Illinois Health and Hospital Association

RULE BRIEF

DECEMBER 2023

CY 2024 Medicare Home Health Prospective Payment System – Final Rule Brief

Overview and Resources

On November 1, 2023, the Centers for Medicare & Medicaid Services (CMS) released its final calendar year (CY) 2024 payment rule for the Medicare Home Health Prospective Payment System (HH PPS). The final rule includes updates to the Medicare fee-for-service (FFS) HH PPS payment rates based on changes set forth by CMS and those previously adopted by the US Congress. Among the adopted updates are:

- Recalibration of the Patient-Driven Grouping Model (PDGM) case-mix weights, low utilization payment adjustment (LUPA) thresholds, functional levels, and comorbidity adjustment subgroups;
- Payment adjustments to reflect the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate payment expenditures under the HH PPS;
- Updates to the expanded HH value-based purchasing (HHVBP) program;
- Updates to the HH quality reporting program (QRP);
- Payment rates for the administration of Home Intravenous Immune Globulin (IVIG) items and Services;
- Creation of the Hospice informal dispute resolution and special focus programs;
- Changes to durable medical equipment, prosthetics, orthotics, and supplies outlined by the Consolidated Appropriations Act (CAA) of 2023; and
- Changes to provider and supplier enrollment requirements.

A link to this final rule and other resources related to the HH PPS are available on the CMS website. An online version of this final rule is available.

A brief summary of the final rule is provided below. Program changes adopted by CMS are effective for services provided on or after January 1, 2024, unless otherwise noted. CMS estimates the overall economic impact of this final rule to be an increase of $140 million in aggregate payments to Home Health Agencies (HHA) in CY 2024 over CY 2023, which includes an $455 million decrease due to the adopted permanent behavior adjustment and a $70 million increase due to the updated fixed-dollar loss amount.

HH PPS Payment Rates

The tables below show the final CY 2024 30-day standard payment rate compared to the final CY 2023 30-day standard payment rate and the components of the annual update factor:

	Final CY 2023	Final CY 2024	Percent Change
30-Day Period Standard Payment Rate	**$2,010.69**	**$2,038.13** (proposed at $1,974.38)	**+1.36%** (proposed at -1.81%)

Final CY 2024 Update Factor Components	Change to 30-Day Standard Rate
Market Basket (MB) Update	3.3% (proposed at +3.0%)
Affordable Care Act (ACA)-Mandated Productivity Adjustment	-0.3 percentage points (PPTs) (as proposed)
Permanent Behavior Assumption Adjustment	0.97110 (proposed at 0.94347)
Wage Index and Labor-Related Share Budget Neutrality	1.0010 (proposed at 1.0013)
Case-Mix Weights Recalibration Budget Neutrality	1.0124 (proposed at 1.0121)
Overall Final Rate Update	**+1.36%** (proposed at -1.81%)

The final market basket update percentage is based on IHS Global Inc.'s third quarter 2023 forecast with historical data through second quarter 2023.

Update to the HH Market Basket Base Year

CMS periodically rebases the market basket to reflect the changes in the goods and services needed to furnish HH services. CMS is rebasing and revising the home health market basket using 2021 as a base year using cost report data from Medicare-participating freestanding HHAs rather than the current 2016 base year. CMS believes that the cost reports for this year represents the most complete cost reporting data available that also captures recent cost trends. Due to the potential impact that the COVID-19 public health emergency (PHE) had on cost report data, CMS will monitor these data going forward and propose adjustments as necessary in the future rulemaking.

Behavioral Assumptions and Adjustments

Starting in CY 2020, CMS was required to change the unit of payment from a 60-day episode to a 30-day period of care. Part of this statute required CMS to make assumptions about behavior changes that could occur as a result of implementing a 30-day unit of payment and case-mix adjustment factors that eliminated the use of therapy thresholds when calculating the CY 2020 standard payment amount. The CAA of 2023 requires CMS to determine the impact of differences between assumed and actual behavior on estimated aggregate expenditures, beginning in CY 2020 and ending with CY 2026, and make permanent and temporary adjustments as necessary through notice and rulemaking. CMS is also required to provide data sets underlying the simulated 60-day episodes and provide time for stakeholders to make comments on the development of the CY 2023 payment rate.

CMS analyzed the CY 2020 and CY 2021 30-day payment rates to account for changes in actual versus assumed behavior that would have caused payments to be different than what were finalized for those two years. Based on claims data, CMS found that the CY 2020 30-day payment rate with actual behavior changes would have been $1,742.52, compared to the rate of $1,864.03 when using the assumed behavioral changes that had been adopted in the CY 2020 final rule. Using this new CY 2020 rate, CMS recalculated a CY 2021 30-day payment rate of $1,777.19 using the adopted update factors and assumed behavior changes from the CY 2021 final rule. CMS then analyzed CY 2021 claims data to determine a 30-day payment rate of $1,751.90 to account for actual behavior changes, which is -7.85% lower than the adopted CY 2021 rate of $1,901.12. Based on comments received in the CY 2023 HH PPS proposed rule outlining the potential hardship of implementing the full -7.85% prospective adjustment in a single year, CMS adopted a permanent adjustment of 0.96075 (-3.925%) which was applied to the CY 2023 30-day base payment rate. As this adjustment only accounted for half of the adjustment deemed necessary, CMS stated that they would make further adjustments as needed in future rulemaking to account for behavior changes.

Using the same process outlined in the CY 2023 HH PPS proposed rule, CMS analyzed the available CY 2022 home health claims to estimate 30-day payment rates to account for changes in actual versus assumed behavior that would have caused payments to be different than what were finalized. CMS updated their analysis of these claims now that more complete information is available. This revised analysis shows that the CY 2022 30-day payment rate should have been $1,872.18 ($1,841.55 under the preliminary analysis) based on actual behavior rather than the finalized rate of $2,031.64 based on assumed behavior. This estimate includes the aforementioned updated CY 2021 30-day payment rate adjusted by all finalized CY 2022 update factor components which account for the full -7.85% permanent adjustment to the standard rate and includes an additional adjustment due to half of the permanent adjustment being applied for CY 2023. This results in a new total prospective payment adjustment of -9.477% (proposed at -9.356%) to be applied between CY 2023 and CY 2024. To account for this, CMS determined that they would need to apply a permanent factor of 0.94221 (-5.779%) (proposed at 0.94347 [-5.653%]) to the CY 2024 base 30-day payment rate to account for overpayments in previous years. However, similarly to CY 2023 rulemaking, CMS is finalizing to instead only implement half of this adjustment for CY 2024. As such, the permanent behavior adjustment that will be applied to the 30-day standard rate for CY 2024 will be 0.97110 (-2.890%). Since CMS is only applying half of the -5.779% adjustment in CY 2024, there will be a need for further permanent adjustments in future rulemaking. This will also increase the accrual of the temporary payment dollar amount that will need to be recouped.

The same CMS analysis also found that, due to updating these rates for actual behaviors in CYs 2020 – 2022, total estimated payments for these two years were higher than they should have

been. CMS estimates these overpayments to be $873 million for CY 2020, $1.211 billion for CY 2021, and $1.405 billion (proposed at $1.355 billion) for CY 2022. This results in a combined $3.490 billion (proposed at $3.439 billion) in temporary payment reconciliation, requiring a temporary adjustment to the 30-day payment rate as well. However, in order to avoid significant negative adjustments in a single year, CMS did not adopt the temporary payment reconciliation for CYs 2020 and 2021 in the CY 2023 rulemaking cycle. Similarly to CY 2023, CMS continues to believe that implementing both the permanent adjustment and temporary adjustment in the same year could adversely affect HHAs, especially given the magnitude of the two adjustments. As such, CMS will not make the temporary adjustment for CY 2024 and will instead propose the adjustment factor in future rulemaking.

National Per-visit Amounts

CMS uses national per-visit amounts by service discipline to pay for LUPA periods of care as well as to compute outliers. LUPA payments are made when the number of visits is less than the LUPA threshold for their PDGM classification. This threshold is set at either two visits, or the 10th percentile value of visits, whichever is higher. CMS typically uses the most current utilization data available to set LUPA thresholds at the time of rulemaking.

CMS will update LUPA thresholds using CY 2022 home health claims data. Of these thresholds, 391 case-mix groups would have no change in threshold, 25 would increase by one visit, and groups would have their threshold decrease by one visit. A list of all final LUPA thresholds can be found in Table B12 on *Federal Register* pages 77714 – 77725 and on the CMS website

The final CY 2023 national per-visit rates compared to the final CY 2024 national per-visit rates are shown below and do subject to permanent behavior adjustment.

Per-Visit Amounts	Final CY 2023	Final CY 2024	Percent Change	Final CY 2024 with LUPA Add-On*
Home Health Aide	$73.93	$76.23 (proposed at $76.03)	+3.11% (proposed at +2.84%)	N/A
Medical Social Services	$261.72	$269.87 (proposed at $269.16)		N/A
Occupational Therapy (OT)	$179.70	$185.29 (proposed at $184.81)		$309.43 (1.6700 adj.) (proposed at $308.63)
Physical Therapy (PT)	$178.47	$184.03 (proposed at $183.55)		$307.33 (1.6700 adj.) (proposed at $306.53)
Skilled Nursing (SN)	$163.29	$168.37 (proposed at $167.93)		$310.66 (1.8451 adj.) (proposed at $309.85)
Speech Language Pathology (SLP)	$194.00	$200.04 (proposed at $199.52)		$325.39 (1.6266 adj.) (proposed at $324.54)

* For OT, PT, SN, or SLP visits in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, CMS will continue to use the LUPA add-on factors established in the CY 2014 final rule.

The CAA of 2021 included a provision allowing occupational therapists to conduct initial and comprehensive assessments to home health beneficiaries. CMS allows these assessments when the plan of care does not initially include SN but does include PT or SLP. Due to this, CMS established a LUPA add-on factor to be used for payment for the first 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. In CY 2022 rule making, CMS stated that due to insufficient data regarding initial and comprehensive visits conducted by occupational therapists, the PT LUPA add-on factor of 1.6700 will be used as an appropriate proxy for the OT add-on factor until there is sufficient data to create a distinct OT add-on factor. CMS estimates that CY 2022 data will be needed before a distinct OT add-on factor can be established. CMS states that they are still analyzing these data and will continue to use the PT LUPA add-on factor as a proxy for OT for CY 2024 but plans to propose a LUPA add-on factor specific to OT in future rulemaking.

Wage Index and Labor-Related Share

As has been the case in prior years, CMS will use the most recent inpatient hospital wage index, which is the Federal Fiscal Year (FFY) 2024 pre-rural floor and pre-reclassified hospital wage index, to adjust payment rates under the HH PPS for CY 2024. The wage index is applied to the labor-related portion of the HH payment rate. Using the adopted 2021-based market basket, CMS will decrease the labor-related share of the HH 30-day period standard rate from 76.1% in CY 2023 to 74.9% (as proposed) for CY 2024 and onwards.

In the CY 2023 final rule, CMS adopted a 5% cap on any decrease of the CY 2023 HH PPS wage index, and all future HH PPS wage indexes, compared with the previous year's final wage index. The cap is applied regardless of the reason for the decrease and is implemented in a budget neutral manner. This also means that if the wage index for a site of service is calculated with the application of the 5% cap, the following year's wage index will not be less than 95% of the capped HH PPS wage index in the prior CY. CMS will continue this policy CY 2024.

The wage index and labor-related share budget neutrality factors are for CY 2024 will be 1.0010 (proposed at 1.0013) for the standard rate and 1.0011 (proposed at 1.0014) for the per-visit rates to ensure that aggregate payments made under the HH PPS are not greater or less than will otherwise be made if wage adjustments had not changed.

A complete list of the wage indexes adopted for CY 2024 is available on the CMS website.

Patient-Driven Grouping Model

CMS assigns HH stays into PDGM 30-day period of care groupings that are consistent with how clinicians differentiate between patients and the primary reason for needing home health care. Case-mix adjustments for home health payment are based solely on patient characteristics,

relying more heavily on clinical characteristics and other patient information to place patients into 432 clinically meaningful payment categories.

Each year CMS recalibrates the PDGM case-mix weights in a budget neutral manner to ensure that the case-mix weights reflect current home health resource use and change in utilization patterns. For CY 2024, CMS will recalibrate case-mix weights based on data from CY 2022 claims data. Compared to CY 2023 weights, 424 groups will see a +/- 5% difference, and 8 groups will change between +5% and +10% for CY 2024. CMS is adopting a case-mix budget neutrality factor of 1.0124 (proposed at 1.0121) to be applied to the standardized 30-day period payment rate.

The adopted case-mix weights for CY 2024 are listed in Table B12 on *Federal Register* pages 77714 – 77725 and on the CMS website.

CMS is updating functional impairment levels and functional points by clinical group using CY 2022 claims data. Tables B7 and B8 on *Federal Register* pages 77700 – 77701 show the finalized OASIS points and thresholds for functional levels by clinical group, respectively, for CY 2024. CMS is also updating the comorbidity adjustment applicable to 30-day periods of care using the same methodology as CY 2022, which would result in 22 low comorbidity adjustment subgroups and 101 high comorbidity subgroups. These groups are listed on tables B9 and B10, respectively, on *Federal Register* pages 77703 – 77711.

Details on these reassignments can be found in the following supplemental file on the HH PPS webpage.

Outlier Payments

Outlier payments are intended to mitigate the risk of caring for extremely high-cost cases. An outlier payment is provided whenever an HHA's cost for an episode of care exceeds a fixed-loss threshold, defined as the HH PPS payment amount for the episode plus a FDL amount.

Currently, there is a cap of 8 hours or 32 units per day (1 unit = 15 minutes), summed across the six disciplines of care, on the amount of time per day that will be counted toward the estimation of an episode's costs for outlier. The discipline of care with the lowest associated cost per unit is first discounted in the calculation of episode cost, in order to cap the estimation of an episode's cost at 8 hours of care per day.

The FDL amount is an FDL ratio multiplied by the wage index-adjusted 30-day period payment. This is added to the HH PPS payment amount for that episode. If calculated cost exceeds the threshold, the HHA receives an additional outlier payment equal to 80% of the calculated excess costs over the fixed-loss threshold.

Each HHA's outlier payments are capped at 10% of total PPS payments. By law, a limit of 2.5% of total HH PPS payments is set aside for outliers. CMS is adopting a FDL ratio of 0.27 (proposed at 0.31) for CY 2024, based on CY 2022 data.

Expanded Home Health Value-Based Purchasing Model

On January 8, 2021, CMS announced the certification of the HHVBP for national expansion as well as its intent to expand the model through notice and comment rulemaking. In the original model, CMS implemented an ACA mandated HHVBP demonstration model for certain Medicare-certified HHAs, which started on January 1, 2016, and concludes on December 31, 2022, with the last year of data collection having ended on December 30, 2020.

The Medicare-certified HHAs required to participate in the original demonstration were from 9 randomly selected states: Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington. The demonstration program resembled the inpatient acute care hospital VBP program. CMS found that this model resulted in an average 4.6% improvement in HHA quality scores while also saving Medicare an average of $141 million annually without denying or limiting coverage to beneficiaries.

CMS previously adopted the expansion of the HHVBP model to all 50 states, the District of Columbia (DC), and all territories, starting with performance adjustments in CY 2025, which will be budget neutral by cohort. This will apply to all HHAs certified before January 1, 2022, and will be based on the HHAs' CMS Certification Numbers (CCN). CY 2022 was a pre-implementation year which allowed HHAs to prepare and learn about the model with support from CMS. Each HHA will have a reduction or increase to their Medicare payments by up to 5%, dependent on their performance on specified quality measures relative to other similar, competing HHAs in their cohort.

Changes to the Applicable Measure Set

CMS determined that five of the adopted measures for the expanded HHVBP require further consideration for inclusion in the program beginning CY 2025 and would be replaced with three other measures. These changes used in the HHVBP model will align with the measures in the HH QRP and publicly reported on HH Care Compare. Specifically, CMS is adopting the following measure replacements for the CY 2025 performance year (2027 Payment year) onwards:

- Claims-based Discharge to Community-Post Acute Care (DTC-PAC) Measure for Home Health Agencies will replace:
    - OASIS-based Discharged to Community (DTC);
- OASIS-based DC Function will replace:
    - OASIS-based Total Normalized Composite Change in Self-Care (TNC Self-Care); and
    - OASIS-based Total Normalized Composite Change in Mobility (TNC Mobility).
- Claims-based Home Health Within-Stay Potentially Preventable Hospitalization (PPH) will replace:

- Claims-based Care Hospitalization During the First 60 Days of Home Health Use (ACH); and
- Claims-based Emergency Department Use without Hospitalization during the First 60 Days of Home Health.

CMS states that even though the measure set is changing, they intend to maintain the existing measure categories and their relative weights. Table D3 on Federal Register page 77782 shows the current and adopted measures within each measure category by cohort and corresponding category weights. Due to the replacement of current measures, CMS will update the measure weight distributions within each measure category. Table D4 on Federal Register page 77784 shows the adopted redistributions of each measure weight by cohort and measure category.

The following measure topics will be taken into consideration in future rulemaking as CMS looks to expand the HHVBP:

- Further aligning HHVBP measures with measures in the HH QRP and publicly reported on HH Care Compare;
- Streamlining quality measures across CMS quality Programs for the adult and pediatric populations; and
- Incorporation of health equity goals into the model.

Updates to Model Baseline Year

CMS previously adopted a change to the HHA baseline year to CY 2022 for all applicable measures used in the expanded model, beginning with the CY 2025 program year. In this rule, CMS will again update the model baseline year to CY 2023 for all applicable measures (current and adopted) except for the adopted claims-based DTC-PAC measure, since that measure utilizes two years of data. All measures besides DTC-PAC will continue to use the previously finalized performance year CY 2025 for payment year 2027. The DTC-PAC measure will have baseline years CY 2022 and CY 2023 with performance years CY 2024 and CY 2025 for payment year 2027. Detail on these data periods for the adopted measure sets can be found on table D6 on Federal Register page 77787. Additionally, CMS will provide final achievement thresholds and benchmarks in the July 2024 Interim Performance Report.

Changes to the Appeals Process

CMS is finalizing revisions to the appeals process to acknowledge the ability of the CMS Administrator to review reconsideration decisions and to change the time for filing a request for reconsideration. Specifically, CMS is adopting the following revisions to the appeals process:

- An HHA may request Administrator review of a reconsideration decision within 7 days from CMS' Notification to the HHA for the outcome of the reconsideration request;

- The CMS reconsideration official issues a written decision that is final and binding 7 calendar days after the decision unless the CMS Administrator renders a final determination reversing or modifying the reconsideration decision; and
- An HHA may request within 7 calendar days of the decision that the CMS Administrator review the reconsideration decision. The CMS Administrator may decline to review the reconsideration decision, render a final determination, or choose to take no action on the request for administrative review. Reconsideration decisions are considered final if the CMS Administrator declines an HHA's request for review or if the CMS Administrator does not take any action on the HHA's request for review within 14 days.

Home Health Quality Reporting Program

CMS collects quality data from HHAs on processes, outcomes, and patient experience of care. HHAs that do not successfully participate in the HH QRP are subject to a 2.0 percentage point reduction to the market basket update for the applicable year. CMS lists these measures in Table C1 on Federal Register page 77753.

Summary of Measure Currently Adopted for the CY 2024 HH Quality Reporting Program	
Measures	**Data Source**
Improvement in Ambulation/Locomotion (CBE #0167)	OASIS
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #0674)	OASIS
Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (CBE #2631)	OASIS
Improvement in Bathing (CBE #0174)	OASIS
Improvement in Bed Transferring (CBE #0175)	OASIS
Drug Regimen Review Conducted with Follow-Up for Identified Issues - Post Acute Care (PAC) HH QRP	OASIS
Improvement in Dyspnea	OASIS
Influenza Immunization Received for Current Flu Season	OASIS
Improvement in Management of Oral Medications (CBE #0176)	OASIS
Changes in Skin Integrity PAC	OASIS
Timely Initiation Of Care (CBE #0526)	OASIS
Transfer of Health Information to Provider-PAC	OASIS
Transfer of Health Information to Patient-PAC	OASIS
Acute Care Hospitalization during the First 60 Days of HH (CBE #0171)	Claims-based

Discharge to Community- PAC HH QRP (CBE #3477)	Claims-based
Emergency Department Use without Hospitalization during the First 60 Days of HH (CBE #0173)	Claims-based
Total Estimated Medicare Spending Per Beneficiary (MSPB)— PAC HH QRP	Claims-based
Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program	Claims-based
Home Health Within Stay Potentially Preventable Hospitalization	Claims-based
How well did the home health team communicate with patients	HHCAHPS
How do patients rate the overall care from the home health agency	HHCAHPS
How often the home health team gave care in a professional way	HHCAHPS
Did the home health team discuss medicines, pain, and home safety with patients	HHCAHPS
Will patients recommend the home health agency to friends and family	HHCAHPS

CMS is adopting the following changes for HH QRP reporting requirements, beginning CY 2025:

- Replacing the Application of Functional Assessment/Care Plan measure with the Discharge Function Score (DC Function) measure;
- Removing the "Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function" measure; and
- Adding the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine)" measure.

CMS also adopting the removal of two items from the Outcome and Assessment Information Set (OASIS-E) Data Set, effective January 1, 2025:

- M0110 – Episode Timing; and
- M2220 – Therapy Need

Lastly, CMS will begin public reporting of the "Transfer of Health Information to the Provider-PAC", "Transfer of Health Information to the Patient-PAC", and "DC Function Score" measures beginning with the January 2025 refresh of Care Compare, or as soon as feasible, using data collected from April 1, 2023 to March 31, 2024. CMS also plans to publicly report the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure on Care Compare beginning January 2026, or as soon as feasible, using data collected from January 1, 2025 – March 31, 2025.

Disposable Negative Pressure Wound Therapy

Payments for disposable negative pressure wound therapy (dNPWT) devices are mandated by the CAA of 2023 to be paid separately from the HH benefit beginning CY 2024. Payment for the

services to apply the device is to be included under the home health prospective payment system. This payment would be set equal to the supply price used to determine the relative value for the service under the Physician Fee Schedule as of CY 2022 for CY 2024. This payment is to be adjusted using the Consumer Price Index for All Urban Consumers (CPI-U) for the 12-month period ending with June of the preceding year minus the productivity adjustment, which could result in a percentage being less than 0% for a year. Therefore, the payment amount for CY 2024 will be set equal to $263.25, updated by the percent increase of the CPI-U for the 12-month period ending June 2023 minus a productivity adjustment. For CY 2024, this adjustment is 3% with a corresponding protectivity adjustment of 0.4PPTs. This results in a 2.6% adjustment which, when applied to the dNPWT supply price as of January 1, 2022, yields a payment rate of $270.09 for CY 2024

For CY 2025 going forward, this payment rate will be calculated using the previous year's payment adjusted by CPI-U for the 12-month period ending with June of the preceding year minus the productivity adjustment finalized for that year.

This payment will no longer include payment for nursing or therapy services that would otherwise be paid under the PPS. Claims for the separate payment amounts would be submitted on TOB 32X ("other home health services") as of January 1, 2024, rather than TOB 34X ("furnishing NPWT using a disposable device").

Home Intravenous Immune Globulin Items and Services

The IVIG Demonstration Project was established in the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 to evaluate the benefits of providing coverage and payment for these items and services as well as determine if the inclusion would improve access to home IVIG therapy. Currently, IVIG is covered in the home if all the following criteria are met:

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

The IVIG demonstration program is set to end December 31, 2023. The CAA of 2023 establishes permanent coverage and payments of items and services related to administration of IVIG in a patient's home for patients diagnosed with a primary immune deficiency disease (PIDD) as of January 1, 2024. Prior to this legislation, Medicare provided coverage for IVIG product for treatment of PIDD but not for the items and services involved in administration.

For services to be covered, the following conditions must be met:

- The services must be furnished while the beneficiary is in a period of entitlement;
- The services must be furnished by a facility or other entity as specified in the regulations set by the CAA of 2023; and
- If the services are subject to physician certification requirements, they must be certified as being medically necessary, and as meeting other applicable requirements, in accordance with standing regulations.

Payment for these items and services are required to be a bundled payment separate from the payment for IVIG product made to a supplier and may be based on the amount established under the demonstration.

Under the demonstration, the bundled payment for in-home administration of IVIG was based on the LUPA amount for skilled nursing based on an average 4-hour infusion. The full skilled nursing LUPA rate was used for the first 90 minutes of infusion and 50% of the LUPA for each hour thereafter for an additional 3 hours. CMS believes this payment structure under the demonstration to be appropriate for the implementation of the permanent IVIG benefit. As such, CMS will update the CY 2023 payment amount of $408.23, established under the demonstration, by the CY 2024 HH payment rate update of 3% (proposed at 2.7%). The wage index budget neutrality factor is not included in this update as statute does not require this payment to be geographically wage adjusted. Therefore, the adopted CY 2024 IVIG items and services payment rate would be $420.48 (proposed at $419.25). CMS is finalizing that, for CY 2025 and onwards, this payment be updated using the home health update percentage but without the adjustment for wage index budget neutrality.

Hospice Informal Dispute Resolution and Special Focus Program

The CAA of 2021 directed CMS to create a Special Focus Program (SFP) for poor performing hospice programs which will have authority to impose enforcement remedies for noncompliant programs and to develop and implement remedies and procedures for appealing these remedies. This was initially proposed to be implemented for CY 2022, but CMS decided to revise the proposal to be included in 2024 rulemaking. Since then, CMS initiated a hospice technical expert panel to provide input on how to best develop an SFP. Details from these meetings and recommendations for creating the SFP can be found here.

The SFP is intended to address issues that would place beneficiaries at risk for poor quality of care through increased oversight. This program will begin as of the publishing date of the CY 2024 HH PPS final rule with SFP hospices selected starting in CY 2024. This process will be periodically reviewed for effectiveness in the methodology and algorithm with adjustments being made through rulemaking, if necessary. To identify hospices with poor quality indicators for potential SFP enrollment, CMS will multiple indicators from the most recent hospice data

from hospice surveys and the hospice QRP (HQRP). These indicators, and corresponding scoring methodology, will include:

- Hospice Surveys
    - Quality-of-Care Condition-level Deficiencies
        - Score would consist of the total number of quality-of-care condition-level deficiencies (CLD) for the following conditions of participation from the previous 3 consecutive years
            - Patient's rights;
            - Initial and comprehensive assessment of the patient;
            - Interdisciplinary group, care planning, and coordination of services;
            - Quality assessment and performance improvement;
            - Infection control;
            - Core services;
            - Hospice aid and homemaker services;
            - Medical director;
            - Short-term inpatient care;
            - Hospices that provide inpatient care; and
            - Hospices that provide hospice care to residents of a SNF/NF or ICF/IID.
    - Substantiated Complaints
        - Score would consist of the total number of substantiated complaints received against a hospice in the last 3 consecutive years.
- HQRP
    - Claims Data – Hospice Care Index (HCI)
        - Score would include the overall HCI score based on eight quarters of claims data and would be a composite score of 10 indicators (range 0-10, higher being better). Hospices with less than 20 claims would be exempt from public reporting and this measure would be suppressed if any 1 of the 10 indicators is not reported.
    - Consumer Assessment of Healthcare Providers and Systems (CAHPS) Hospice Survey measures
        - Measures include (with adopted weights into the scoring methodology):
            - Help for Pain and Symptoms (1.0)
            - Getting Timely Help (1.0)
            - Willingness to Recommend this Hospice (0.5)
            - Overall Rating of this Hospice (0.5)

- Scoring would be calculated across eight rolling quarters for all hospices with at least 30 completed surveys unless the hospice is exempt from CAHPS reporting. From these data for the four measures, CMS will take a weighted sum of the adjusted bottom-box scores of these measures to create a CAHPS Hospice Survey Index that is a single index.

Once the above data is compiled, CMS will standardize each indicator so that the indicators can be compared with each other, with the CAHPS indicator being double the weight of other measures. The standardization formula for each indicator is adopted to be:

$$Standardized\ Value = \frac{Hospice\ Value - Overall\ Average\ for\ all\ Hospices}{Standard\ Deviation}$$

With this, CMS developed an algorithm that would identify a subset of 10% of hospice programs, based on highest aggregate scores, from which a subset would be selected for the SFP. To identify hospices with poor quality indicators, this algorithm would use data from hospice surveys and the hospice QRP. More detail on this algorithm, including how these data sources will be utilized and how hospitals will be determined to be in the highest 10% of aggregate scores, can be found on Federal Register pages 77799 – 77810.

To be in line with the CAA of 2021, CMS is adopting that, once in the SFP, a hospice would be surveyed not less than once every 6 months and be subject to remedies based on noncompliance with one or more conditions of participation. If subsequent surveys also result in additional deficiencies, the enforcement remedies imposed could increase in severity, based on CMS discretion. To graduate from the SFP, a hospice must have no CLD cited for two consecutive 6-month recertification surveys in an 18-month timeframe and have no pending complaint survey at an immediate jeopardy (IJ) or condition-level. If there are complaint investigations or a 36-month recertification survey for a hospice while in SFP, the timeline for the SFP may be extended beyond the 18-month timeframe. Furthermore, CMS is adopting that a hospice in the SFP would be considered for termination from the Medicare program pending the result of complaint investigations at an IJ or condition-level, or if that hospice fails any two SFP surveys in an 18-month period due to having any CLDs on the survey.

CMS is also finalizing a hospice IDR process to provide hospice programs an informal opportunity to resolve disputes related to condition-level survey findings following a hospice program's receipt of the official survey Statement of Deficiencies and Plan of Correction. This process will be similar to the process already in place for HHAs and would provide hospice programs an informal opportunity to resolve disputes regarding survey findings for those hospice programs seeking recertification from the state survey agency (SA), CMS, or reaccreditation from the accrediting organization for continues participation in Medicare. CMS believes that these new

policies will balance the need for hospice programs to avoid unnecessary disputes and protracted litigation by being able to quickly correct deficiencies.

CMS is adopting that SFP information be publicly reported, at least on an annual basis, at the link found at the beginning of this section or a successor website. The information posted would include general information, program guidance, the 10% of hospice programs determined by the SFP algorithm, the SFP selections from the 10% subset, and SFP status. To establish the SFP, CMS will add new regulatory definitions for Hospice SFP, informal dispute resolution (IDR), SFP status, and SFP survey. These new definitions can be found on Federal Register page 77798.

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

CMS is adopting several updates to policies related to DMEPOS, which include:

- DMEPOS fee schedule adjustments (Federal Register pages 77812 – 77814);
- Scope of benefit and payment for lymphedema compression treatment items (Federal Register pages 77814 – 77837);
- The definition of "brace" (Federal Register pages 77837 – 77840); and
- Documentation requirements for DMEPOS products supplied as refills to the original order (Federal Register pages 77840 – 77843).

Changes to the Provider and Supplier Enrollment Requirements

CMS is changing existing Medicare provider enrollment regulations to further clarify and strengthen certain components of the enrollment process while also allowing action to be taken against providers and suppliers that take advantage of the Medicare system. These adopted regulations include:

- Establishing the definition of a "new" provider or supplier as one who is a new enrolling Medicare provider or supplier; or a certified provider or supplier undergoing a change of ownership, change in majority ownership (CIMO), or 100% change of ownership; as well starting the provisional period of enhanced oversight should start for these providers as of the date the provider or supplier submits its first claim (Federal Register pages 77843 – 77844);
- Update policy to allow providers who voluntarily terminate their Medicare provider agreement to request a retroactive termination effective date, but only if no Medicare beneficiary received services on or after the requested date (Federal Register page 77844);
- In an effort to reduce the potential of fraud, placing initially enrolling hospices and those submitting applications to report new owners into the "high" level of categorical

screening, which requires all hospice owners with 5% or greater direct or indirect ownership to submit fingerprints for a criminal background check (Federal Register pages 77844 – 77845);

- Expanding the scope of the HHA "36-month" rule (if a HHA has a CIMO by sale within 36 months of the effective date of the HHA's initial enrollment in Medicare or most recent CIMO, the provider agreement and billing privileges do not convey to the new owner) to also include hospice providers, including the exceptions to this policy (Federal Register pages 77846 – 77847);
- Reducing the timeframe after which a provider or supplier would have their billing privileges deactivated due to not submitting claims from 12 consecutive months to 6 consecutive months (Federal Register pages 77847 – 77848);
- Update the definition of "managing employee" currently defined 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"* to include hospice or skilled nursing facility administrators and medical directors (Federal Register page 77848);
- Begin performing fingerprint-based criminal background checks and to revalidate high-risk providers and suppliers (Including DMEPOS suppliers, HHAs, opioid treatment program suppliers, Medicare diabetes prevention program suppliers, and skilled nursing facilities) that were enrolled as Medicare suppliers during the COVID-19 PHE due to this requirement having been waived for the PHE, including reserving the right to conduct off-cycle revalidations for any waived providers in the future (Federal Register pages 77848 – 77849);
- For providers or suppliers that were found submitting false or misleading information on or with its application to enroll with Medicare, the maximum length that the offender would be barred from reapplying to Medicare would be increased from 3 years to 10 years (Federal Register page 77849); and
- Providers or suppliers that are subject to a Medicare reapplication bar, or any physician or eligible professional who has had a felony conviction within the past 10 years, may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs and Medicare would not pay for any of these items or services furnished by these groups otherwise (Federal Register pages 77849 – 77850).

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