42 percent to the 2021 30-day payment rate would be required to offset such increases in estimated aggregate expenditures in

future years. It also calculates that a temporary adjustment of $1.2 billion would be required to achieve budget neutrality. Table B2 (reproduced below) details these results.

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**
Base Payment Rate	$1,777.19*	$1,751.90	**Permanent** -1.42%
Aggregate Expenditures	$17,068,503,155**	$15,857,500,202	**Temporary** -$1,211,002,953
Source: 2021 Home Health Claims Data. Periods that begin and end in 2021 accessed on the CCW March 21, 2022. *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 B1) 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.			

f. 2022 Final Results

In the final rule, CMS updated its preliminary 2022 analysis presented in the proposed rule based on more complete data available from the latter half of 2022. It followed the same methodology described previously. 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 2022.

CMS determined that a permanent prospective adjustment of -1.767 percent to the 2022 30-day payment rate would be required to offset such increases in estimated aggregate expenditures in future years (this is higher than the -1.636 percent estimated in the proposed rule). It also calculates that a temporary adjustment of $1.405 billion would be required to achieve budget neutrality (about 3.7% higher than the $1.355 billion in the proposed rule). Table B3 (reproduced below) details these results.

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 * 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 wage index budget neutrality factor (1.0019) and the CY 2022 home health payment update (1.026).			

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**
** The estimated aggregate expenditures for assumed behavior ($16.6 billion), uses the actual CY 2022 payment rate of $2,031.64 as this is what CMS actually paid in CY 2022.			

g. 2024 Permanent and Temporary Adjustments

CMS calculates the 2024 permanent and temporary adjustments by combining the 2020, 2021, and 2022 permanent and temporary adjustments. In 2023, CMS implemented a -3.925 percent permanent behavior adjustment and must account for it in the 2024 permanent adjustment. CMS calculates that 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, it would need to apply a -5.779 percent permanent adjustment to the CY 2024 base payment rate. To calculate the temporary adjustment, CMS adds the 2022 temporary adjustment dollar amount of $1.405 billion to the previously finalized 2020 and 2021 dollar amounts for a total of $3.489 billion. These numbers were updated based on the revised 2022 permanent and temporary adjustments. It notes that applying the full permanent and temporary adjustment immediately would result in a significant negative adjustment in a single year.[5]

Detailed results are shown in Table B4 and B5.

Table B4: Total Permanent Adjustment for CYs 2020, 2021, and 2022		
Actual 2022 Base Payment Rate (Assumed Behavior)	**Recalculated 2022 Base Payment Rate (Actual Behavior)**	**Total Permanent Prospective Adjustment**
$2,031.64	$1,839.10	-9.48%*
Source: 2022 Home Health Claims Data. Periods that begin and end in 2022 accessed on the CCW July 15, 2023. *This is the total permanent adjustment based on 2022 data which did not have any previous behavior adjustments applied. As described above, 2024 must account for the adjustments made in 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: 2020 Home Health Claims Data, with periods that begin and end in 2020 accessed on the CCW July 12, 2021. 2021 Home Health Claims data, with periods that end in 2021 accessed on the CCW July 15, 2022. 2022 Home Health Claims Data, Periods that end in 2022 accessed on CCW July 15, 2023.			

[5] Based on the numbers provided in the rule, the percentage decrease in HHAs' payments would be more than 20 percent from the temporary adjustment alone (a $3.4 billion decrease from overall estimated HHA payments of $16.2 billion) if fully implemented in 2024.

CMS has the discretion to implement any behavior adjustment in a time and manner determined appropriate, and is finalizing only a −2.890 percent (half of the −5.779 percent) permanent adjustment for CY 2024 given the potential burden on some providers. This is consistent with the approach finalized in the CY 2023 HH PPS final rule. It notes that it will have to account for the remainder and any other potential adjustments needed to the base payment rate, to account for behavior change based on data analysis in future rulemaking. It also reminds 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.

Overall, commenters raised concerns that the proposed rate cut would be a threat to home health access. They cite evidence that HHA referrals for Medicare beneficiaries are increasingly being rejected and the number of patients referred to home health and subsequently admitted is dropping. In response, CMS stated that it looked closely at its data as maintaining access is one of its top priorities when making policy decisions. It raises doubts about the commenters' assertions as it cites data reported by MedPAC that HHAs, in general, continue to experience high profit margins and the increase in payments in 2021 far exceeded the increase in costs. Further, MedPAC estimates that the projected Medicare margin for HHAs for 2023 is 17 percent, which includes the statutory adjustment to the base payment rate. CMS also states that the commenters' analyses had methodological weaknesses. It does express concern, as some commenters claimed, that HHAs may be strategically admitting or denying beneficiaries to maximize their margins.

2. 2024 PDGM Low-Utilization Payment Adjustment (LUPA) Thresholds and PDGM Case-Mix Weights

a. 2024 PDGM LUPA Thresholds

Low utilization payment adjustments (LUPAs) are paid when a certain visit threshold for a payment group during a 30-day period of care is not met. LUPA thresholds are set at the 10th percentile value of visits or 2 visits, whichever is higher for each payment group. That is, the LUPA threshold for each 30-day period of care varies based on the PDGM payment group to which it is assigned. If the LUPA threshold is met, the 30-day period of care is paid the full 30-day period payment. If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment is made using the per-visit payment amount.

CMS adopted a policy that the LUPA thresholds would be updated each year based on the most current utilization data available. However, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID-19 PHE, CMS maintained the thresholds adopted for 2020 for 2022. In 2023, CMS updated the LUPA thresholds using 2021 home health claims linked to OASIS assessment data. For 2024, CMS finalizes its proposal to update the LUPA thresholds using 2022 home health claims utilization data (as of July 15, 2023).

The LUPA thresholds for the 2024 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in Table B12 of the final rule.

Some commenters continue to disagree with the policy to revaluate the LUPA thresholds annually, while other commenters suggested reducing the LUPA threshold for all case-mix groups to two visits or reassess the impact of using 2023 data before making any adjustments. CMS disagrees and notes that, consistent with its policy established in 2019, the LUPA threshold is set at the 10th percentile of visits or 2 visits, whichever is higher, and that it reevaluates this every year based on the most current utilization data.

b. 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 and risk of hospitalization. A home health period of care receives points based on responses from these functional OASIS items, which are converted to a table of points. The sum of all these points is used to group home health periods into low, medium, and high functional impairment levels, designed so that about one-third of home health periods fall within each level.

For 2024, CMS finalizes its proposal to use the 2022 claims data to update the functional points and functional impairment levels by clinical group and to use the same methodology previously finalized to update the functional impairment levels for 2024. The updated OASIS functional points table and the table of functional impairment levels by clinical group for 2024 are listed in Tables B7 and B8, respectively.

Several commenters opposed the proposed updates, with some recommending it be delayed until 2025 using post pandemic 2023 claims data. CMS disagreed and noted its current practice of yearly 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. Others continue to be concerned that the proposed functional inpatient levels do not accurately reflect the actual functional impairment levels of home health patients or the cost to provide care for higher acuity patients. Some questioned why it appears there would be a reduction in reimbursement for higher acuity patients. CMS notes in its response that, 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. CMS emphasizes that it expects the provision of services to be made to best meet the patient's care needs and thus HHAs should not 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 conditions of participation and could also subject HHAs to program integrity measures.

c. 2024 Comorbidity Groups

Thirty-day periods of care receive a comorbidity adjustment based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home health list of clinically and statistically significant secondary diagnosis subgroups with similar resource use. A comorbidity adjustment is applied to the 30-day period of care when there is the following: (1) low comorbidity adjustment – a reported secondary diagnoses on the health-

specific comorbidity subgroup list that is associated with higher resource use; or a (2) high comorbidity adjustment – two or more secondary diagnoses on the home health-specific comorbidity subgroup list.

For 2024, CMS finalizes a proposal to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using 2022 home health data. Using these data, CMS' final update to the comorbidity subgroups includes 22 low comorbidity adjustment subgroups and 102 high comorbidity adjustment interaction subgroups as identified in Tables B9 and B10 in the final rule.

A commenter requested clarification on the number of proposed low comorbidity subgroups for 2024 noting that the table in the proposed rule included 22 subgroups, but the preamble listed the number as 21. CMS clarifies that the subgroups listed in the table are accurate and the number of low comorbidity groups remains 22 for the final rule.

d. 2024 PDGM Case-Mix Weights

The PDGM case-mix methodology (as finalized in the 2019 HH PPS final rule) results in 432 unique case-mix groups called home health resource groups (HHRGs). CMS annually recalibrates the PDGM case-mix weights using a fixed effects regression model with the most recent and complete utilization data available at the time of annual rulemaking. For 2024, CMS finalizes its proposal to generate the recalibrated case-mix weights using 2022 home health claims data with linked OASIS assessment data (as of July 15, 2023). CMS believes that recalibrating the case-mix weights using data from 2022 would be reflective of PDGM utilization and patient resource use for 2024.

Table B11 in the final rule shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use for PDGM payment groups. The final 2024 case-mix weights are provided in Table B12 in the final rule and will also be posted on its HHA Center webpage.

To determine the case-mix budget neutrality factor for 2024, CMS continues its practice of using the most recent complete home health claims data at the time of rulemaking, which is 2022 data. CMS calculates a case-mix budget neutrality factor for 2024 of 1.0124.

Several commenters opposed recalibrating the PDGM case-mix weights for 2024 stating that annual updates create instability for home health agencies. CMS acknowledges their concerns but believes that prolonging recalibration, rather than doing so on an annual basis, could lead to more significant variation in the case-mix weights than what is observed using the most recent utilization data.

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

Beginning with CY 2024, CMS finalizes its proposal, without modification, to rebase and revise the 2016-based Home Health market basket cost weights to a 2021 base year reflecting 2021 Medicare cost report data submitted by freestanding HHAs.[6] CMS believes that 2021 represents the most recent and complete set of Medicare cost report data available. The cost reports are for providers with cost reporting periods beginning on or after October 1, 2020 and before October 1, 2021.

The final rule details the methodology used to rebase the market basket, which is generally the same methodology CMS used in creating the current 2016-based HHA market basket. That involves using Medicare cost report data to calculate weights for seven cost categories: Wages and Salaries; Employee Benefits; Transportation; Professional Liability Insurance; Fixed Capital; Movable Capital; and Medical Supplies.

A residual "All Other" category captures all remaining costs. Detailed weights are calculated for 8 categories within this residual by using the 2012 Benchmark Input-Output (I-O) "Use Tables/Before Redefinitions/Purchaser Value" for North American Industry Classification System (NAICS) 621600, HHAs, published by the Bureau of Economic Analysis (BEA). This data is publicly available at Input-Output Accounts Data | U.S. Bureau of Economic Analysis (BEA).

Table B15, reproduced below, compares the 2021-based home health market basket to the current 2016-based market basket cost weights. Overall, the home health market basket compensation cost weight decreased from 76.1 to 74.9 percent. 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 B15: Home Health Market Basket Cost Weights, Comparison of 2016 to 2021 Based Weights

Cost Category	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

[6] Freestanding HHAs account for about 93 percent of HHAs and CMS has determined that cost data for hospital-based HHAs can be affected by the allocation of overhead costs over the entire institution.

Table B15: Home Health Market Basket Cost Weights, Comparison of 2016 to 2021 Based Weights		
Cost Category	**2021-based**	**2016-based**
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

The price proxies are generally the same as used for the 2016-based market basket. For the medical supplies, CMS will 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 #WPU 1571), which would replace the current price proxy for the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code #WPU 156). For all the other categories, CMS will use the same proxy that was used for the 2016-based home health market basket. CMS provides a detailed discussion of the price proxies for each of the cost categories in the final rule.

Table B22, reproduced below, compares the percent change in the 2016-based and the 2021-based HHA market baskets for 2019 through 2026. Forecasted updates from 2023 through 2026 are the same on average; however, there is year-to-year variation of -0.1 percentage point for any given year.

Table B22: Comparison of the 2016 to 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

In general, most commenters supported the rebasing and revising of the home health market basket from a 2016 base year to a 2021 base year, but some asked CMS to consider rebasing the home health market basket to a later base year, such as 2022 or 2023, to more fully incorporate changes to HHA cost structures. CMS states the importance of periodically rebasing and revising the home health market basket and that the 2021 Medicare cost report data were the most complete at the time of 2024 rulemaking. It notes that the preliminary 2022 data suggest that a decline in the compensation weights may have continued.

4. 2024 Home Health Payment Rate Updates

a. 2024 Home Health Market Basket Update

The update will equal the projected increase in the market basket adjusted for changes in economy-wide productivity. Based on IHS Global Insight Inc.'s fourth-quarter 2023 forecast for 2024 with historical data through second-quarter 2023 and the 2021-based home health market basket, the HH PPS market basket update is as follows:

Market Basket Update	**Change (in %)**
Market basket forecast	3.3
Total factor productivity	-0.3
Net update for HHAs reporting quality data	**3.0**
Net update for HHAs NOT reporting quality data	**1.0**

As noted below, the final update factor also includes budget neutrality adjustments for the wage index and case-mix recalibration.

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 2021 through 2023. CMS disagrees and notes that due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, in evaluating the difference between the forecasted increase and actual data for the period 2012 through 2020 (excluding 2018 and 2020 which were set by statute), CMS found the forecasted market basket updates for each payment years for HHAs were higher than the actual market basket update.

b. Labor-Related Share

For 2024, CMS finalizes its proposal to update the labor-related share to reflect the 2021-based home health market basket compensation cost weights. The labor-related share is 74.9 percent and the non-labor related share is 25.1 percent. Table B23 in the final rule (reproduced below) detailed 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**
Wages and Salaries	65.1	64.2
Employee Benefits	10.9	10.7
Total Labor-Related	76.1	74.9
Total Non-Labor-Related	23.9	25.1

CMS states that the revised labor-related share will be implemented in a budget neutral manner through the use of a labor-related share budget neutrality factor so that aggregate payments do not increase or decrease due to these changes. The labor-related share budget neutrality factor for 2024 is 0.9998.

Some commenters expressed concern that the decrease in the labor-related share is in direct contradiction to their real-time experience that labor and associated costs continue to increase. Others were 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 report contract labor costs. CMS replies that these cost weights were calculated using the 2021 Medicare cost report data which is submitted by both rural and urban freestanding home health agencies and is the most comprehensive data source to determine the labor-related share. It also notes that the labor-related share has been trending downward since 2010, and preliminary Medicare cost report data from 2022 (reflects about 80 percent of HHAs) suggest that this trend may continue despite recent increases in utilization of contract labor.

c. 2024 Home Health Wage Index

CMS finalizes its proposal to continue to use the pre-floor, pre-reclassified hospital wage index as the wage index to adjust the labor portion of HH PPS rates for 2024, using FY 2020 hospital cost report data as its source for the updated wage data. The 2024 HH PPS wage index would not take into account any geographic reclassification of hospitals, but it would include the 5 percent cap on wage index decreases. In the 2023 HH PPS final rule (87 FR 66851 through 66853), CMS finalized for 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. In addition, if a geographic area's prior calendar year wage index is calculated based on the 5 percent cap, then the following year's wage index would not be less than 95 percent of the geographic area's capped wage index.

The final wage 2024 wage index is available on the CMS website at: https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.

d. 2024 Annual Payment Update

(1) Background

CMS discusses the methodology it uses to compute the case-mix and wage-adjusted 30-day period rates as set forth in §484.220. It first multiplies the national, standardized 30-day period rate by the patient's applicable case-mix weight. It then divides the case-mix adjusted amount into labor (74.9 percent) and non-labor (25.1 percent) portions. The labor portion is multiplied by the appropriate wage index based on the site of service and summed to the non-labor portion. These portions differ from prior years based on CMS' rebase of the home health market basket using 2021 Medicare cost report data.

Next, CMS may adjust the resulting 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect:

- A LUPA provided on a per-visit basis (§§484.205(d)(1) and 484.230).
- A partial episode payment (PEP) adjustment (§§484.205(d)(2) and 484.235).
- An outlier payment (§§484.205(d)(3) and 484.240).

Implementation of the PDGM and the 30-day unit of payment began in 2020, and CMS is required to annually analyze data (for 2020 through 2026) to assess the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. As discussed above, CMS 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.

(2) 2024 National, Standardized 30-Day Period Payment Amount

To determine the 2024 national, standardized 30-day period payment rate, CMS applies a permanent behavioral adjustment factor, case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor, labor-related share budget neutrality factor, and the home health payment update percentage. The 2024 30-day payment amount ($2,038.13) is 1.4 percent more than the 2023 30-day payment amount ($2,010.69).

The following table shows the standardized amounts, as displayed in Tables B24 and B25.

2024 National, Standardized 30-Day Episode Payment Amounts for HHAs		
	HHAs submitting quality data	HHAs not submitting quality data
2023 30-day budget neutral standardized amount	$2,010.69	
Permanent behavior adjustment factor	x 0.97110	
Case-mix weights recalibration neutrality factor	x 1.0124	
Wage index budget neutrality factor	x 1.0012	
Labor-Related Share Budget Neutrality Factor	x 0.9998	
HH payment update percentage	x 1.030	x 1.010
2024 30-day payment amount	**$2,038.13**	**$1,998.56**

(3) 2024 National Per-Visit Rates for 30-Day Periods of Care

Computations are presented for the 2024 per-visit amounts for each type of service. These amounts are used for LUPAs and in outlier calculations. The per-visit amounts for those HHAs submitting the required quality data (Table B26 in the final rule) are as follows:

2024 National, Per-Visit Payment Amounts for HHAs that Submit Quality Data					
HH Discipline	**CY 2023 Per-Visit Rates**	**Wage Index Budget Neutrality Factor**	**Labor-Related Share Budget Neutrality Factor**	**CY 2024 HH Payment Update Factor**	**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

HHAs that do not submit required quality data would have the payment update for per-visit services reduced from 3.0 percent to 1.0 percent, resulting in the following payment rates (Table B27 in the final rule):

2024 National, Per-Visit Payment Amounts for HHAs that Submit Quality Data					
HH Discipline	**CY 2023 Per-Visit Rates**	**Wage Index Budget Neutrality Factor**	**Labor-Related Share Budget Neutrality Factor**	**CY 2024 HH Payment Update Factor**	**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

(4) LUPA Add-on Factors

Under previously adopted policy, to determine the LUPA add-on payment for a 30-day period of care, CMS multiplies the per-visit payment amount for the first skilled nursing, PT, or speech-language pathology (SLP) visit in a LUPA period that is the first 30-day period of care or the initial 30-day period of care in a sequence of adjacent periods. The add-on factors are 1.8451 for skilled nursing, 1.6700 for PT, and 1.6266 for SLP. For example, if the first skilled visit is

skilled nursing, the payment for that visit for HHS that submit the required quality data would be $309.85 (1.8451 multiplied by $167.93)

(5) Occupational Therapy LUPA Add-On Factor

CMS finalized changes to regulations at §§484.55(a)(2) and 484.55(b)(3) to implement requirements of CAA 2021 in the 2022 HH PPS final rule. These revisions allow OTs to conduct initial and comprehensive assessments for all Medicare beneficiaries under the home health benefit when the plan of care does not initially include skilled nursing care but includes either PT or SLP. Because of this change, CMS established a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled OT visit in LUPA periods that occurs as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care. Because CMS did not have sufficient data to estimate an OT specific LUPA add-on factor, CMS finalized the PT LUPA add-on factor of 1.6700 as a proxy until it has 2022 data to establish a more accurate OT add-on factor. CMS states that it is analyzing the 2022 data and will continue to use the PT LUPA add-on factor for OT LUPAs and plans to propose a LUPA add-on factor, specific to OT in future rulemaking.

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

Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a threshold amount. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and a wage-adjusted fixed-dollar loss (FDL) amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost for the episode that surpasses the wage-adjusted threshold; this proportion is referred to as the loss-sharing ratio.

CMS notes that the FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the aggregate level of 2.5 percent of estimated total HH PPS payments as required by statute. CMS has historically used a value of 0.80 for the loss-sharing ratio, meaning that Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount. No changes were proposed to the loss-sharing ratio for 2024.

For 2024 payment, CMS finalizes an FDL ratio of 0.27 for 2024 based on analysis of 2022 claims data (as of July 15, 2023). CMS also reviews the history of HH PPS policy regarding outlier payments. In the 2017 HHS PPS final rule (81 FR 76702), CMS finalized changes to its methodology used to calculate outlier payments, switching from a cost-per-visit approach to a cost-per-unit approach. CMS now converts the national per-visit rates into per 15-minute unit rates. CMS also limits 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. CMS will publish the cost-per-unit amounts for 2024 in the rate update change request to be issued after the publication of the 2024 HH PPS final rule.[7]

[7] The per-unit amounts for 2023 are found in the November 10, 2022 HH PPS change request: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/transmittals/r11702cp

5. Disposable Negative Pressure Wound Therapy

a. 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 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.

Coverage for dNPWT is determined based upon a doctor'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 to best achieve wound healing.

b. Current Payment for Negative Pressure Wound Therapy using a Disposable Device

Under current policy, CMS pays a separate payment amount for dNPWT 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 includes furnishing the service as well as the dNPWT device. 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.

In instances where the sole purpose of a home health visit is to furnish dNPWT, Medicare does not pay for the visit 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.

c. CAA, 2023

Under statute, Division FF, section 4136 of the CAA, 2023 (Pub. L.117-328) amended section 1834 of the Act (42 U.S.C. 1395m(s)), and mandated several amendments to the Medicare separate payment for dNPWT devices beginning in 2024. It requires that CMS establish a separate payment amount for an applicable dNPWT device equal to the supply price used to determine the relative value for the service under the Physician Fee Schedule (PFS). This payment amount would be adjusted by an inflationary factor less a productivity adjustment. Specifically, the percent increase in the CPI–U for the 12-month period ending with June of the preceding year minus the productivity adjustment (as described in section 1886(b)(3)(B)(xi)(II)) for such year. Payment for 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.

The statue also required that CMS change its claims processing for the separate payment amount for an applicable disposable device. Claims for these devices will now be accepted and processed on claims submitted (on or after January 1, 2024) 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), and not TOB 34x.

d. Payment Policies for dNPWT Devices

For the purposes of paying for a dNPWT device for a patient under a Medicare home health plan of care, CMS finalizes its proposal that the payment amount for 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 is $263.25. Therefore, the payment amount for 2024 would 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 this period is 3.0 percent and the corresponding productivity adjustment is 0.4 percent (IHS Global Inc.’s third quarter 2023 forecast). Thus, the final update percentage will be 2.6 percent.

The 2024 payment for dNPWT devices under Medicare home health plan of care will be $270.09 ($263.25*1.026).

CMS also finalizes its proposal 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 type of bill TOB 32. The code HCPCS A9272 is defined as a wound suction, disposable, includes dressing, all accessories and components, any type, each. CMS states that it 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.

Services related to the application of the device will be included in the HH PPS and would be excluded from the separate payment amount for the device. In addition, only the home health services for the administration of the device will be geographically adjusted and the payment amount for HCPCS A9272 will not be subject to geographic adjustment.

Commenters were generally supportive of the proposals to codify the statutorily mandated changes to dNPWT for beneficiaries under a home health plan of care. Another commenter requested clarification regarding which practitioners are authorized to order dNPWT and wanted to ensure that nurse practitioners (NP), clinical nurse specialists (CNS), and physician assistants (PAs) are authorized to establish, review, and certify home health plans of care that include dNPWT. CMS replies that "allowed practitioner" was inadvertently omitted from the dNPWT preamble language, which would include NPs, CNSs, and PAs. Allowed practitioners can certify and recertify beneficiaries for eligibility, order home health services (including dNPWT), and establish and review the plan of care. CMS also provides further clarification regarding the billing process for dNPWT.

III. Home Health Quality Reporting Program (HH QRP)

A. Statutory Authority, Background, and Overview

The HH QRP[8] is a pay-for-reporting program authorized under section 1895(b)(3)(B)(v) of the Act. Under the program the annual HH market basket percentage increase is reduced by 2 percentage points for HHAs that do not report required quality data.[9] The program was modified by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), which added requirements for HHAs to begin entering standardized patient assessment data elements (SPADEs) into the HH assessment tool, the Outcome and Assessment Information Set (OASIS). The SPADEs are grouped into categories, one of which aggregates social determinants of health (SDOH) and currently includes SPADEs for race, ethnicity, language preference, health literacy, transportation needs, and social isolation.

In the final rule, beginning with the CY 2025 HH QRP, CMS finalizes its proposals to:

- Adopt 2 new measures (the Discharge Function Score (DC Function) measure and the Patient/Resident COVID-19 Vaccine);
- Remove the Application of Functional Assessment/Care Plan Measure;
- Remove 2 OASIS items;
- Begin public reporting of 4 measures in the HH QRP; and
- Codify its 90 percent data submission threshold policy.

[8] More information on the HH QRP can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits.

[9] Depending on the HH market basket percentage increase applicable for a particular year, as further reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, the 2 percentage-point reduction may result in the market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the HH PPS for a year being less than payment rates for the preceding year.

CMS also provides an update on its efforts to close the health equity gap, and discusses responses to its request for information on principles that could be used to select and prioritize HH QRP quality measures in future years.

CMS estimates that, beginning with January 1, 2025 HHA discharges, these changes to the HH QRP will result in a net reduction of 58,540.1 hours of clinician burden across all HHAs (5 hours for each of the 11,700 active HHAs) and a net reduction of $5,123,430 across all HHAs ($438 reduction for each HHA).

B. General Considerations Used for the Selection of Quality Measures

CMS refers readers to the CY 2016 HH PPS final rule[10] for considerations it uses for measure selection for the HH QRP quality, resource use, and other measures, and to the CY 2019 HH PPS final rule[11] for the removal factors considered for removing HH QRP measures.

C. Table of Measure Set Adopted for the CY 2024 and Newly Finalized for CY 2025

The table below lists the current HH QRP measures, based on Table C1 of the rule, with finalized changes for CY 2025 HH QRP shown.

Short Name	Measure Full Name & Data Source
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 HH 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) Home Health Quality Reporting Program
Dyspnea	Improvement in Dyspnea
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medication (CBE #0176)
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation of Care (CBE #0526)
ToH-Patient *	Transfer of Health Information to the Patient-PAC Measure
ToH-Provider *	Transfer of Health Information to the Provider-PAC Measure
DC Function ##	*Discharge Function Score*
Patient/Resident COVID-19 Vaccine ##	*COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date*
** Data collection delayed due to COVID-19 PHE.* *# Finalized removal beginning with CY 2025 HH QRP* *## Finalized addition beginning with CY 2025 HH QRP*	
Claims-based	
ACH	Acute Care Hospitalization During the First 60 Days of Home Health (CBE #0171) ***

[10] 80 FR 68695 through 68696.
[11] 83 FR 56548 through 56550.

Short Name	Measure Full Name & Data Source
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of Home Health (CBE #0173) ***
PPH	Home Health Within Stay Potentially Preventable Hospitalization
DTC	Discharge to Community-Post Acute Care (PAC) HH QRP (CBE #3477)
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB) –PAC HH QRP
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP
**** Note that in the CY 2022 HH PPS Rate Update Final Rule (86 FR 62340-62344), the ACH and ED Use measures were replaced by the PPH measure beginning with the CY 2023 HH QRP, though the measures are included in Table C1 of this rule.*	
HHCAHPS-based (CAHPS Home Health Care Survey CBE #0517)**	
Communication	How well did the home health team communicate with patients
Overall Rating	How do patients rate the overall care from the home health agency
Professional Care	How often the home health team gave care in a professional way
Team Discussion	Did the home health team discuss medicines, pain, and home safety with patients
Willing to Recommend	Would patients recommend the home health agency to friends and family
***The HHCAHPS has 5 components (all listed) that together are used to represent one measure.*	

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

1. Addition of Discharge Function Score (DC Function) Measure

Overview. CMS finalizes its proposal to adopt the DC Function measure to replace the topped-out Application of Function Assessment/Care Plan measure (finalized for removal under section III.D.2. of the rule), beginning with the CY 2025 HH QRP.

In the CY 2018 HH PPS final rule,[12] CMS adopted, consistent with the requirements of the IMPACT Act of 2014,[13] the Application of Function Assessment/Care Plan process measure, a cross-setting process measure that allowed for the standardization of functional assessments across assessment instruments. However, performance on the measure has been so high and unvarying across the PAC settings, including most HH providers, that the measure no longer provides for a meaningful distinction in performance (i.e., the measure is "topped out").

The newly adopted DC Function measure is an assessment-based outcomes measure that evaluates functional status by calculating the percentage of HH patients who meet or exceed an expected discharge function score. The measure uses a set of cross-setting assessment items, which will facilitate data collection, quality measurement, outcome comparison, and interoperable data exchange among PAC settings. The measure considers two dimensions of function (self-care and mobility activities) and accounts for missing data by recoding missing functional status data to the most likely value had the status been assessed (i.e., using statistical imputation), based on a patient's clinical characteristics and codes assigned on other standardized functional assessment data elements. This is in contrast to the topped-out measure, which treats patients with missing values the same as patients who were coded to the lowest functional status.

[12] 82 FR 51722 through 51725.
[13] The IMPACT Act required CMS to develop and implement standardized quality measures from 5 quality measure domains (including functional status, cognitive function, and changes in function and cognitive function) across the PAC settings.

There will be no additional provider burden since the newly adopted measure is calculated using standardized patient assessment data from the OASIS that are already reported for payment and quality reporting purposes.

Measure Calculation. The DC Function measure is calculated as follows:

- *Numerator*. The number of HH episodes with an observed discharge function score that is equal to or greater than the calculated expected discharge function score.
    - The observed discharge function score is the sum of individual function item values at discharge.
    - The calculated expected discharge function score is computed by risk-adjusting (for resident characteristics, such as admission function score, age, and clinical conditions) the observed discharge function score for each HH episode.
- *Denominator*. The total number of HH stays in the measure target period (four rolling quarters) that do not meet the measure exclusion criteria.
- *Exclusion Criteria*. The following episodes are excluded: (1) Patients with incomplete stays; (2) Patients in a coma or certain other states; (3) Patients under 18 years of age; and (4) Patients discharged to hospice.

Selected Comments/Responses. In response to comments encouraging greater transparency on the expected score calculations, CMS responded that it anticipates baseline performance for CY 2023 will be shared in July 2024 as part of the HH VBP Model. Another comment suggested CMS consider alternative assessments that better incorporate cognition and communication into the measure calculation. CMS responded that the measure indirectly captures an HHA's ability to impact a patient's cognition and communication to the extent they are correlated to self-care and mobility improvements. However, the agency also noted that the HH QRP measures are regularly assessed and that it will consider feedback going forward on how to measure communication and cognition.

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 (Application of Functional Assessment/Care Plan) Measure

Overview. CMS finalizes its proposal to remove the Application of Function Assessment/Care Plan measure as a topped-out measure and replace it with the DC Function measure beginning with the CY 2025 HH QRP.

- Public reporting on the measure will end by January 2025 or as soon as technically feasible, when public reporting of the finalized DC Function measure will begin (see section III.F.2. of the rule).
- HHAs will not be required to report a Self-Care Discharge Goal (GG0130, Column 2) or a Mobility Discharge Goal (GG0170, Column 2) on the OASIS beginning with patients with a start of care or resumption of care (SOC/ROC) on January 1, 2025.
- CMS will remove the items for Self-Care Discharge Goal and Mobility Discharge Goal with the next release of the OASIS so that the items will not be required beginning with the CY 2025 HH QRP.

The removal is based on the measure satisfying measure removal factor 1 (the measure is "topped out")[14] and measure removal factor 6 (there is an available measure that is more strongly associated with desired resident functional outcomes, i.e., the DC Function measure adopted in section III.D.1, which has the predictive ability to distinguish patients with low expected functional capabilities from those with high expected functional capabilities).[15]

Selected Comments/Responses. All commenters supported the removal.

3. COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) Measure

Overview. CMS finalizes its proposal to adopt the Patient/Resident COVID-19 Vaccine measure beginning with the CY 2025 HH QRP.

CMS describes how COVID-19 remains a major challenge to PAC facilities, including HHAs. CMS details that studies have shown vaccinations against COVID-19 provide strong protection against severe disease, hospitalization, and death. The agency also describes multiple studies that have shown protection is higher among individuals receiving booster doses than among those only receiving the primary series. Yet, CMS describes there was a significantly higher rate of vaccination for the primary vaccination series as compared to boosters. CMS also describes variations in vaccination rates by race, gender, and geographic location.

CMS outlines the adopted measure's importance to:

- Increase the rate of vaccination of HHA patients to reduce the spread of the virus;
- Support the goal of CMS' Meaningful Measure Initiative 2.0;
- Assist patients and caregivers with informed decision-making; and
- Provide care coordination and education at discharge about vaccination.

Measure Calculation.[16] The adopted measure is an assessment-based process measure that reports the percent of HH patients who are up to date[17] on their COVID-19 vaccinations per the CDC's latest guidance. The measure has no exclusions and is not risk adjusted.

- *Numerator*. Total number of HH patients who are up to date with their COVID-19 vaccination (per CDC's latest guidance) during the reporting period.
- *Denominator*. Total number of HH stays with an End of Care OASIS (Discharge, Transfer or Death at Home) during the reporting period.
- *Data Source*. The OASIS instrument for HH patients.

[14] The average performance rates on the measure over the 3-year period (2019-2021) have been near 100 percent, indicating the measure has "topped out," and the measure no longer provides for any variation that would show distinction among HHAs.
[15] 42 CFR 484.245(b)(3) specifies the eight factors considered for measure removal from the HH QRP.
[16] For additional details on the technical information about the measure, see HH QRP Patient COVID-19 Vaccine Measure Specifications (cms.gov).
[17] The definition of "up to date" can be found on the CDC webpage, "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).

Selected Comments/Responses. Some commenters opposed the measure because it does not have exclusions, while others opposed the measure because of burden concerns. CMS justifies the lack of exclusions, pointing to input from a patient and family/caregiver advocate focus group during the pre-rulemaking process that supported a measure of raw vaccination rates as being most helpful in resident and family/caregiver decision-making. With respect to the burden concern, the agency responded that HHAs should be assessing the data required for the measure as part of routine care and infection control processes and that CMS has heard that HHAs are routinely inquiring about COVID-19 vaccination status as part of those processes.

Other commenters opposed the measure because it has not been tested for validity and reliability. CMS intends to complete such testing once the COVID-19 vaccination item has been added to the OASIS and it has collected sufficient data. Since the item does not yet exist within OASIS, the agency tested item-level reliability of a draft Patient/Resident COVID-19 Vaccine measure using clinical vignettes it developed as a proxy for patient records with the most common and challenging cases HHAs would encounter. The results showed strong agreement.

Many commenters raised concern that HHAs cannot control patient decisions around vaccinations and therefore HHAs do not have control to affect the measure. CMS restates the intent of the measure is to provide information to patients and their caregivers for informed decision-making.

E. Form, Manner, and Timing of Data Submission

1. Final Schedule for Data Submission of the DC Function Measure

For the DC Function measure finalized in section III.D.1. of the rule, CMS finalizes that:

- For the CY 2025 HH QRP, HHAs will report the OASIS assessment data beginning with patients discharged between January 1, 2024 and March 31, 2024.
- No additional information collection will be required from HHAs since the measure is calculated based on data already submitted to Medicare.

2. Final Schedule for Data Submission of Patient/Resident COVID-19 Vaccine Measure

For the Patient/Resident COVID-19 Vaccine measure finalized in section III.D.3. of the rule, HHAs will be required to report the OASIS assessment data beginning with patients discharged between January 1, 2025 and March 31, 2025 for public reporting of the measure in the CY 2026 HH QRP.

3. Data Elements for Removal from OASIS-E

CMS finalizes its proposal to remove, effective January 1, 2025, two OASIS items – the M0110 Episode Timing and the M2220 Therapy Needs – explaining that the items are no longer used to calculate any of the measures in the HH QRP or for other purposes unrelated to the HH QRP.

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

1. Background

Section 1899B(g) of the Act requires the Secretary to publicly report PAC provider, including HHA, performance on the quality measures on which the respective provider must report. Information with respect to a measure and PAC provider must be made publicly available not later than 2 years after the specified date applicable to the measure and provider. Measure data are publicly displayed on the Care Compare website.

2. Public Reporting of DC Function Measure Beginning with the CY 2025 HH QRP

CMS finalizes its proposal for public display of data for the DC Function measure to begin with the January 2025 refresh of Care Compare, or as soon as technically feasible, using data collected from April 1, 2023 through March 31, 2024. 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. CMS will not publicly report an HHA's performance on the measure for a quarter if the HHA had fewer than 20 eligible cases.

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

These measures were adopted in the FY 2020 IPPS/LTCH PPS final rule,[18] but because of the COVID-19 PHE the compliance date for the collection and reporting of the measures was delayed.

CMS finalizes that public display of data for the measures will begin with the January 2025 refresh of Care Compare (or as soon as technically feasible) based on 4 rolling quarters, initially using discharges from April 1, 2023 through March 31, 3024. CMS will not publicly report an HHA's performance on the measures for a quarter if the HHA had fewer than 20 eligible cases.

4. Public Reporting of Patients/Residents COVID-19 Vaccine Measure Beginning with the CY 2026 HH QRP

CMS finalizes that public display of data for this measure will begin with the January 2026 refresh of Care Compare (or as soon as technically feasible) using data collected for January 1, 2025 through March 31, 2025. Provider preview reports will be distributed in October 2025, or as soon as technically feasible. The percent of patients who are up to date on their COVID-19 vaccinations will be displayed based on one quarter of data and updated quarterly. CMS will not publicly report an HHA's performance on the measures for a quarter if the HHA had fewer than 20 eligible cases.

[18] 84 FR 42525 through 42535.

G. Health Equity Update

Background. The agency describes goals outlined in the CMS *Framework for Health Equity 2022-2023*[19] as consistent with Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government."[20] CMS seeks to advance health equity (HE)[21] and whole-person care. The CMS National Quality Strategy (NQS) identifies potential methods of supporting the advancement of equity, including by establishing a standardized approach for patient-reported data and stratification; using quality programs and VBP to close equity gaps; and developing equity-focused data collections, regulations, oversight strategies, and quality improvement initiatives. CMS further describes that stratification, by looking at measure results for different populations separately (rather than at an overall score), helps it to better fulfill its HE goals.

In the CY 2023 Home Health Payment Rate Update (HH PRU) proposed rule,[22] CMS included an RFI on several questions related to a proposed HE measure concept and a potential HE structural composite measure.

HH and Hospice Health Equity (HE) Technical Expert Panel (TEP). After consideration of comments in response to the RFI in the CY 2023 HH PRU proposed rule, the HH and Hospice HE TEP was convened in the fall of 2022 to provide input on a potential cross-setting HE structural composite measure concept presented in the RFI, as well as to provide input for additional HE measure concepts in the HH and hospice settings.[23]

Anticipated Future HE Activities. CMS is considering different approaches to incorporate HE into the HH QRP. The agency describes considering HE measures used in other settings. The SDOH data for PACs under the IMPACT ACT, which are collected as SPADES on the OASIS, are different from SDOH data used in the acute care HE quality measures. The data collected on SPADES assess health literacy, social isolation, transportation problems, preferred language, race, and ethnicity, whereas the SDOH domains for screening used in the acute care settings include housing instability, food instability, transportation needs, utility difficulties, and interpersonal safety. Consistent with the goal to align quality measures across care settings, CMS may consider adding into the HH QRP the SDOH data items used in the acute care setting. CMS explains that while some of its future HE efforts will be through rulemaking, others will be through subregulatory methods.

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[19] https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.
[20] Executive Order 13985 can be found at: Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government | The White House.
[21] CMS describes 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."
[22] 87 FR 66866.
[23] A summary of the HH and Hospice HE TEP meetings and recommendations is available at 2022 Technical Expert Panel Meetings: Home Health & Hospice Health Equity Summary Report (cms.gov).

H. Finalizing Codification of HH QRP Data Completion Thresholds

Background. Under section 1895(b)(3)(B)(v) of the Act, the annual HH market basket percentage increase otherwise applicable to an HHA for a year is reduced by 2 percentage points if the HHA does not satisfy the pay-for-reporting requirement by reporting required quality data for the year. HHAs are required to score at least 90 percent on the Quality Assessment Only (QAO) metric of the pay-for-reporting performance requirement. CMS proposed in the 2018 HH PPS final rule[24] to apply the 90 percent threshold to the submission of SPADEs beginning with the CY 2019 HH QRP.

Overview. CMS finalizes its proposal to codify these already-finalized data completeness thresholds at §484.245(b)(2)(ii), but with a language change suggested pursuant to public comments received (discussed below). Specifically, the agency is codifying at that section that HHAs must submit through the CMS designated data submission systems at least 90 percent of all required OASIS data, both quality measure data and SPADES, to avoid receiving the 2-percentage point reduction.

Selected Comment/Response. The language proposed for codification included a reference that submissions be "within 30 days of the beneficiary's admission or discharge". Several commenters suggested the removal of such language since a strict 30-day deadline is not the only factor in the application of submission requirements during the calculation of quality assessments only (QAO) compliance. CMS agrees with the suggestion since the change will account for the overall submission requirements for OASIS data collection. The finalized language, as revised, reads: "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. Request for Information (RFI): Principles for Selecting and Prioritizing HH QRP Quality Measures and Concepts under Consideration for Future Years

1. RFI

In the RFI included in the CY 2024 proposed rule, CMS solicited public comment on:

- Guiding principles for selecting HH QRP measures: Specifically, comment was requested on the stated objectives of actionability, comprehensiveness and conciseness, focus on provider response to payment, and compliance with statutory requirements, including on the extent of agreement with the principles for selecting and prioritizing measures, if there are principles that should be eliminated from or added to the measure selection criteria, and on how CMS could best consider equity in measures;
- Identified measurement gaps in the current HH QRP: Specifically, in the domains of cognitive function, behavioral and mental health, and chronic conditions and pain management;

[24] 82 FR 51737 through 51738.

- Suitable measures for filling gaps: Specifically, on whether there are measures available for immediate use or that could be adapted or developed for use in the HH QRP in the gap areas identified below or other areas not mentioned in the RFI; and
- Data available to develop measures, approaches for data collection, perceived barriers or challenges, and approaches for addressing challenges.

In the final rule, CMS does not respond to specific comments submitted in response to this RFI, but summarizes the comments received and states it intends to use the comments to inform future policies.

2. Comments on Principles for Selecting and Prioritizing QRP Measures

Generally, commenters supported the principles. Many commenters were in favor of adding a guiding principle for stakeholder engagement. Other suggested additions included a guiding principle related to discontinuing metrics without continually adding more metrics, the principle of timeliness and clarity of CMS data, the principle of incorporating objectivity, and the principle that only measures for which data elements are clearly defined, valid, and well standardized be prioritized.

3. Comments on HH QRP Measurement Gaps

Cognitive Function / Behavioral and Mental Health. There was overall opposition to a measure related to cognitive function and/or behavioral and mental health, with many commenters not seeing the benefit or feasibility of developing performance measures in this area because of limited ability to affect these types of disorders in the home health setting.

Chronic Conditions. There was overall support for addressing gaps and performance measures related to chronic conditions. Commenters emphasized such measures should focus on maintenance or stabilization (rather than improvement) since maintenance and stabilization would better reflect the quality of home health care. Support was also expressed for stratification in quality measurement for patients with chronic conditions and complex needs.

Pain Management. There was overall support for addressing gaps and performance measures related to pain management, especially the assessment of pain and its effect on sleep, therapy activities, and day-to-day activities. Commenters emphasized the need to have options for pain scale metrics and encouraged CMS to identify tools to address inequities in pain assessment and treatment.

Other Measure Gaps. Other gaps suggested for further exploration included identifying and addressing social risk factors for patients, support for caregivers and caregiver status, and assessment, treatment and referral for patients with chronic obstructive pulmonary disease.

Data Available to Develop Measures. Commenters suggested the agency limit additional administrative burdens while aiming to gather equity-related information, specifically by using claims data.

Challenges with Current Measures. Most commenters expressed opposition to the agency's emphasis on keeping patients in the community as the gold standard for quality home health care, saying that this standard contributed to some HHAs avoiding patients with complex needs. Commenters suggested that measures that address delays in transfers to higher levels of care for those with complex or chronic care needs would be a better indication of quality home health care.

IV. Changes to the Expanded Home Health Value-Based Purchasing (HHVBP) Model

A. Background and Overview

The CMS Center for Medicare and Medicaid Innovation (CMMI) tested under section 1115A of the Act the "original" Home Health Value-Based Purchasing Model (HHVBP-O) in 9 states during 2016 through 2021. Payments were adjusted based on performance on the model's measures as summed into a Total Performance Score (TPS). The model produced average annual savings to Medicare of $141 million with an average TPS increase of 4.6 percent and without evidence of adverse risks. The model's results met statutory criteria to be certified for expansion, as announced by CMS on January 8, 2021. Final payment adjustments under the HHVBP-O model were made during 2021.

The expanded HHVBP Model began nationwide testing January 1, 2022, starting with a "pre-implementation year" of 2022 during which agencies could familiarize themselves with the expanded model and their performances would not trigger future payment adjustments. Beginning with the 2023 performance year, measures are scored and TPSs are calculated annually and will trigger payment adjustments two years after each performance year. Payment adjustments range from -5% to +5% for all model test years. The model requires all Medicare-certified HHAs to participate and they are termed "competing HHAs."

The overall economic impact of the expanded HHVBP Model for 2024 through 2027 was estimated in the CY 2023 HH PPS final rule[25] to be $3.376 billion in total savings to FFS Medicare from a reduction in unnecessary hospitalizations and SNF usage. The changes finalized in this rule will not change that estimate since they would not change the number of HHAs in the model or the payment methodology.

B. Changes to the Applicable Measure Set

CMS finalizes its proposals to codify the 8 measure removal factors effective 2024, to remove 5 measures and to add 3 measures in 2025, to adjust the weights for the measures in the OASIS-based and claims-based measure categories starting in 2025, and to update the Model baseline year for all measure beginning in 2025.

[25] 87 FR 66883.

1. Codification of Measure Removal Factors

To be consistent with the HH QRP and other quality reporting programs, CMS finalizes its proposal to codify the 8 measure removal factors at §484.380 that were adopted in the CY 2022 HH PPS final rule (86 FR 62312).[26]

2. Changes to the Applicable Measure Set

Background. The current measure set for the expanded HHVBP Model includes 5 OASIS-based measures, 2 claims-based measures, and 5 HHCAHPS measures.[27] The removal or addition of a measure and any substantial change to the nature of a measure requires notice and comment rulemaking. Names of measures added to the expanded Model measure set are posted on the CMS website by the December 1 following the publication of the applicable final rule.

Overview of Finalized Changes. CMS finalizes its proposal, beginning with the CY 2025 performance year (CY 2027 payment year), to remove 5 of the measures in the measure set and replace them with 3 other measures as follows:[28]

(1) CMS will replace the OASIS-based Discharged to Community (DTC) measure with the claims-based Discharge to Community-Post Acute Care (DTC-PAC) measure.
- *Adopted measure description*: The DTC-PAC measure[29] assesses successful discharge from a HHA to the community.
  Numerator. The number of HH stays for patients discharged to the community, based on a Medicare FFS claim with a Patient Discharge Status code 01 or 81, excluding discharges with an unplanned rehospitalization (to an acute care hospital or LTCH admission) or death in the 31-day post-discharge observation window.
  Denominator. The number of home health stays that begin during the 2-year observation period.
- *Differences between measures*: The newly adopted claims-based measure uses 2 years of claims data, whereas the current OASIS-based measure (finalized for removal) uses 1 year. The claims-based measure is aligned across PAC settings for risk-adjustment, exclusions, numerator, and measure intent, and the OASIS-based measure is not.

[26] To be removed from the measure list a measure would need to satisfy 1 of the following 8 factors: (1) The measure is topped out; (2) Performance or improvement on the measure does not result in better patient outcomes; (3) The measure does not align with current clinical guidelines or practice; (4) A more broadly applicable measure for the particular topic is available; (5) A measure that is more proximal in time to desired patient outcomes for the particular topic is available; (6) A measure that is more strongly associated with desired patient outcomes for the particular topic is available; (7) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and (8) The costs associated with a measure outweigh the benefit of its continued use in the program.
[27] The current measure set was finalized in the CY 2022 HH PPS final rule (86 FR 66308 through 66310). Tables 26 and 27 of that final rule (86 FR 35923 through 35926) provide details of the measures.
[28] Table D2 of the rule provides details on the measure set for the expanded HHVBP model.
[29] The DTC-PAC measure was adopted into the HH QRP in the CY 2017 HH PPS final rule (81 FR 76765 through 76770). Details about the measure can be found in that final rule and the CY 2018 HH PPS final rule (84 FR 60564 through 60566).

- *Rationale*: The replacement is consistent with measure removal factor 4 (a more broadly applicable measure for the particular topic is available); aligns measures with the HH QRP[30]; and allows for broader assessment of outcomes by assessing post-discharge hospitalization and mortality.

(2) CMS will replace both the OASIS-based Total Normalized Composite Change in Self-Care (TNC Self-Care) measure and the OASIS-based TNC Change in Mobility (TNC Mobility) measure with the OASIS-based Discharge Function Score (DC Function) measure.
- *Measure description*: The DC Function measure determines how successful each HHA is at achieving an expected level of functional ability for patients at discharge. The measure is also being finalized for adoption in the HH QRP. (See details on the measure in section III.D. of the rule and above in this summary.)
- *Differences between measures*: The DC Function measure addresses self-care and mobility through a single measure rather than two measures.
- *Rationale*: The DC Function measure has been proposed and/or finalized for adoption in all PAC settings. The OASIS data elements used to calculate the measure have been collected since 2019. Replacement is in accordance with measure removal factor 4 (a more broadly applicable measure for the particular topic is available).

(3) CMS will replace 2 claims-based measures (the Acute Care Hospitalization During the First 60 Days of Home Health (ACH) Measure and the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (ED Use) Measure) with the one claims-based Home Health Within Stay Potentially Preventable Hospitalization (PPH) Measure.
- *Measure description*:[31] The PPH measure compares the number of patients with at least one potentially preventable hospitalization or observation stay during the HH stay, to the number of Medicare FFS patients in the HH setting that do not meet the exclusion criteria.
- *Rationale*: Under the HH QRP, the ACH and ED Use measures were replaced by the PPH measure under measure removal factor 6 (measure that is more strongly associated with desired patient outcomes for the particular topic is available).[32] To align the expanded model's measure set with that of the HH QRP, CMS finalizes the same replacement.

The following table combines information shown in tables D1 and D2 of the rule, showing the current measure set for the expanded HHVBP model, with the newly finalized changes for the CY 2025 performance year/CY 2027 payment year included. The measure additions are shown in bold and measure removals are shown in italics.

[30] The claims-based DTC measure was added to the HH QRP in 2017 and the OASIS-based DTC measure has not been publicly reported since 2017.
[31] See Specifications for the Home Health Within-Stay Potentially Preventable Hospitalization Measure for the Home Health Quality Reporting Program (cms.gov) for a detailed description of the PPH measure.
[32] See CY 2022 HH PPS final rule (86 FR 62340 through 62345).

Table: Quality Measure Set for the Expanded HHVBP Model, with Finalized Changes Shown	
Short Name	**Measure Name & Data Source**
OASIS-based	
Dyspnea	Improvement in Dyspnea
DTC	*Discharged to Community*
Oral Medications	Improvement in Management of Oral Medication (CBE #0176)
TNC Mobility	*Total Normalized Composite Change in Mobility*
TNC Self-Care	*Total Normalized Composite Change in Self-Care*
DC Function Score	**Discharge Function Score**
Claims-based	
ACH	*Acute Care Hospitalization During the First 60 Days of Home Health CBE #0171)*
ED Use	*Emergency Department Use without Hospitalization During the First 60 Days of Home Health (CBE #0173)*
PPH	**Home Health Within-Stay Potentially Preventable Hospitalization**
DTC-PAC	**Discharge to Community**
HHCAHPS-based (CBE #0517)	
Communication	How well did the home health team communicate with patients
Overall Rating	How do patients rate the overall care from the home health agency
Professional Care	How often the home health team gave care in a professional way
Team Discussion	Did the home health team discuss medicines, pain, and home safety with patients
Willing to Recommend	Would patients recommend the home health agency to friends and family

Selected Comments/Responses. A few commenters expressed that it was too soon to make changes to the measure set since HHAs have invested in improving their performance on the original measure set and changes will require updates that are costly. CMS believes that there is sufficient notice to provide HHAs with enough time to make the changes. Most commenters who expressed concerns about adoption of the DC Function measure expressed the same concerns regarding its inclusion in the HH QRP (discussed above). To address some of these concerns, CMS responds that the final achievement thresholds and benchmarks will be provided in the July 2024 Interim Performance Report. The agency plans to make the most current HHA-specific performance data for the applicable measures available to each HHA in the Internet Quality Improvement and Evaluation System (iQIES) and intends for that to include current performance relative to other HHAs nationally before the start of the CY 2025 performance year and again before the IPR for July 2025.

3. Measure Categories

To calculate the TPS, the measure categories are weighted as follows:

- For HHAs in the larger volume cohort: 35 percent for OASIS-based measures, 35 percent for claims-based measures, and 30 percent for HHCAHPS survey-based measures.
- For HHAs in the smaller volume cohort: 50 percent for OASIS-based measures and 50 percent for claims-based measures.[33]

CMS had not proposed any changes to these categories or weights assigned to the categories.

[33] Note that per Table 28 in the CY 2022 HH PPS final rule (86 FR 62323 through 62324), if a measure category is missing for an HHA the remaining categories are reweighted accordingly.

4. Weighting and Redistribution of Weights Within the Measure Categories

Overview. To account for the changes in the number of measures within each measure category that would result from the measure set changes finalized in section IV.B.2. of the rule, while maintaining the total weight for each category, CMS finalizes its proposed changes in the weights of individual measures within the OASIS-based and claims-based measure categories beginning with the CY 2025 performance year. These changes include: (1) giving the sum of the weights of the 2 TNC measures to be removed from the OASIS-based category to the DC Function measure replacing those 2 measures, (2) distributing the weight of the OASIS-based DTC measure being removed from the OASIS-based category to the remaining measures in that category (though not equally), and (3) allotting the weights of the ACH and ED Use measures to be removed from the claims-based category to the PPH measure that will be added to that category.

The following table shows the current and newly finalized measure and measure category weights and is based on Table D4 of the rule:

MEASURE WEIGHT REDISTRIBUTIONS FOR HHAS IN THE LARGER-VOLUME AND SMALLER-VOLUME COHORT				
	Current Measure Weights		**Newly Finalized Measure Weights**	
Measure	**Larger-Volume Cohort**	**Smaller-Volume Cohort**	**Larger-Volume Cohort**	**Smaller-Volume Cohort**
OASIS-Based				
Discharged to Community	5.833	8.333	-	-
Improvements in Dyspnea	5.833	8.333	6.0	8.571
Improvement in Management of Oral Medications	5.833	8.333	9.0	12.857
TNC Mobility	8.750	12.50	-	-
TNC Self-Care	8.750	12.50	-	-
DC Function	-	-	20.0	28.571
Sum of Oasis-based	**35.0**	**50.0**	**35.0**	**50.0**
Claims-Based				
ACH	26.250	37.5	-	-
ED Use	8.750	12.5	-	-
PPH	-	-	26.0	37.143
DTC-PAC	-	-	9.0	12.857
Sum of Claims-Based	**35.0**	**50.0**	**35.0**	**50.0**
HHCAHPS Survey-Based				
Care of Patients	6.0	0.0	6.0	0.0
Communications between Providers and Patients	6.0	0.0	6.0	0.0
Specific Care Issues	6.0	0.0	6.0	0.0
Overall Rating of HH Care	6.0	0.0	6.0	0.0
Willingness to Recommend the Agency	6.0	0.0	6.0	0.0
Sum of HHCAHPS Survey-Based	**30.0**	**0.0**	**30.0**	**0.0**
Sum of All Measures	**100.0**	**100.0**	**100.0**	**100.0**

Selected Comments/Responses. Some commenters expressed concern that the PPH measure is being disproportionately weighted higher than other measures. CMS responds that the weight for PPH is to encourage further improvement in reducing hospitalizations that are potentially preventable and put focus on accountability for areas of significant Medicare spending. In addition, even though no changes had been proposed to the measure categories' weights, some commenters expressed concern about those weights. MedPAC believes the OASIS-based measure category weight is too heavy and a national associated stated concern that the HHCAHPS measure category is weighted too highly. CMS responds that it will include the weighting of the categories in the TEP agenda for November of this year.

5. Updates to the Model Baseline Year

Overview. CMS finalizes its proposal that beginning with the 2025 performance year (with corresponding 2027 payment year), for all measures other than the DTC-PAC measure, the model baseline year will be 2023. Since the DTC-PAC measure uses a 2-year data period, the model baseline year will be 2022 and 2023 for the 2-year performance period spanning 2024-2025 (and corresponding 2027 payment year).[34] For performance years 2023 and 2024, the Model baseline year will continue to be 2022.

CMS will provide HHAs with the final achievement thresholds and benchmarks in the July 2024 Interim Performance Report (IPR).

Selected Comments/Responses. Many commenters requested that CMS not change the Model baseline year, believing that the change negates the quality improvement efforts already made in preparation for the expanded Model. CMS explains that in order to add new measures it must establish a Model baseline year for the measures and it is beneficial to align the baseline year for all measures (existing and new). It also responds that expanded Model performance scoring methodology rewards improvement and achievement, and achievement is prioritized relative to improvement.

Future Topics for Measure Considerations. CMS will take into consideration opportunities to further align measures in the HH QRP and measures publicly reported on Home Health Care Compare. The agency is moving towards an approach to streamline quality measures across quality programs, consistent with the Universal Foundation, and will consider future modifications in support of health equity. Any changes will be proposed in future rulemaking.

C. Changes to the Appeals Process

CMS finalizes its proposed revisions to the expanded HHVBP model's appeals process at §484.375(b)(5) that would specify:[35]

[34] Table D7 in the rule shows the effects of the 2-year baseline and performance years, including overlap in CY 2024 performance year data used for the OASIS-based DTC measure and claims-based DTC-PAC measure, and overlap of 1 year of data for each 2-year performance period for the claims-based DTC-PAC measure, beginning with CY 2025 performance year data.

[35] See CY 2022 HH PPS final rule (86 FR 62331 through 62332) for details of the appeals process.

- An HHA may request the CMS Administrator to review a reconsideration decision not later than 7 days after receiving notification of the outcome of the reconsideration.
- The CMS reconsideration official will issue a final and binding written decision 7 days after the decision unless the Administrator renders a final determination reversing or modifying the reconsideration decision.
- The 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 will be final if the Administrator declines a request for review or does not take any action on the request for review within 14 days.

D. Public Reporting Reminder

No changes were proposed to the policies codified at §484.355(c), under which CMS is to make publicly available on the CMS website on or after December 1, 2024: (1) Information on measure benchmarks and achievement thresholds for the small and large-volume cohorts, and (2) The applicable measure results and improvement thresholds, the HHA's TPS, TPS percentile ranking, and payment adjustment for each HHA that qualified for a payment adjustment.

E. Health Equity (HE) Update

The agency describes goals outlined in the CMS *Framework for Health Equity 2022-2023*[36] as consistent with Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government."[37] CMS seeks to advance HE and whole-person care as one of the goals comprising the CMS National Quality Strategy (NQS).[38]

CMS included in the CY 2023 HH PPS Proposed Rule an RFI on future approaches to HE in the expanded HHVBP Model, specifically on whether an HE-based adjustment should be included under the Model. CMS says it will take these comments into account in future development of policies, but intends to give HHAs time to learn the requirements of the expanded Model, including by gathering at least two years of performance data, before incorporating any potential changes regarding health equity.

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

A. Background

Medicare began covering IVIG for treatment of primary immune deficiency disease (PIDD) in the home effective January 1, 2004. The statute authorizing payment for IVIG also did not authorize payment for "items and services" related to the administration of IVIG in the patient's home.

[36] https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.
[37] Executive Order 13985, can be found at: Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government | The White House.
[38] The NQS is available at CMS National Quality Strategy | CMS.

Section 101 of the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 mandated a 3-year demonstration 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. Under the demonstration, Medicare pays a per visit amount for the items and services needed for the administration of IVIG in the home. Items may include the infusion set and tubing, and nursing services to complete an infusion of IVIG lasting on average three to five hours. The demonstration has been extended by law through December 31, 2023.

Effective January 1, 2024, the Consolidated Appropriation Act, 2023[39] mandates that CMS establish permanent coverage and payment for items and services related to administration of IVIG in the home of a patient with PIDD. Payment must be a separate bundled payment made to a supplier for all administration items and services furnished in the home during a calendar day and may be based on the amount established under the demonstration. Part B deductible and coinsurance applies. Payment for IVIG administration items and services does not apply for individuals receiving services under the Medicare home health benefit. A supplier who furnishes these services must meet the durable medical equipment (DME) supplier requirements and be enrolled as a DME supplier.

B. Scope of the Expanded IVIG Benefit

The same eligibility requirements will apply to IVIG items and services as currently apply to receive Medicare payment for IVIG administered in the patient's home. For a beneficiary to be eligible for the expanded IVIG home items and services benefit, the patient must be diagnosed with at least one of the below diagnosis codes:

Table E1: ICD-10-CM Codes Supporting 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

[39] Division FF, section 4134 of the CAA, 2023 (CAA, 2023) (Pub. L. 117-328)

Table E1: ICD-10-CM Codes Supporting Medical Necessity for Home IVIG	
Code	**Description**
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

Through LCD L33610[40], the DME Medicare Administrative Contractors (MACs) specify the Healthcare Common Procedure Coding System (HCPCS) codes for IVIG derivatives a beneficiary must be receiving to qualify to receive home administration of IVIG. CMS proposed these same HCPCS codes would apply to be eligible to receive items and services covered under the expanded IVIG benefit in the home.

To be eligible for home IVIG items and services, the treating practitioner must make a determination that administration of IVIG in the patient's home is medically appropriate. All other Medicare requirements for coverage of IVIG items and services (e.g., must have a Medicare benefit category, be reasonable and necessary, etc.) will also apply.

Public commenters agree with all of these policies. CMS is revising the regulation to include "items and services" related to the administration of IVIG in the patient's home in addition to IVIG as a Medicare benefit category.

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

CMS interprets the statutory provision to make permanent coverage of the same items and services under the existing IVIG demonstration project. These items and services include those necessary to administer the drug intravenously in the home such as the infusion set and tubing, and nursing services to complete an infusion of IVIG lasting on average three to five hours. Nursing services would include such professional services as IVIG administration, assessment and site care, and education.

It is up to the provider to determine the services and supplies that are appropriate and necessary to administer 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. As such, under the IVIG demonstration, coverage does not extend to the DME pump, and thereby, would not be covered separately under the home IVIG items and services payment.

CMS requested comment on additional items and services that may be covered under the scope of the home IVIG benefit. No comments were received. CMS is finalizing the policy as proposed with Medicare covering the same items and services for the home IVIG benefit as are covered under the demonstration. The final rule advises there Medicare will make two payments for home IVIG—one for the IVIG itself and one for IVIG items and services.

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

2. Relationship to Home Health and Home Infusion Therapy Services

A patient does not need to be homebound to receive benefits for home IVIG infusion therapy. However, if the patient is receiving Medicare home health benefits, the statute permits payment for home infusion therapy services under the home health benefit but not the home IVIG infusion therapy benefit.

To be eligible for home infusion therapy (HIT) services, the drugs and biologicals being infused must require infusion through an external infusion pump as specified in the DME LCD for External Infusion Pumps (L33794).[41] 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.

CMS notes that while it is not possible to receive payment under the HIT and home IVIG administration benefit for administration of SCIg and IVIG on the same day, a beneficiary could potentially receive services under both benefits on the same day 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. 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.

CMS invited comments in the proposed rule on how typical it is for a patient to alternate between receiving IVIG and SCIg and the frequency with which it may occur. Commenters explained 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. CMS will consider these comments as it moves forward with implementation of this new benefit.

C. IVIG Administration Items and Services Conditions of Payment

1. Home IVIG Administration Suppliers

Under the statute, suppliers of IVIG administration items and services must enroll as a DMEPOS supplier and comply with the Medicare program's DMEPOS supplier and quality standards and conditions for Medicare payment. The DMEPOS supplier may subcontract with a provider for professional nursing services specified above.

[41] LCD - External Infusion Pumps (L33794) (cms.gov)

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.

CMS did not receive any comments on the supplier type who may furnish home IVIG items and services. The above policies are being finalized as proposed.

2. Home IVIG Administration

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. CMS did not receive any comments on the definition of "home." The definition of "home" is being finalized without change.

D. Home IVIG Items and Services Payment Rate

Under the statute, payment for home infusion IVIG items and services must be made as a separate bundled payment to a supplier for all administration items and services furnished in the home during a calendar day. It may be based on the amount established under the demonstration.

Under the demonstration, CMS established a per visit payment amount for the items and services needed for the in-home administration of IVIG based on the national per visit low-utilization payment amount (LUPA) under the prospective payment system for home health services. 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.

CMS proposed to base the home IVIG items and services payment rate on LUPA without a wage index adjustment as there is no statutory requirement for geographic adjustments. As CMS proposed to use the LUPA without the wage index adjustment, CMS will also not apply the wage index budget neutrality factor to the LUPA. CMS proposed to update the per visit payment by the home health update percentage amount.

Several public commenters requested that CMS reevaluate the LUPA-based rate calculation to avoid undervaluing significant services and resources involved in the provision of home-based IVIG therapy. CMS' response indicates that the commenters did not specify which additional services are being provided that are being undervalued.

In addition, CMS indicates that the statute requires the IVIG items and services benefit to include the same items and services covered under the demonstration. The demonstration payment 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 further states that the LUPA amount is appropriate because it is based on infusion services furnished by a skilled nurse under the HH PPS—the same services that are being paid under the IVIG items and services benefit.

Under CMS' proposal, the home IVIG items and services payment rate for 2024 would be the LUPA for 2023 updated by the home health update percentage amount. Using the final rule home health update percentage will make the home IVIG items and services payment $408.23*1.030 = $420.48.

Although CMS notes that the statute states that payment is for the items and services furnished to an individual in the patient's home during a calendar day, CMS believes that alignment with the demonstration would make the payment amount per visit with the expectation that only one visit would be made per calendar day.

E. Billing Procedures

CMS 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") to bill for home IV infusion items and services. The final rule instructed billing the Q-code to the DME MACs 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.

In order to implement the requirements for this separate bundled payment under section 1861(s)(2)(Z) of the Act, the final rule indicated CMS will issue a Change Request outlining the requirements for the claims processing changes needed to provide the IVIG home administration payment.

CMS does not present any public comments on these proposals.

F. Payment Impact

CMS estimates a net cost of the home IV infusion items and services benefit to be $252,350 in 2024 or the difference between the total cost of the benefit ($8,661,888) and the estimated cost of the demonstration in 2023 ($8,409,538).

VI. Hospice Informal Dispute Resolution and Special Focus Program

A. Background and Statutory Authority

The Consolidated Appropriations Act, 2021 (Pub. L. 116-260) required the Secretary to create a Special Focus Program (SFP) for poor-performing hospices that, through increased regulatory oversight, would address issues that place hospice beneficiaries at risk of receiving unsafe and poor-quality care. In the 2022 HH PPS final rule, CMS stated it would consider public comments it received and seek additional collaboration with stakeholders to develop a revised proposal and methodology for the SFP. As part of the SFP development, a Technical Expert Panel (TEP) was held in October and November 2022; the TEP provided feedback and considerations on preliminary SFP concepts, including the development of a methodology to identify hospice poor-performers.[42]

B. Regulatory Provisions

1. Overview

As discussed below, CMS finalizes its proposals for the hospice SFP which includes the criteria for selection and completion of the SFP, hospice termination from Medicare, and public reporting of the SFP. The SFP will commence as of the effective date of the final rule. CMS anticipates selecting SFP hospices in CY 2024.

CMS also finalizes its proposal for a hospice informal dispute resolution process (IDR) to align with the process for home health agencies. The IDR will address disputes related to condition-level survey findings after a hospice program receives the official survey statement of deficiencies.

The majority of commenters agreed with the intent and purpose of the SFP and the IDR process but had comments about the specific criteria for selection and completion of the SFP.

2. Definitions (§488.1105)

CMS finalizes its proposals to add the following definitions for hospice programs:

- *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 they meet Medicare requirements. Selected hospices either successfully complete the SFP program or are terminated from the hospice program.
- *IDR* stands for informal dispute resolution.
- *SFP status* means the status of a hospice provider 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.

[42] The TEP summary report is available at https://www.cms.gov/medicare/quality-safety-oversight-certification-compliance/hospice-special-focus-program.

- *SFP survey* refers to a standard survey as defined in §488.1105 and is performed after a hospice is selected for the SFP and is conducted every 6 months, up to three occurrences.

3. Informal Dispute Resolution (§488.1130)

CMS finalizes its proposal for an IDR process for condition-level survey findings that may result in an enforcement action. CMS notes that standard-level findings do not trigger an enforcement action and are not accompanied by appeal and hearing rights. The IDR process will provide an opportunity to settle disagreements prior to a formal hearing, and could conserve resources spent by the hospice, the state survey agency (SA), and CMS. The IDR process will not be used to refute an enforcement action or selection into the SFP. In addition, CMS finalizes that failure of CMS, or the SA, or the accrediting organization (AO), to complete the IDR would not delay the effective date of any enforcement activity.

The IDR process will provide hospices an informal opportunity to resolve disputes about survey findings for hospices seeking recertification from the SA, CMS, or reaccreditation from the AO for continued Medicare participation. In addition, IDRs may be initiated for programs under SA monitoring (either through a complaint or validation survey) and those in the SFP.

When survey findings indicate a condition-level deficiency, the hospice will be notified in writing of the opportunity to request an IDR. This notice will be provided with the CMS-2567 Statement of Deficiencies and Plan of Correction. For hospice programs deemed through a CMS-approved AO, the AO will receive the IDR request from their deemed facility program, following the same process and coordination with CMS for any enforcement actions. CMS finalizes that the hospice's request for an 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 allowed for submitting an acceptable plan of correction.

CMS finalizes if any survey findings are revised or removed by the SA or CMS based on the IDR, and if CMS accepts the IDR results, the CMS-2567 will be revised and CMS will adjust any enforcement actions imposed solely due to those cited and revised deficiencies. If the survey findings are upheld by CMS or the state, the Form CMS-2567 will not be revised and there will not be adjustments to the enforcement actions.

Comments/Responses: In response to comments, CMS states that after publication of this final rule it will publish guidance for the hospice IDR process. This guidance will be similar to the guidance established for the HHA IDR and will include timeframes for the process and for completing the IDR. CMS also responds that the IDR process will be tracked using the national surveyor database [Internet Quality Improvement and Evaluation System (iQIES)]. CMS reiterates that if findings are changed due to an IDR a revised CMS-2567 will be sent to the provider and the national database will be updated.

Some commenters believed that the IDR should be available for hospices to refute SFP selection. CMS states 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 finalized survey reports (CMS-2567); these finalizes survey reports are not pending IDR or subject to disputes.

4. Special Focus Program (§488.1135)

a. Hospice Special Focus Program Algorithm

CMS finalizes its proposal to use multiple data sources to provide a comprehensive view of the quality of care provided by hospices. The SFP algorithm is designed as an initial step in identifying poor quality indicators. CMS finalizes its proposal to identify a subset of 10 percent of hospice programs based on the highest aggregate scores determined by the algorithm. CMS will determine the hospices selected for the SFP from this subset.

b. Use of Medicare Data Sources to identify Poor Performing Hospices

To identify hospices with poor quality indicators, CMS proposed to use the most recent Medicare hospice data from two data sources: (1) hospice surveys and (2) Medicare Hospice Quality Reporting Program (HQRP). The proposed primary indicators to identify poor performing hospices are listed below in Table F1.

Table F1. Proposed Primary Medicare Data Sources and Indicators in the SFP

Data Source	Hospice Surveys	HQRP	
		Claims Data	CAHPS Hospice Survey
Indicators	Quality-of-Care Condition-Level Deficiencies	Hospice Care Index (HCI)	Help for Pain and Symptoms
			Getting Timely Help
	Substantiated Complaints		Willingness to Recommend Hospice
			Overall Rating of this Hospice

Hospices would be identified for potential SFP enrollment if they have data from any of the data sources; are listed as an active provider (billed at least one claim to Medicare FFS in the last 12 months); and operate in the U.S., including D.C. and the territories. Based on the proposed criteria and an examination of the analytic files for 2019 through 2021, CMS identified 5,943 hospices that would be eligible for participation in the SFP.

(1) Hospice Survey Data

Quality of Care Condition-Level Deficiencies (CLDs). 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 all hospices are required to meet to participate in Medicare. In January 2023, CMS made significant changes in the hospice survey protocol[43] and identified 11 quality-of-care CoPs that directly contribute to the quality of care delivered to patients, their caregivers, and families. CMS believes that a cited CLD on any one of these CoPs may indicate a hospice is providing poor quality of care. CMS proposed to include these 11 quality-of-care CLDs as data indicators in the

[43] CMS issued a memo on January 27, 2023 which discussed that a significant change was made in the hospice survey protocol to provide an enhanced approach to investigating the quality-of-care provided to hospice patients (QSO-23-08-hospice).

SFP algorithm (listed below in Table F2). CMS did not include all 23 hospice CoPs because they did not want to dilute the methodology's ability to identify quality concerns. CMS proposed to count the total number of quality-of-care CLDs from the previous 3 consecutive years of data.

Table F2. Quality of Care	
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.

In the proposed rule, CMS noted that stakeholders expressed concerns about inter-surveyor reliability and state-to-state variability as potential drawbacks of including survey data as part of the methodology. The TEP acknowledged the importance of survey data and supported using the total count of quality-of-care CLDs to indicate significant noncompliance with multiple CoPs. To address concerns, CMS has implemented improvements to surveyor training guidelines to improve surveyor training.

Substantial Complaints. CMS also proposed to include the total number of substantial complaints received against a hospice in the last three consecutive years 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 by a patient, a caregiver, and hospice staff members. Once a complaint is filed with the SA, the SA can conduct an unannounced complaint investigation survey to substantiate or refute the complaint. If the allegation is found to be substantiated or confirmed, the SA informs the hospice and submits findings to the iQIES. A post-survey revisit or follow-up survey may occur. A hospice may have complaints filed against them, but not all complaints may be substantiated upon SA review.

Analysis of 2019-2021 survey data found that 81.8 percent of SFP-eligible hospice programs had no substantial complaints over the past 3 years.

(2) Hospice Quality Reporting Program (HQRP) Data

The HQRP includes data submitted by hospices via the Hospice Item Set (HIS), Medicare hospice claims, and the CAHPS Hospice Survey. All Medicare-certified hospices must comply with these reporting measures or face for a failure to report, but some hospices may be exempt

from reporting measures. The proposed HQRP measures are identified in Table F1, reproduced above.

Hospice Care Index (HCI). CMS proposed including the HCI overall score based on eight quarters of Medicare claims data. The HCI includes ten indicators that are used to develop a composite HCI overall score; hospices earn a point for each indicator met. The HCI score is based on Medicare claims data. For public reporting, hospices with less than 20 claims over the eight quarters are excluded from reporting the measure. The HCI is also suppressed if any one of the ten indicators is not reported for any reason. The TEP and stakeholders generally supported the inclusion of HCI data.

Analysis of 2019 to 2021 (excluding January through June 2020) HCI data found 78.3 percent of SFP-eligible hospice programs have a publicly reported HCI score; 86.1 percent of these hospices received an HCI score of 8 or more out of 10.

CAHPS Hospice Survey. CMS proposed including 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. New hospices and hospices with fewer than 50 survey eligible decedents/caregivers in a given calendar year may be exempt from CAHPS. The TEP and other stakeholders agreed that the algorithm should include these four CAHPS measures.

CMS proposed to use adjusted bottom-box score of the four measures to create a CAHPS Hospice Survey Index. The bottom-box score for each response is calculated as a "100" if the least positive response categories for a question is elected or a "0" if the respondent selected a different response category. Different questions have different response options.[44] CMS proposed to calculate a single score for each hospice by taking a weighted sum of the bottom-box scores for the four CAHPS measures. CMS proposed that the two measures that represent overall assessment of hospice care (Willingness to Recommend this Hospice and Overall Rating of this Hospice) each be given a weight of 0.5 and weigh the other two measures, Help for Pain and Symptoms and Getting Timely Help, at 1.0 each. CMS provided an example in the proposed rule.

Analysis of 2019 to 2021 (excluding January through June 2020) CAHPS Hospice Survey data found the 49.3 percent of SFP-eligible hospices report the four CAHPS measures. The average CAHPS Hospice Survey Index value for these four measures combined is 24, with an overall range of 3 to 83 (lower scores indicate better performance).

c. Data Source Preparation

CMS proposed to compile the data for the algorithm indicators and remove hospices not eligible for SFP to create a single score for every hospice. A Medicare-certified hospice program would

[44] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospice-quality-reporting/current-measures.

be included in the algorithm if it is an active provider that has billed at least one claim to Medicare FFS in the last 12 months as captured in iQIES and has data for at least one algorithm indicator.

CMS proposed to use the latest HCI and CAHPS data from the Hospice PDC. For example, it would use data from November 2023 to identify hospices eligible to be in the SFP on or after January 1, 2024.

(1) Survey Data and HCI.

CMS proposed the following steps to prepare survey data for the algorithm:

- Step One: CMS 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). CMS proposed to use 2020-2023 data to identify hospices eligible to be on the SFP on or after January 1, 2024.
- Step Two: Using the survey data in Step One, CMS proposed to count the total number of quality-of-care CLDs for each hospice.
- Step Three: Using the survey data in Step One, CMS proposed to count the total number of substantiated complaints for each hospice. Substantiated complaints can be found in complaint and follow-up surveys.

To address missing data for the algorithm's indicators, CMS proposed standardizing each indicator for quality-of-care CLDs, substantial complaints, and HCI. Specifically, for hospices missing any of these three indicators, CMS would assign a value of zero for that indicator after standardization (discussed below in section d).

(2) CAHPS Hospice Survey Data.

CMS will not assign the average value of the CAHPS Hospice Survey Index to hospices that are exempt from participating in the CAHPS Hospice Survey Data or hospices that have fewer than 30 completed surveys over an eight-quarter reporting period.

The CAHPS Hospice Survey measures will be standardized using the same methodology proposed for the Survey Data and HCI. CMS 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 would be based solely on all other indicators (CLDs, complaints, and HCI). The score for hospices with available CAHPS Hospice Survey data includes the CAHPS Hospice Survey Index in addition to all other indicators.

d. Data Source Standardization.

CMS proposed standardizing each indicator to compare indicators equally despite each data source's different units of measurement. By standardizing the indicators, CMS shifts its interpretation from what value a hospice received to an estimation of how likely the hospice is to receive the value if they were an average hospice. For example, because the quality-of-care CLDs and substantiated complaints are continuous variables there is no ceiling to how many

CLDs or substantiated complaints a hospice can receive. In contrast, a hospice can only receive a maximum value of 10 from the HCI quality measure. CMS states that if it does not rescale the HCI, the importance of the HCI for the SFP would be deemphasized because the range of possible values for the HCI is much smaller than the range of possible values for CLDs and substantial complaints.

CMS proposed to calculate the standardization value by taking the indicator's observed value for the hospice and subtracting the indicator's average value for all hospices. CMS would divide this difference by the standard deviation to determine how clustered the data are around the average.

$$Standardized\ Value = \frac{(Hospice\ Value - Overall\ Average)}{Standard\ Deviation}$$

Using this approach, all indicators are centered with a mean of zero and a standard deviation of one. The transformed indicator informs CMS how likely a value for a given hospice would be observed and allows comparison of indicators to determine which hospices have the most unlikely values compared to other hospices.

(1) Weighting of the Standardized Values

CMS proposed to weigh each indicator by multiplying an indicator by a constant value to account for their relative importance in the methodology. Based on the feedback from the TEP and stakeholders, CMS proposed to weigh the CAHPS Hospice Survey by twice that of the other measures; the CAHPS Hospice Survey Index will be multiplied by two.

(2) Approach for Missing CAHPS Data

CMS proposed replacing missing values in quality-of-care CLDs, substantial complaints, and HCI with the average value for each of those indicators. CMS notes that for these indicators, the data exhibits an exceptional amount of concentration around the average value for the indicator.

The CAHPS Hospice Survey Index does not exhibit the same high concentration around the average value; this indicates there is more variability in the CAHPS Hospice Survey Index than in the other indicators. Because of this increased variability, CMS believes it is increasingly unlikely that those values that are missing are close to the average value. In addition, CMS notes that due to reporting exemptions for small and/or newer hospices, missing values are disproportionately from these providers. This makes it difficult for CMS to draw any conclusions about the missing values because there is no data from small hospices for comparison to determine if these hospices CAHPS average is similar for those for which it has observed data. CMS is also concerned that if it replaces missing CAHPS Hospice Survey measure values with the average value, poor performing small hospices could benefit by being treated as an average hospice by becoming exempt from reporting CAHPS Hospice Survey measures.

Instead of replacing missing CAHPS Hospice Survey measure scores with the average value for these measures, CMS proposed to evaluate hospices with data for CAHPS Hospice Survey measures through a version of the algorithm that includes the CAHPS Hospice Survey Index.

Hospices without the CAHPS Hospice Survey data would be evaluated through a version of the algorithm that does not consider the CAHPS Hospice Survey Index. To make the two resulting scores comparable, CMS would average the scores based on the total number of indicators used to calculate the score. CMS proposed the following:

- 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:

$$CLDs\ over\ 3\ years + Complaints\ over\ 3\ years - HCI = \frac{Score}{3}$$

CMS provides two examples of how the proposed algorithm score would be calculated for two hospices based on their indicator values.

Comments/Responses

CAHPS Hospice Survey. Commenters expressed various concerns over the use of the CAHPS Hospice Survey measures and the CAHPS Hospice Survey Index in the SFP algorithm. Concerns included the possibility that the absence of CAHPS data would make a hospice less likely to be placed in the SFP; the algorithm may creative an undesirable incentive for hospices to not report CAHPS data or to try to influence caregiver responses; the reliability and subjectivity of the CAHPS Hospice survey data; and the potential disproportional impact on providers that serve underserved communities.

CMS acknowledges commenters' concerns regarding the strengths, limitations, and potential drawbacks of the CAHPS Index. CMS maintains that the CAHPS Hospice Survey data is appropriate to include because it monitors hospice performance and publicly reports poor performing hospices to aid patients and caregivers in making decisions about a hospice. CMS acknowledges that the number of providers not reporting the data is a limitation but believes the CAHPS data represents an essential component to identify-provide level issues addressed in the SFP. CMS reiterates that comparable scores are calculated for hospices that do and do not have publicly reported CAHPS Hospice Survey data. Thus, CMS does not think there is an incentive for providers to opt out of reporting CAHPS Hospice Survey data in order to avoid SFP eligibility. In addition, beginning in FY 2024, if the required quality data is the HQRP is not reported, the hospice will be subject to a payment reduction of 4 percentage points from its annual payment update (APU) (86 FR 42528). CMS also discusses how the CAHPS Hospice Survey contains guidelines that prevent providers from unfairly influencing how caregivers respond to the survey. In addition, CMS notes that the vast majority of providers that do not report CAHPS Hospice Survey data are either small (that is, fewer than 50-survey eligible patient/family caregiver pairs during the reference year) or new. CMS discusses the published literature that does not demonstrate that the CAHPS Hospice Survey is biased and disadvantages providers that provide care to historically underserved populations. CMS will monitor the rates of exemption and non-exempt reporting of the CAHPS Hospice Survey data and evaluate whether changes to the algorithm are necessary for future rulemaking.

HCI Data. In response to comments regarding the HCI, CMS notes that approximately 21 percent of hospices did not publicly reported HCI score but that 94 percent of these hospices had fewer than 11 discharges per year. CMS acknowledges that preliminary analyses indicates that hospice providers without a publicly reported HCI score were significantly less likely to be identified in the SFP list. CMS believes the benefits of using the HCI score, including that it is based on claims data outweigh the concerns. Based on analysis of the HCI data, CMS continues to believe that it is reasonable to assume that a non-reporting hospice's HCI data would be close to the average HCI score.

Data Source Standardization. Many commenters believed that survey data measures, condition-level deficiencies (CLDs), and complaints should be scaled in the algorithm based on the size of a hospice. Commenters also expressed concerns about the accreditation survey process including the backlog in surveys due to the COVID-19 Public Health Emergency (PHE), the possibility of duplicated CLDs or substantiated complaints, and issues related to staffing shortages and surveyor training.

In response to these concerns, CMS discusses how it 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. Thus, CMS concludes that providers of all sizes have the same opportunity to have a CLD cited. CMS agrees that large hospices have more opportunities to receive complains but it does not believe this changes the opportunity for a complaint to be substantiated. As to commenters' concerns about the timeliness and quality of survey data, CMS anticipates the backlog of routine surveys to clear over the next year and states that as of May 2023, a revised SOM Appendix M and Survey Basic Training was completed. CMS acknowledges there is a possibility a substantial complaint might be counted twice if a specific complaint is investigated by both the SA and AO on separate dates and it will monitor the data to determine the incidence of such an occurrence.

Monitoring the Algorithm. In response to questions about how CMS would monitor and review the SFP program, CMS discusses its plan to monitor the algorithm inputs for changes to the measures that would affect the results of the SFP algorithm. CMS will also continue to monitor providers that opt-out of reporting quality measures, large swings in input summary statistics and distributions, input outliers, and provider recidivism. CMS will also evaluate how potential SFP provides will be differentiated from providers that do not need additional attention. In response to concerns that the proposed algorithm differs from the algorithm present to the TEP, CMS explains that feedback provided by the TEP and from listening sessions, contributed to the development of the final specifications to the SFP methodology.

Final Decision*:* CMS finalizes its proposed SFP algorithm including the proposals to use data from hospice surveys and the HQRP program and methodology for data source standardization. Specifically, CMS finalizes:

- The inclusion of CAHPS Hospice Survey data in the SFP algorithm, 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.
- The inclusion of the HCI score, the standardization of the HCI score, and how missing HCI scores are handled in the SFP algorithm. CMS finalizes that after standardization

missing HCI scores will be replaced with zero which is equivalent to replacing it with the average value.

- The inclusion of unscaled CLDs and unscaled substantial complaints from 3 consecutive years of data, the standardization of both inputs, and replacing a hospice's missing CLDs or substantial complaints with zero after standardization.
- The use of Medicare data sources, 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.

CMS will continue discussion with interested parties and will make potential refinements in future rulemaking as appropriate.

e. Selection Criteria

Based on feedback from the TEP and stakeholders, CMS proposed a SFP election process that utilizes a no-stratification approach. The poorest performing hospices would be selected regardless of characteristics such as size or location.

The number of hospices selected to participate in the SFP would be determined in the first quarter of each calendar year. CMS notes the claims-based quality measure data used in the proposed algorithm is not available until November of each calendar year. A hospice that is selected for a SFP would not be removed from the SFP until they either meet the criteria for graduation or are terminated from the Medicare program.

Comments/Responses. Many commenters requested clarification of how CMS would select hospices and the process for providers selected for the SFP. CMS will select the poorest performing hospices, from the 10 percent selectee list, based on the finalized SFP algorithm score, in sequential value. CMS will not include hospices under an active enforcement action for which they are already on a 6-month termination track or subject to other remedies. CMS will send a letter to hospices selected for the SFP program. Hospices selected for the SFP will receive a survey every 6 months. A deemed hospice program selected for the SFP will have its deemed status removed and will be under CMS oversight until the hospice completes the SFP. CMS notes that it will not provide technical assistance but will ensure that SFP hospices are aware of the resources and tools available to help them improve quality. CMS states it is still considering the TEP's recommendation to use a third party for the hospice SFP activity. CMS notes, that regardless of whether or not it uses a third party, it will maintain the ultimate responsibility for the implementation and evaluation of the SFP.

Final Decision: CMS finalizes its proposal for the SFP selection criteria.

f. Survey and Enforcement Criteria

The CAA, 2021 requires that a hospice in the SFP must be surveyed not less than once every 6 months. CMS proposed this 6-month recertification survey frequency for hospices in the SFP.

SFP hospices would be subject to one or more remedies specified in §488.1220 and progressive enforcement remedies, at the discretion of CMS and consistent with 42 CFR part 488, Subpart N.

The remedies would be applied on the basis of noncompliance with one or more CoP and may be based on failure to correct previous deficiency findings as evidence by repeat condition-level deficiencies. If subsequent surveys result in the citation of a condition-level deficiency or deficiencies, the enforcement remedies could be of increasing severity, including a higher CMP.

Comments/Responses. In response to concerns about variability between surveyors, CMS reiterates that all SA and AO surveyors must have successfully completed the updated CMS Basic Hospice Surveyor Training and any other additional training as specified by CMS. For hospices selected for the SFP, CMS will provide oversight to ensure adherence to survey processes and schedules. CMS appreciates commenters' recommendation that CMS provide technical assistance to hospices and reiterates that it already provides access to educational materials and it will continue to assess the need for additional educational opportunities for all hospices. CMS notes that hospice programs can obtain technical assistance and private consulting services that are separate from the SFP.

Final Decision: CMS finalizes its proposals for the SFP survey and enforcement criteria.

g. SEP Completion Criteria

The TEP generally agreed that to complete and graduate from the SFP, hospices should have no CLDs cited for two consecutive 6-month recertification surveys in an 18-month timeframe. Some TEP members also suggested that hospices should have no substantiated complaints and less than a defined number of standard-level deficiencies on two consecutive 6-month recertification surveys within the 18-month timeframe.

CMS considered these recommendations. However, CMS proposed that a SFP hospices have no CLDs for any two SFP surveys in an 18-month period. Specifically in a new §488.1135(d), CMS proposed that a hospice will have completed the SFP if it has, in an 18-month timeframe, no CLDs cited or immediate jeopardy (IJ) for any two 6-month SFP surveys, and has no pending complaint survey triaged as an IJ 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 one-year post SFP survey and then would start a new standard 36-month survey cycle.

Final Decision: CMS finalizes its proposals for the SFP completion.

h. Termination Criteria

CMS proposed that a hospice in the SFP that fails any two SFP surveys, by having any CLDs in an 18-month period, or pending complaint investigations triaged at IJ or condition-level would be considered for termination. Agreeing with the TEP recommendation, this criterion would apply to all hospices, regardless of location. CMS would issue the termination letter in accordance with §489.53.

CMS recognizes that a provider may need a reasonable time to achieve substantial compliance. CMS believes, however, that if the hospice is not able to achieve substantial compliance at any time during the 18 months, they would be considered for termination. Providers that are unable to resolve deficiencies and cannot meet the proposed completion criteria would also 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.

Final Decision: CMS finalizes its proposals for the SFP terminal criteria.

i. Public Reporting of SFP Information

The CAA, 2021 requires hospice survey findings to be publicly available. CMS proposed to publicly report, at least on an annual basis, the hospice programs selected for the SFP. 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. CMS proposed the website will include general information, program guidance, a subset consisting of 10 percent of hospice programs based on the highest aggregate scores determined by the algorithm, SFP selections, and SFP status.

Comments/Responses. Some commenters noted that CMS may be exceeding its authority by publicly posting both the bottom 10 percent list and the SFP participant list; other commenters supported the publication of both lists because it would be important information for consumers. CMS does not believe it is exceeding its authority because the statute states that survey reports, enforcement actions, and any other information determined appropriate by the Secretary shall be published on a CMS website. CMS notes the Special Focus Facility (SFF) program also posts information about nursing homes that have been terminated from the Medicare program and also graduated from the SFF program. CMS intends to follow a process similar to the SFF. The list will be reported annually and updated periodically as hospices complete the program.

Final Decision: CMS finalizes its proposals for public reporting of SFP information.

VII. Changes Regarding Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

A. Medicare DMEPOS Competitive Bidding Program (CBP)

The federal PHE for COVID-19, declared by the Secretary under Section 3310 of the Public Health Service Act, expired on May 11, 2023. CMS finalizes its proposal to make conforming changes to the regulation at 42 CFR §414.210(g)(9) to account for these changes, consistent with requirements in section 4139(a) and (b) of the CAA, 2023.

For DMEPOS items and services furnished in rural and non-contiguous non-competitive bidding areas (CBAs), CMS states that section 4139 of the CAA, 2023 does not change the current policy under §414.210(g)(9)(iii) of paying based on a 50/50 blend of adjusted and unadjusted fee schedule amounts. While section 4139 of the CAA, 2023 does not specifically mention §414.210(g)(9)(iii), CMS believes 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. It revises §414.210(g)(9) by removing the date "February 28, 2022" and adding in its place the date "January 1, 2024".

CMS finalizes its proposal to revise §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 or December 31, 2023, whichever is later, 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. It makes 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.

CMS also finalizes its proposal to revise §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 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. It also removes outdated text from §414.210(g)(9)(v).

Furthermore, CMS finalizes its 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). This section defines how CMS uses the payment determined under the Medicare DMEPOS CBP to adjust the fee schedule amounts for DME items and services furnished in all non-CBAs.

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, CMS states it intends to issue program instructions or other subregulatory guidance to effectuate the changes.

B. Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

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 amended the Act to establish a new Part B benefit category for lymphedema compression treatment items.

1. Scope of the Benefit for Lymphedema Compression Treatment Items

CMS finalizes its proposal to amend 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; and other items determined to be lymphedema compression treatment items under the process established under §414.167. This also includes accessories necessary for the effective use of a gradient compression garment or wrap with adjustable straps such as zippers in garments, liners worn under garments or wraps with adjustable straps, and padding or fillers. 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 CMS finalizes that payment may be made in these circumstances. In addition, CMS also finalizes 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 the purpose of establishing the scope of the benefit for these items, CMS finalizes 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.

Lymphedema compression treatment items 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.

CMS received numerous comments from individual health care providers and suppliers, medical associations, medical device companies, as well as healthcare consulting and medical technology organizations.

Many commenters requested CMS ensure inclusion of bandaging for various body parts including stretch bandages, firm bandaging, custom and adjustable wraps, and Kinesio tape, among others. CMS agrees that bandaging may be provided at different phases of the

beneficiary's treatment of lymphedema. It clarifies 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). In response to comments about ensuring inclusion of bandaging for various body parts, CMS adds more HCPCS codes, in addition to those originally proposed, to be clearer about the inclusion of bandaging and accessories for the various body parts.

Many commenters requested that CMS provide separate payment for the measurement and fitting services so that clinicians, therapists, and certified fitters are paid fairly and directly for the services provided. CMS states that it appreciates the many concerns commenters expressed both in support of and against the idea of separate payment for fitting services. CMS notes that it did not propose separate payment for fitting services because of the many complexities involved requiring careful analysis and consideration. It states that it is something it could consider in future rulemaking.

2. Healthcare Common Procedure Coding System (HCPCS) Codes for Lymphedema Compression Treatment Items

Based on comments received, CMS modifies and adds to the existing HCPCS codes for surgical dressings and lymphedema compression treatment items. CMS identified 57 HCPCS codes that it is finalizing for lymphedema compression treatment items and accessories. It also added more codes to describe the various compression bandaging systems used for the treatment of lymphedema. These codes are shown in Table FF-A 2 reproduced from the final rule. In addition to the new codes in this table, CMS is finalizing the additional new A codes that align with the codes and descriptors of S8420 through S8428 for upper extremity gradient compression garments. CMS is 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. Detailed comments and CMS responses on the proposed HCPCS codes lymphedema compression treatment items can be found in the final rule.

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

Table FF-A 2: Final New HCPCS Codes for Lymphedema Compression Treatment Items	
Code	**Description**
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
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

Table FF-A 2: Final New HCPCS Codes for Lymphedema Compression Treatment Items	
Code	**Description**
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

3. Procedures for Making Benefit Category Determinations and Payment Determinations for New Lymphedema Compression Treatment Items

CMS finalizes its proposal that 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.[45] It also finalizes its 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. The preliminary determinations would 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

[45] This is described at https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings

changes.

4. Enrollment, Quality Standards, and Accreditation Requirements for Suppliers of Lymphedema Compression Treatment Items and Medicare Claims Processing Contractor 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 amended section 1834(j)(5) 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.

CMS notes that 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).

CMS finalizes its proposal to include lymphedema compression treatment items as DMEPOS items and thus claims for these items would be processed by the DME MACs.

5. Payment Basis and Frequency Limitations for Lymphedema Compression Treatment Items

CMS finalizes its 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. It adds §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). Specifically, 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, CMS will use the average of 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).

These rates would be updated by an inflationary factor each year. Specifically, CMS finalizes its proposal under §414.1650(c) that, 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.

CMS also finalizes its proposal to add §414.1660 to address continuity of pricing when HCPCS codes for lymphedema compression treatment items are divided or combined. Similar to current regulations at §§414.110 and 414.236, CMS finalizes 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, CMS finalizes that the payment amounts for the new code be established using the average (arithmetic mean), weighted by allowed services, of the payment amounts for the formerly separate codes.

The following table presents a preliminary example of what payment amounts may be, based on the methodology described above, as well as certain HCPCS codes classified under the Medicare Part B benefit category for lymphedema treatment items.

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

CMS finalizes §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 (instead of two proposed) daytime garments or wraps with adjustable straps for each affected limb or area of the body, replaced every 6 months.
- Two (instead of the one proposed) nighttime garment for each affected limb or area of the body, replaced once every 2 years (instead once every year).

It also finalizes its proposal to cover replacements of garments or wraps that are lost, stolen, irreparably damaged, or when needed due to a change in the patient's medical or physical condition. CMS also finalizes that specific replacement frequencies for compression bandaging systems or supplies 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."

6. Application of Competitive Bidding for Lymphedema Compression Treatment Items

CMS finalizes its proposal to revise 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. It modifies the list of items that may be included in competitive bidding to include lymphedema treatment items and 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.

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). CMS finalizes its proposal to apply the same methodologies for adjusting payment amounts based on payments determined under the DMEPOS CBP for lymphedema compression treatment items.

7. Economic Analysis

CMS estimates that this benefit for lymphedema compression treatment would cost Medicare an estimated $150 million from 2024 to 2028. The copayments from beneficiaries is expected to be about $30 million. Overall, CMS believes that this Medicare payment will 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.

C. Definition of Brace

The term "brace" is not defined in the Act or in regulation. 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 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.

CMS finalizes its proposal 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. It believes that adding the definition of a brace in regulation will expedite coverage and payment for newer technology and powered devices, potentially providing faster access to these new healthcare technologies for Medicare beneficiaries. The definition of brace at 42 CFR §410.2 will be consistent with CMS's longstanding brace policy and information defined in the Medicare Benefit Policy Manual. Thus, it specifies in the definition that a brace is rigid or semi-rigid and that the stiffness of the material used in making the device is essential to the definition of a brace for purposes of the scope of this Medicare benefit. 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 as compared to materials that completely immobilize.

CMS also finalizes its proposal at 42 CFR §410.2 to specify in the definition that a brace is 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. In addition, it specifies 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.

CMS notes that three HCPCS codes were established to permit billing of the powered upper extremity devices and powered lower extremity exoskeleton devices. Two of these codes, L8701 and L8702, were established effective October 1, 2019. One HCPCS was established effective October 1, 2020. However, corresponding Medicare benefit category and Medicare payment determinations were not finalized for these HCPCS codes, to permit CMS more time for evaluation. As a result of amending the regulations at 42 CFR §410.2 to add the definition of brace, CMS states that these codes will be classified under the definition of brace. These items will be classified as braces effective on the effective date of this final rule. It intends to obtain public consultation on the payment determinations for these codes at an upcoming HCPCS Level II public meeting.[46]

CMS received 55 comments from a diverse set of stakeholders including individuals, health care providers, medical technology manufacturers, patient and medical technology advocacy

[46] The agenda and dates for a public meeting will be available on the CMS HCPCS website: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings

organizations, academic research institutions, and health care providers. Most commenters supported finalizing the definition of brace at 42 CFR §410.2. A few commenters opposed the definition and 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. CMS did not agree with these comments as the proposed definition focuses on 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. CMS emphasizes that a device must be rigid or semi-rigid in order to be able to provide support or restrict or eliminate motion. It states that it is 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.

Several commenters recommended to finalize the definition of brace to include the words "including powered device." CMS states that it is not necessary to include those words in the definition as certain powered devices perform the key bracing function of supporting weak or deformed body members and therefore is included in the definition.

D. Documentation Requirements for DMEPOS Supplied as Refills to the Original Order

1. Background

DMEPOS items and supplies may be furnished on a recurring basis to beneficiaries with chronic or longer-term conditions. For these items, the practitioner may write an order for immediate use and refills for later dates of service.

Section 1893(b)(1) of the Act, authorizes the review of activities of providers of services or other individuals and entities furnishing items and services for which Medicare payment may be made, including medical and utilization review. Due to concerns related to auto-shipments and delivery of DMEPOS supplies that may no longer be needed or not needed at the same frequency of volume, CMS included policies in the Medicare Program Integrity Manual to require timeframes for suppliers to contact the beneficiary prior to dispensing DMEPOS refills.[47] Since 2011, DMEPOS suppliers must contact the beneficiary or designee about refills no sooner than 14 calendar days prior to the delivery/shipping date and delivery of the DMEPOS product should occur no sooner than 10 calendar days prior to the end of the use of the current product. The policy allowed for uninterrupted supply of the necessary items and allow for claims the processing of claims for refills delivered/shipped prior to the beneficiary's complete exhaustion of their supply (referred to as "pending exhaustion").

CMS notes that these timeframes are applicable to all refillable items but are most pertinent to the mail/delivery model because these beneficiaries could potentially be more at risk for receiving unnecessary or unsolicited items and supplies. 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

[47]Internet Only Manual 100-08, Program Integrity Manual, available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c05.pdf

documentation of a refill request. Due to ongoing compliance concerns, CMS proposed to codify and update its refill documentation requirements.

2. Provisions of the Regulations

CMS finalizes its proposal to add the following requirements at new §410.38(d)(4):

- Require documentation indicating that the beneficiary or their representative confirmed the need for the refill within the 30-day period prior to the end of the current supply.
- Remove the term "pending exhaustion" and use the phrase "the expected end of the current supply."
- Delivery of DMEPOS items (that is, date of service) be no sooner than 10 calendar days before the expected end of the current supply.
- Define the shipping data as either the date the delivery/shipping service label is created or the date the item is retrieved for shipment by the mail carrier/delivery party.
- 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 refill request.

CMS notes that documentation of the need for the refill is to confirm the need for the next refill and is not expected to require information about the specific quantities remaining. Suppliers need to confirm both that the beneficiary is using the item and requires the refill.

In response to comments, CMS clarifies that it is not prescribing the mode of communication that providers use for contacting the beneficiary to affirm the need for a refill. Suppliers can use any mode of communication as long as the beneficiary affirmation is received, documentation of the contact is captured, and can be provided upon request. CMS notes that commenters recommendation that suppliers should be permitted to bill a single time for a 90-day supply of CGM sensors, instead of every 30-days, is outside the scope of the proposed regulation but CMS will take this comment under advisement.

In the proposed rule, CMS sought comments for consideration in future rulemaking on ways to balance the beneficiary burden to the potential risks of not verifying the beneficiary's actual need for recurring supplies for certain individuals with permanent conditions. Commenters provided examples of certain chronic conditions, such as type I and type II diabetes and obstructive sleep apnea, that should not require beneficiary contact prior to refill and 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 that supplies continue to be medically necessary. CMS will consider these comments in conjunction with program integrity concerns for potential future rulemaking.

VIII. Changes to the Provider and Supplier Enrollment Requirements

A. Background

The purpose of the enrollment process is to confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable federal and state requirements. CMS believes the process is a "gatekeeper" that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Provider enrollment regulations are generally codified in 42 CFR part 424, subpart P (§§424.500 through 424.575). These regulations also enable CMS to take actions against providers and suppliers that engage (or potentially engage) in fraudulent or abusive behavior; present a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or are unqualified to furnish Medicare beneficiaries services or items.

Providers or suppliers must complete and submit to their assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS-855 (OMB Control No. 0938-0685), which collects information about the provider or supplier. The application is used for several 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 MAC'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. DMEPOS suppliers must revalidate their enrollment every 3 years and all other providers and suppliers must revalidate 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 of supplier is reporting a change in its existing enrollment information in accordance with §424.516.

CMS proposed several changes to existing Medicare provider enrollment regulations. CMS cited two principal categories of legal authorities for its 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. Provisions

1. Provisional Period of Enhanced Oversight for All Providers and Suppliers

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, would be subject to enhanced oversight. As authorized by section 1866(j)(3)(B) of the Act, CMS implemented procedures for enhanced oversight through sub-regulatory guidance for newly enrolling HHA's requests for anticipated payments (RAP).[48] "New" HHAs were subject to suppression of RAPs for a period between 30 days to 1 year, the timeframe they were in the provisional period of enhanced oversight (PPEO). Beginning January 1, 2022, RAPs for HHAs were eliminated and replaced with a Notice of Admission.

In the proposed rule, CMS stated that when RAPs were in effect, it received inquiries regarding the scope of the term "new HHA" and the commencement of the provisional period. CMS proposed to use rulemaking to clarify these issues. CMS notes that it decided to use rulemaking, though not statutorily required, because it may elect to apply its PPEO statutory authorities to all other categories of providers or suppliers per section 1866(j)(3)(A) of the Act.

CMS finalizes the following proposed provisions that will apply to PPEOs for all types of providers or suppliers.

- CMS finalizes in new §424.527(a) to define a "new" provider or supplier (exclusively for purposes of its PPEO authority) as any of the following:
    - A newly enrolling Medicare provider or supplier, including providers that must enroll as a new provider in accordance with 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.
    - 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.

- CMS finalizes in §424.515(b) that the effective date of the PPEO's commencement is the date on which the new provider or supplier submits its first claim. CMS notes this provision aligns with its current sub-regulatory guidance. CMS believes this provision will help stop the practice of providers or suppliers avoiding the PPEO by delaying billing until the PPEO's expiration, a practice done by some HHAs.

Several commenters supported the proposed PPEO clarifications. CMS considered many comments outside the scope of this final rule.

2. Retroactive Provider Agreement Terminations for All Providers and Suppliers

In accordance with §489.52, a provider may voluntarily terminate its provider agreement and leave the Medicare program. Under existing sub-regulatory policy, the provider may request a retroactive termination effective date. To incorporate this into regulation, CMS finalizes its proposal 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.

[48] RAPs were upfront payments that HHAs received from Medicare before the beginning of a 30-day period of home health services.

3. Hospice-Specific Provisions

a. Categorical Risk Screening

(1) Background

Section 6401(a) of the Affordable Care Act amended section 1866(j) to provide CMS the authority to develop provider screening and other enrollment requirements. Screening categories and requirements are based on 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, the greater scrutiny of providers or suppliers within a specific category.

There are three levels of screening (§424.515(b)): limited, moderate, and high. Irrespective of the screening level, the MAC performs screening activities 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. These screening activities include verification that the provider or supplier meets all applicable federal regulations and state requirements; state license verifications; and conducting a database check on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment requirements.

Providers and suppliers at the moderate and high categorical risk levels also undergo a site visit. The MAC performs two additional functions for the high screening level[49] (§424.518(c)(2)). First, all MACs require 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, the MAC conducts a fingerprint-based criminal background check (FBCBC) of the FBI's Integrated Automated Fingerprint Identification System on these 5 percent or greater owners.

(2) Categorical Risk Designation for Hospices

Hospices are currently in the moderate-risk screening category. CMS has become increasingly concerned about program integrity issues within the hospice community, particularly potential and actual criminal behavior, fraud schemes, and improper billing. In the proposed rule, CMS discussed sixteen criminal and False Claims Act cases involving hospice owners and overseers. In addition, the OIG has noted the prevalence of hospice fraud schemes.[50]

CMS finalizes its proposal to revise §424.518 to move initially enrolling hospices and those submitting applications to report any new owners into the "high" level of categorical screening; revalidating hospices will be subject to moderate risk-level screening. CMS believes this will help it detect parties potentially posing a risk of fraud, waste or abuse. CMS notes that under the hospice CoP at 42 CFR §418.114(d): (1) the hospice must obtain a criminal check on all hospice employees who have direct patient contact or access to patient records; and (2) all hospice

[49] Currently, only five provider and supplier types fall within the high categorical risk level: newly/initially enrolling Opioid Treatment Programs, newly/initially enrolling HHAs, newly/initially enrolling DMEPOS suppliers, newly/initially enrolling Medicare diabetes prevention program suppliers and newly/initially enrolling SNFs.
[50] OIG report "Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity" (OEI-02-16-00570) available at https://oig.hhs.gov/oei-02-16-00570.pdf.

contracts must require all contracted entities obtain criminal background check of contracted employees who have direct patient contact or access to patient records.

b. 36-Month Rule

Effective January 1, 2011, CMS amended the regulations for HHA certification. Known as the 36-month rule," §424.550(b)(1) states if an HHA undergoes a change in majority ownership (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 (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 §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.

In the proposed rule, CMS discussed the two objectives of the 36-month rule for HHAs. First, CMS was concerned about a trend in the HHA community where an HHA applied for Medicare certification, underwent a survey, and became enrolled in Medicare, but then immediately sold the HHA without have seen a Medicare beneficiary or hired an employee. This "turn-key" mechanism circumvented the survey process. Second, CMS was concerned when an HHA had a change of ownership, CMS generally did not perform a survey, and CMS had no way of knowing if the HHA was in compliance with the CoPs.

In addition to the aforementioned OIG report highlighting vulnerabilities in the Medicare hospice program, the GAO issued a report highlighting the increased numbers of Medicare beneficiaries and hospice providers and stressed that CMS' oversight of the quality of hospice care must increase.[51] CMS believes that a comprehensive survey would be the most effective means of confirming that newly purchased hospices are meeting the CoPs.

CMS finalizes its proposal to expand the scope of §424.550(b)(1) to include hospice CIMOs.

CMS notes that there are four exceptions to the 36-month rule (§424.550(b)(2)):

- The HHA submitted 2 consecutive years of full cost reports since initial enrollment of the last CIMO, whichever is later.
- An HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.
- The owners of an existing HHA are changing the HHA's existing business structure and the owners remain the same.
- An individual owner of an HHA dies.

[51] GAO report "Medicare Hospice Care: Opportunities Exist to Strengthen CMS Oversight of Hospice Providers" (GAO-20-10) available at https://www.gao.gov/assets/gao-20-10.pdf.

CMS believes these exceptions balance the need for more scrutiny of new owners while not inadvertently obstructing legitimate transactions involving legitimate parties. CMS finalizes its proposal to extend these exceptions to include hospices.

In response to a commenter's suggestion that CMS require hospices to maintain an active census during the 36-month period, CMS states it will consider the suggestion in the future. CMS notes it welcomes recommendations from concerned stakeholders about ways to strengthen program integrity and improve patient care.

4. Deactivation for 12-Months of Non-Billing

Deactivation means 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 may also file a rebuttal to the action (§424.546). In addition, a deactivated provider or supplier remains enrolled in Medicare and deactivation does not impact the provider's or supplier's existing provider or supplier agreement.

To reactivate billing privileges the affected provider or supplier must recertify that its current enrollment information on file with Medicare is correct, furnish any missing information, and be in compliance with all applicable enrollment requirements in Title 42. CMS also reserves the right to require the submission of a complete Form-855 application prior to any reactivation.

CMS can deactivate a provider or supplier for eight reasons; one of the reasons is that the provider or supplier has not submitted any Medicare claims for 12 consecutive months. The 12-month period begins the first day of the first month without a claim's submission through the last day of the 12th month without a submitted claim.

In the proposed rule CMS discussed its prior rulemaking related to this issue. In 2006, in a final rule that established requirements for providers' and suppliers' Medicare enrollment, CMS established 12 months of non-billing as a basis for deactivation.[52] CMS had proposed a 6-month non-billing basis for deactivation, but based on feedback from commenters, it did not finalize the 6-month timeframe. CMS remains concerned, however, about situations where a supplier does not bill for 6 months and discusses recent fraud schemes involving periods of non-billing less than 12 months. CMS notes that this type of activity is similar to what it cited previously in the 2003 proposed rule as justification for the proposed 6-month deactivation threshold. CMS states that it cannot deactivate a dormant billing number because the applicable 12-month period has not yet expired.

CMS finalizes its proposal to revise §424.540(a)(1) to change the 12-month time to 6 months.

CMS notes that a lack of billing for an extended period can also indicate that the provider or supplier has ceased operations without notifying CMS. Deactivating the number enables CMS to not only prevent it from being accessed by other particles but also confirm via the deactivation

[52] Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment (71 FR 20754.

process whether the provider or supplier is operational. In these cases, the provider or supplier can submit a reactivation application and CMS can validate the credentials and compliance with Medicare requirements. CMS also recognizes that some providers are required to be enrolled in Medicare to enroll in another health care program and do not intend to bill Medicare. CMS notes it retains the discretion to deactivate a provider and supplier; providers and suppliers that have not been typically deactivated for 12 months of non-billing should not assume they would be more likely to be deactivated under the proposed change to 6 months.

Several commenters supported CMS' proposal. A commenter believed the change unfairly burdens good-faith HHAs without reducing fraud and recommended that instead of deactivation, CMS takes other steps to confirm the non-billing HHA is operational. Another commenter recommended CMS establish a provision that allows a provider or supplier to explain why it has not submitted claims before deactivation. In response, CMS reiterates that deactivating dormant billing number strengthens program integrity by preventing unscrupulous parties from improperly accessing another provider's billing number or utilizing a "spare" or unused billing number to effectively circumvent a CMS-imposed adverse action applied to the provider's principal billing number. CMS appreciates the alternative recommendations but notes the provisions are not limited to confirming a provider is operational and compliant with Medicare requirements. The provision is designed to ensure that inactive billing numbers cannot be utilized by parties intent on committing fraud.

5. Definition of "Managing Employee"

In order to enroll in Medicare, providers and suppliers are required to report their managing employees via the applicable Medicare enrollment application. In §424.502, CMS defines a "managing employee" 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), CMS proposed a SNF-exclusive definition of a managing employee that also included 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. CMS received questions from the hospice and SNF stakeholders about whether hospice and SNF facility administrators and medical directors must be disclosed as managing employees on the enrollment application. CMS believes these individuals exercise management control over the hospice or SNF and it has required they be reported as managing employees.

CMS proposed to further revise the managing employee definition in §424.502 by adding the following language immediately after the current definition: For purposes of this definition, this includes, but is not limited to, a hospice or SNF administrator and a hospice or SNF medical director.

CMS stressed this clarification should not be construed as an establishment of a minimum threshold for reporting managing employees of hospices, SNFs, or any other provider or supplier. 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 proposal was meant to address specific questions raised by hospices and SNFs and is not meant to change existing reporting requirement for managing employees.

CMS finalizes its proposed change to this definition with one exception. Because the previously mentioned February 15, 2023 proposed rule has not been finalized, the revision to the proposed definition will apply to the current definition of managing employee in §424.502. CMS notes that if the proposed revision to the managing employee definition in the February 15, 2023 rule is finalized, the finalized changes will apply to that revised definition.

6. Previously Waived Fingerprinting of High-Risk Providers and Suppliers

During the COVID-19 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 within the high-risk screening category (§424.518(c)). To reduce the program integrity risks of this waiver, CMS monitored criminal alerts but remained concerned about the lack of FBCBCs information. CMS wants to perform FBCBCs on providers for high-risk providers and suppliers that initially enrolled during the PHE as part of their revalidation process. Existing regulations, however, classifies revalidation applications as the moderate-risk level and does not include FBCBCs.

CMS finalizes its proposes to add new §424.518(c)(1)(viii) to incorporate the FBCBC requirement within the revalidation requirements for the high-screening DMEPOS suppliers, HHAs, Opioid Treatment Programs (OTPs), Medicare Diabetes Prevention Programs (MDPPs) and SNFs that had the FBCBC requirement waived when they initially enrolled in Medicare. Given the potential for future emergencies during which CMS might waive FBCBCs under applicable legal authority, CMS finalizes that this high-risk category (which could include hospices) will apply to situations where CMS waived FBCBCs due to national, state, or local emergency declared under existing laws. CMS notes that this provision does not obligate CMS to waive the FBCBC requirement in any emergency and it expects any waiver would be reserved for the most exceptional circumstances.

CMS will also revise §424.518(b)(1)(x) to include the moderate-risk category revalidating DMEPOS suppliers, HHAs, OTPs, MDPPs, SNFs and hospices that underwent FBCBCs when they initially enrolled in Medicare or upon revalidation after CMS waived the FBCBC requirement when the provider or supplier initially enrolled in Medicare. CMS notes this clarifies that providers and suppliers that were not fingerprinted upon initial enrollment do not remain in the high-screening category in perpetuity because they were not fingerprinted upon the initial enrollment.

Under §424.515(d) CMS also can perform off-cycle revalidations. CMS notes that it still reserves the right to conduct off-cycle revalidations of the FBCBC-waived high-risk providers and suppliers.

7. Expansion of Reapplication Bar

Section 424.530(f) allows 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.

CMS finalizes its proposal to expand the length of a reapplication bar from 3 years to 10 years. CMS notes there is precedent for a 10-year period; reenrollment bars under §424.535(c)(1)(i) are for a maximum of 10 years. CMS believes it is immaterial from a program integrity perspective whether a denial or revocation and subsequent bar stems from the submission of false or misleading data involving a prospective or an enrolled provider.

In response to a concern that the 10-year reapplication bar would be a burden to honest providers and suppliers, CMS notes that the 10-year reapplication bar will only be used when an analysis indicates that it is warranted.

8. Ordering, Referring, Certifying and Prescribing Restrictions

Using its general authority under sections 1102 and 1871 of the Act, CMS finalizes its proposals for the following provisions:

- CMS finalizes that a provider or supplier that is currently subject to a reapplication bar may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs (§424.530(f)(3)). CMS also finalizes that Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a provider or suppler that is currently under a reapplication bar.
- CMS finalizes that a physician or other eligible professional (regardless of whether they were 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 may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs (§424.542(a)). CMS also finalizes that Medicare does not pay for any otherwise covered service, item, or drug that is ordered, referred, certified, or prescribed by a physician or otherwise eligible professional (as defined in section 1848(k)(3)(B) of the Act) who has a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests of the Medicare program (§424.542(b)).

CMS will apply these provisions regardless of whether the provider or supplier has opted-out of Medicare.

IX. Regulatory Impact Analysis

CMS estimates that the net impact of the HH PPS policies in this final rule is an increase of 0.8 percent, or $140 million, in Medicare payments to HHAs for 2024. The overall impact of the changes in the HH PPS system on payments to HHAs in 2024 is summarized in the following table.

Summary of Overall Impact of HH PPS Changes		
Policy	**2024 impact**	
	Percentage	**Dollars**
HH PPS update	+ 3.0%	+$525 million
Permanent behavioral adjustment	-2.6%	-$455 million
Updated FDL	0.4%	+$70 million
Net impact	**0.8%**	**$140 million**

Table GG1, reproduced below from the final rule, provides details on the impact by facility type and ownership, by rural and urban area, by census region and by facility size. The combined effects of all of the changes vary by specific types of providers and by location. It breaks out the payment effects of the permanent behavioral adjustment, the case-mix weights recalibration budget neutrality factor, the 2024 wage index update, the labor-related share, the 2024 update percentage, and the FDL update. The permanent behavior adjustment impact reflected in column 3 does not equal the -2.890 percent permanent behavior adjustment because the adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods that are LUPAs. Proprietary free-standing HH facilities (about 77 percent of all facilities) would experience an average increase of payments of 0.6 percent. Voluntary/Non-profit HHAs would also experience a 0.8 percent increase. Government-based facilities would experience a 0.5 percent increase.

CMS examined alternatives to the final -2.890 percent permanent payment adjustment, including taking the full adjustment of -5.779. Other alternatives include taking the remaining permanent adjustment not taken in the 2023 HH PPS final rule, which resulted in -4.085 percent, and delaying the permanent adjustment to a future year. CMS believes that the full permanent reduction in a single year may be too burdensome for certain HHA providers at this time. Thus, CMS finalized a -2.890 percent (half of the permanent -5.779 adjustment) permanent adjustment to the 2024 30-day payment rate.

Table GG 1: Estimated HHA Impacts by Facility Type and Area of the Country, CY 2024

	Number of Agencies	Permanent Behavior Assumption Adjustment	CY 2024 Case-Mix Weights Recalibration	CY 2024 Wage Index	CY 2024 Labor-Related Share	CY 2024 HH Payment Update %	Fixed-Dollar Loss (FDL)	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	318	-2.6%	-0.1%	-0.8%	-0.1%	3.0%	0.5%	-0.1%
Outlying	400	-2.6%	-0.2%	1.0%	-0.1%	3.0%	0.4%	1.5%
Facility Size (Number of 30-day Periods)								

	Number of Agencies	Permanent Behavior Assumption Adjustment	CY 2024 Case-Mix Weights Recalibration	CY 2024 Wage Index	CY 2024 Labor-Related Share	CY 2024 HH Payment Update %	Fixed-Dollar Loss (FDL)	Total
< 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).

Notes:

1. The permanent behavior assumption (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 in 2023 to 0.27 in 2024.
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 only add up to 9,099.