

Medicare Program; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies (CMS-1803-F) Summary of Final Rule

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I. Introduction

On November 7, 2024, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register a final rule (89 FR 88354) addressing updates to the Home Health Prospective Payment System (HH PPS) rates for home health agencies (HHAs), disposable negative pressure wound therapy (dNPWT) devices, and intravenous immune globulin (IVIG) items and services for calendar year 2025. In addition, CMS also finalizes a permanent prospective behavior adjustment to the 2025 home health payment rate to account for the impact of the implementation of the PDGM. Specifically, CMS finalizes a -1.975 percent (half of the proposed) 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.

For the Home Health Quality Reporting Program (HH QRP), CMS finalizes adoption of four new OASIS items and a modification to an existing OASIS item, as well as an update to the removal of the suspension of OASIS all-payer data collection. CMS also summarizes comments received regarding future HH QRP quality measure concepts. For the Expanded Home Health Value-Based Purchasing (HHVBP) Model, CMS reviews feedback in response to its Request for Information (RFI) related to the future measure concepts for the expanded HHVBP Model and provides an update on potential future approaches for integrating health equity in the Model.

CMS estimates that the net impact of these policies will increase Medicare payments to home health agencies (HHAs) in 2025 by 0.5 percent (\$85 million). This increase reflects the effects of the +2.7 percent home health payment update, an estimated 1.8 percent decrease from the permanent behavior adjustment,² and an estimated 0.4 percent decrease from the update to the fixed-dollar loss ratio (FDL) used in determining outlier payments.

II. Payment Under the Home Health Prospective Payment System

A. Overview

CMS reviews the statutory and regulatory history of the HH PPS from 1997. As required by the Bipartisan Budget Act of 2018 (BBA of 2018), on January 1, 2020, CMS implemented the home

¹ Henceforth in this document, a year is a calendar year unless otherwise specified.

² CMS finalizes a permanent behavior adjustment of -1.975 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 -1.8 percent includes all payments.

health Patient Driven Groupings Model (PDGM) and a 30-day unit of payment. Most recently in 2024, as required by the Consolidated Appropriations Act, 2023 (CAA, 2023), CMS established separate payment for furnishing negative pressure wound therapy (NPWT) for the device (not for nursing and therapy services as these are already included under the HH PPS).

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—that is, skilled nursing (SN), home health aide, physical therapy (PT), speech-language pathology (SLP), occupational therapy (OT), and medical social services (MSS). Payment for non-routine supplies (NRS), previously paid through a separate adjustment, are 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 (HHRGs). Patient characteristics and other clinical information is 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. 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, 2022, and 2023 for 30-day periods of care. Commenters encouraged CMS to develop policies that ensure the PDGM does not continue to affect access to care as indicated by

declining utilization trends. 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 trends and vulnerabilities with the HH PPS and will consider the additional monitoring suggested by the commenter.

C. Final Rule Payment Adjustments Under the HH PPS

1. Finalized 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 past overspending or repay past 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 of the CAA, 2023, required CMS to publicly post the datasets underlying the simulated 60-day episodes under the HH PPS in effect before the PDGM and to the extent practicable a description of the actual behavior changes occurring under the HH PPS from 2020 through 2026, as well as provide mechanisms for stakeholder input. CMS 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. CMS also conducted a webinar on these issues on March 29, 2023.³

³ These materials can be found at https://www.cms.gov/medicare/medicare-fee-for-service-payment/homehealthpps/hh-pdgm

b. Methodology

In the 2023 HH PPS final rule, CMS finalized the methodology to evaluate the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures. For 2020 through 2026, CMS evaluates 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. In the 2024 HH PPS final rule, CMS provided 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.

Due to an update of the OASIS instrument, CMS updates two minor technical parts and adds new assumptions in the first step (creating simulated 60-day episodes from 30-day periods). CMS uses the OASIS instrument to collect certain quality data from HHAs. Under the prior 153-group system (and the first three years for assessments associated with the PDGM completed prior to 2023), HHAs submitted the OASIS-D version. OMB approved, however, an updated version of the OASIS instrument, OASIS-E, on November 30, 2022, effective January 1, 2023.

There are 13 items from the OASIS-D used in the 153-group system that are included in the OASIS-E; however, the responses for these items are now only recorded at the start of care (SOC) or resumption of care (ROC) assessments in the OASIS-E and not at all for follow-up assessments (shown in figure 3 in the final rule). Three items in the OASIS-E differ slightly from the OASIS-D by incorporating more specific questions and responses than in the OASIS-D. These three items (shown in figure 4) ask about therapies (M1030), vision (M1200), and the frequency of pain interfering with activity (M1242). Additionally, these three items are only asked at SOC/ROC and not follow-up.

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

CMS finalizes, with modification, its proposed changes from the OASIS-D to the OASIS-E to create simulated 60-day episodes from 30-day periods.

• If the simulated 60-day episode matches to a SOC or ROC assessment then CMS will not impute the 13 items. If the simulated 60-day episode matches to an OASIS-E follow-up

assessment, then CMS will look back for the most recent 30-day period that is linked to a SOC or ROC assessment and impute the 13 responses for follow-up using the responses at the most recent SOC or ROC assessment. CMS will limit the look-back period to 12 months. For example, a simulated 60-day episode that began on June 1, 2023, and linked to a follow-up assessment will be limited to a 30-day period that ended on or after June 1, 2022, and linked to a SOC or ROC assessment. If CMS cannot find a SOC or ROC assessment in that time period, it will exclude the claim from analysis.

• If the simulated 60-day episode matches to an OASIS-D assessment, then CMS will use the OASIS-D for the three items (therapies (M1030), vision (M1200), and the frequency of pain interfering with activity (M1242)) responses. If the simulated 60-day episode matches to an OASIS-E assessment, CMS will apply the mapping for the therapies, vision, and pain items as shown in figures 4 – 6 to impute responses as these responses are required for accurate payment calculation under the prior 153-group system. When necessary, CMS will also apply the same 12- month look-back period as described in the previous assumption.

Figures 4, 5, and 6 in the final rule detail the mapping for therapies, vision, and pain response items from the OASIS-E to OASIS-D.

A commenter expressed concerns related to the difference in the versions of questions used for mapping and a potential two-year lookback period, and suggested a narrower lookback period of no more than three months. CMS replies that it reevaluated the crosswalk and found a three-month lookback period could significantly decrease the number of claims available for analysis, skew the data to potentially more clinically severe patients, and thus would not fully represent the population of home health patients. At the same time, CMS acknowledges that an almost two-year lookback period for an assessment may not provide the most updated functional status of a beneficiary for the claims being analyzed. CMS found a 12-month timeframe provided the most accurate and complete data while balancing the need for up-to-date data and will use this lookback period instead of the almost two-year lookback period proposed.

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:

- 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 a temporary increase or decrease is made. CMS refers readers to the 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis of 2020 through 2022 claims.

d. 2023 Final Claims Results

CMS updated its 2023 analysis in the final rule as more data become available from the latter half of 2023. It followed the same methodology described previously. After all exclusions and assumptions were applied, the final dataset for this final rule included 6,541,678 actual 30-day periods of care and 3,870,602 simulated 60-day episodes of care for 2023.

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

CMS determined that a permanent prospective adjustment of -1.004 percent to the 2023 30-day payment rate (which assumes the -5.779 percent adjustment was already taken) would be required to offset such increases in estimated aggregate expenditures in future years. It also calculates that a temporary adjustment of \$971 million would be required to achieve budget neutrality. Table 2 (reproduced below) details these results.

| Table 2: 2023 Final Permanent and Temporary Adjustments | | | | | | | |
|---|-------------------------|------------------|---------------------------------|--|--|--|--|
| | 2023 Only Adjustment | | | | | | |
| Base Payment Rate | \$1,894.49* | \$1,875.46 | Permanent-1.004% | | | | |
| Aggregate Expenditures | \$16,354,432,797** | \$15,383,001,684 | Temporary -\$971,431,113 | | | | |

Source: 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW July 11, 2024 **Notes**: *The \$1,894.49 is equal to the recalculated budget neutral 30-day base payment rate of \$1,839.10 for 2022 (shown in Table 2) multiplied by the 2023 recalibration factor (0.9904), wage index budget neutrality factor (1.0001) and the 2023 home health payment update (1.040). **The estimated aggregate expenditures with assumed behavior changes (\$16.4 billion) uses the actual 2023 payment rate of \$2,010.69 as this is what CMS actually paid in 2023.

f. Final 2025 Permanent and Temporary Adjustment Calculations

The calculation in this section includes any of the remaining adjustments not applied in previous years (that is, 2020 to 2022), as well as the adjustment needed to account for 2023 claims. In calculating the full permanent adjustment needed to the 2025 30-day payment rate, CMS compares estimated aggregate expenditures under the PDGM and the prior system. Unlike the annual adjustments described in table 2, CMS does not assume the full adjustment from prior years had been taken.

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

| Table 4: Total Permanent Adjustment for CYs 2020, 2021, 2022, and 2023 | | | | | | |
|---|------------|----------|--|--|--|--|
| Actual 2023 Base Payment Rate (Assumed Behavior) Recalculated 2023 Base Payment Rate (Actual Behavior) Total Permanent Prospective Adjustment | | | | | | |
| \$2,010.69 | \$1,875.46 | -6.726%* | | | | |

Source: 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW July 11, 2024. *This is the total permanent adjustment based on 2023 data which includes the previous permanent adjustment of -3.925% applied. However, as described later, CMS recognizes for 2025 it must account for adjustment made in 2024.

Taking into account the permanent adjustment applied in 2024 of -2.890 percent, the current remaining permanent adjustment of **-3.95 percent** in 2025 would account for the permanent adjustments for 2020-2023. This would satisfy the statutory requirements at section 1895(b)(3)(D) of the Act to offset any increases or decreases on the impact of differences between assumed behavior and actual behavior changes on estimated aggregate expenditures, reduce the need for any future large permanent adjustments, and help slow the accrual of the temporary payment adjustment amount. CMS illustrates the calculation of the -3.95 percent based on the permanent adjustments calculated and as applied.

| Permanent Adjustments Calculated | Permanent Adjustments Applied | | |
|--|---|--|--|
| CY 2020 Claims= -6.52% (87 FR 66805) | CY 2023 Rate= -3.925% (88 FR 66808) | | |
| CY 2021 Claims= -1.42% (87 FR 66806) | CY 2024 Rate= -2.890% (88 FR 77697) | | |
| CY 2022 Claims= -1.767% (88 FR 77692) | CY 2025 Rate = -1.975 percent (89 FR 88354) | | |
| CY 2023 Claims= -1.004% (Table 2 final rule) | • | | |

Accounting for the previous permanent adjustments applied to the 30-day payment rate in 2023 and 2024, CMS illustrates this calculation in the final rule and determines that a permanent adjustment of -3.95 percent would be needed to the 2025 home health base payment rates. Accordingly, CMS proposed to apply the full remaining permanent adjustment to the 2025 home health base payment rate. In response to comments (as described in more detail below) and concerns about potential beneficiary access issues, CMS finalizes a -1.975 percent permanent adjustment for 2025, or half of the proposed permanent adjustment.

Table 5 in the final rule (reproduced below and modified to include the 2025 adjustment) provides a summary of the permanent adjustments. This includes the base payment rate for assumed behaviors (simulates all prior adjustments were taken), the recalculated base payment rate for actual behaviors, the annual permanent adjustments calculated (assuming prior adjustments had been taken), the cumulative permanent adjustments calculated in each year, the final permanent adjustments implemented in rulemaking, and the temporary adjustment dollar amount based on actual payment rates.

| Table 5: Summary of Permanent Adjustments for CYs 2020-2026 | | | | | | | |
|---|--|---|--------------------------------------|--|--|--|--|
| Claims Analysis Year | Base Payment Rate for Assumed Behaviors (Actual Amount Paid to HHAs in the Claims Analysis Year) | Base Payment Rate that Reflects Actual Behavior Changes (As Determined After Later Claims Analysis) | Adjustment Between Assumed and | Permanent Adjustment CMS Finalized and Implemented in Rulemaking | | | |
| CY 2020 | \$1,864.03 | \$1,742.52 | -6.52% | n/a | | | |
| CY 2021 | \$1,901.12 | \$1,751.90 | -7.85% | -3.925% applied to CY 2023 rates | | | |
| CY 2022 | \$2,031.64 | \$1,839.10 | -5.78% | -2.890% applied to CY 2024 rates | | | |
| CY 2023 | \$2,010.69 | \$1,873.17 | -3.95% | -1.975%, applied to CY 2025 rates | | | |
| CY 2024 | \$2,038.13 | TBD | TBD | TBD | | | |
| CY 2025 | TBD | TBD | TBD | TBD | | | |
| CY 2026 | TBD | TBD | TBD | TBD | | | |

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

Given the magnitude of the temporary adjustment dollar amount (currently estimated at \$4.5 billion), CMS did not propose to take the temporary adjustment in 2025. Table 6 (reproduced below) shows the temporary adjustment dollar amounts by year. CMS remains concerned that implementing both the permanent and temporary adjustments in the same year may adversely affect HHAs. In future year rulemaking, CMS states it will propose a temporary adjustment factor to the national, standardized base payment rate in a time and manner determined appropriate. CMS also notes that because it did not apply the full permanent adjustment (-3.95 percent), the total temporary dollar amount will continue to increase until the full permanent adjustment is implemented.

| Table 6: Summary of Anticipated Temporary Adjustments Calculated for CYs 2020-2026. | | | | |
|---|------------------|--|--|--|
| Claims Analysis Year | Dollar Amount | | | |
| CY 2020 | -\$873,073,121 | | | |
| CY 2021 | -\$1,211,002,953 | | | |
| CY 2022 | -\$1,405,447,290 | | | |
| CY 2023 | -\$971,431,113 | | | |
| CY 2024 | TBD | | | |
| CY 2025 | TBD | | | |
| CY 2026 | TBD | | | |
| Total | -\$4,460,954,477 | | | |

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

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

CCW July 15, 2023. CY 2023 Home Health Claims Data, periods that end in CY 2023 accessed on CCW July 11, 2024.

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

The majority of commenters opposed the proposed permanent adjustment to the 2025 home health rate and requested that CMS postpone this adjustment in order to preserve access to home health services and the scope of care available. The most common themes commenters presented as support for their concern that another permanent adjustment in 2025 would exacerbate an already unstable home health benefit included negative margins, increasing costs, labor shortages, and increasing referral rejections by HHAs. CMS responds in detail that its analysis has not identified sufficient evidence that delaying the implementation of the permanent adjustment would have a significant effect on access to care or the issues commenters describe as destabilizing the home health benefit. Overall, CMS analyses continue to suggest that the permanent adjustment it is finalizing should not materially affect beneficiary access to the Medicare home health benefit. It makes the following specific conclusions and observations based on its analysis:

- CMS analysis of cost reports submitted by HHAs show that Medicare payment rates exceed costs of care by 32 percent (89 FR 55321) and that HHAs continue to experience high Medicare margins. This conclusion is also supported by MedPAC.⁴
- CMS notes that staff shortages are not just limited to home health care and workforce shortages are a wider issue in healthcare as well as the general labor market. It notes that the statute limits behavioral adjustments to those attributable to the implementation of the PDGM.
- Based on the industry's suggestion and data that there has been an increase in referral rejections, CMS conducted its own referral analysis using Medicare claims data and its findings differ from the industry's. CMS' analysis shows that there is a 4.2 percent reduction in the referral acceptance rate between 2020 and 2023 which is less than half the approximate 10 percent reduction in the referral acceptance rate the industry found for that same period. CMS also notes that it does not expect that all referrals to home health would result in acceptance of those referrals. In addition, the agency notes that these analyses do not show that an increase of non-acceptance to home health necessarily indicate that delaying the permanent adjustment would increase referral acceptance.
- In response to commenters' assertion that the PDGM has resulted in a decrease in the number of HHAs and thus contributes to the lack of access to care and increased referral rejections, CMS disagrees and states that changes in the home health landscape may be due to other changes, such as the increase of private equity firm ownership. In their 2024 report, MedPAC describes a continuous decline in the number of HHAs since 2013, while the supply of agencies remained relatively stable after the implementation of PDGM in 2020.⁵

content/uploads/2024/03/Mar24 Ch7 MedPAC Report To Congress SEC.pdf.

https://www.medpac.gov/wp-content/uploads/2024/03/Mar24 MedPAC Report To Congress SEC-2.pdf.

⁵ Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, Washington, D.C. (March 2024) - https://www.medpac.gov/wp-

CMS states, however, that it is committed to remaining responsive to commenter concern regarding on-going permanent rate adjustments. While CMS must comply with the statutory requirement that the estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that would have been made under the prior system, the agency has the discretion to implement any adjustment in a time and manner determined appropriate. Therefore, in response to commenter concerns, CMS finalizes a -1.975 percent permanent adjustment for 2025, (half of the -3.95 percent). This approach of applying half of the amount proposed for the permanent adjustment is aligned with the approach finalized in the 2023 HH PPS final rule (87 FR 66808) and the 2024 HH PPS final rule (88 FR 77697).

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

1. 2025 PDGM Low-Utilization Payment Adjustment (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. In 2023, CMS updated the LUPA thresholds using 2021 home health claims linked to OASIS assessment data. For 2024, CMS updated the LUPA thresholds using 2022 home health claims utilization data (as of March 17, 2023).

For 2025, CMS finalizes its proposal to update the LUPA thresholds using 2023 home health claims utilization data (as of July 11, 2024). The final LUPA thresholds for the 2025 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in Table 7 of the final rule.⁶

2. 2025 Functional Impairment Levels

Under the PDGM, the functional impairment level is determined by responses to certain OASIS items associated with activities of daily living and risk of hospitalization. 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.

⁶ Also available at <u>Home Health Agency (HHA) Center | CMS</u>.

For 2025, CMS finalizes its proposal to use the 2023 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 2025. The updated OASIS functional points table and the table of functional impairment levels by clinical group for 2025 are listed in Tables 7 and 8, respectively. CMS sought comment on the updates to functional points and the functional impairment levels by clinical group.

Several commenters opposed the proposed updates to the 2025 function impairment points and levels. They noted this was the fourth consecutive year in which changes to functional item scoring have been finalized without fully considering the impacts of the changes implemented in the previous year. Commenters also requested that CMS delay finalizing any updates until 2026 when post-pandemic data from 2024 can be fully analyzed to assess the appropriateness of additional modifications. CMS disagrees with delaying updates to the functional impairment points and levels for 2025 stating that it is critical to ensure that all variables used in the case-mix adjustment process align with the actual costs of delivering home health care. CMS also emphasizes that regardless of whether patients entering home health are more impaired due to the post-COVID environment or any other influence, the functional levels capture the relationship between functional status as indicated on the OASIS with resource use captured on claims.

3. 2025 Comorbidity Subgroups

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 (2) a high comorbidity adjustment – two or more secondary diagnoses on the home health-specific comorbidity subgroup list.

For 2025, CMS finalizes its proposal to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using 2023 home health data with linked OASIS data (as of July 11, 2024). The final updated comorbidity subgroups include 22 low comorbidity adjustment subgroups and 94 high comorbidity adjustment interaction subgroups as identified in Tables 9 and 10 in the final rule.

In response to a concern that there should be additional comorbidity subgroups for certain clinical conditions, such as anemias, CMS reminds commenters that only subgroups of diagnoses representing more than 0.1% of periods of care, and demonstrating at least the median resource use, qualify for a low comorbidity adjustment.

4. 2025 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 2025, CMS finalizes its proposal to generate the recalibrated case-mix weights using 2023 home health claims data with linked OASIS assessment data (as of July 11, 2024). CMS believes that recalibrating the case-mix weights using data from 2023 would be reflective of PDGM utilization and patient resource use for 2025.

Table 11 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 12 in the final rule and will also be posted on its HHA Center webpage.

To determine the case-mix budget neutrality factor for 2025, CMS continues its practice of using the most recent complete home health claims data at the time of rulemaking, which is 2023 data. CMS calculates a case-mix budget neutrality factor for 2025 of 1.0039.

Commenters continue to oppose recalibrating the PDGM case-mix weights on an annual basis stating that annual updates create financial 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. The agency also noted that it is statutorily required that any adjustments to case-mix weights must be made in a budget neutral manner.

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

CMS states that although it is not its intent to review all ICD-10-CM diagnosis codes each year, it recognizes that occasionally some ICD-10-CM diagnosis codes may require changes to their assigned clinical groups and/or comorbidity subgroup. CMS also specifies that any addition or removal of specific diagnosis codes or minor tweaks to a short descriptor of an existing ICD-10-CM diagnosis code could be implemented as appropriate without rulemaking. CMS relies on the expert opinion of its clinical reviewers (for example, nurse consultants and medical officers) and current ICD-10-CM coding guidelines to determine if the ICD-10-CM diagnosis codes under review for reassignment are significantly similar or different to the existing clinical group and/or comorbidity subgroup assignment.

CMS received a request to reassign N30.00 (acute cystitis) to the same clinical and comorbidity group as N39.0 (urinary tract infection, site not specified). Based on its clinical review and resources use analysis, CMS determine that N30.00 (acute cystitis) is currently assigned to the most appropriate comorbidity group and thus is not proposing reassignment.

For future requests for ICD-10 code reassignments, readers can send their request(s) to the Home Health Policy mailbox: https://example.com/home-nearth-policy@cms.hhs.gov.

E. Home Health Payment Rate Updates

1. 2025 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 third-quarter 2024 forecast for 2025 with historical data through second-quarter 2024, the final HH PPS market basket update is as follows:

| Market Basket Update | Change (in %) |
|--|---------------|
| Market basket forecast | 3.2 |
| Total factor productivity | -0.5 |
| Net update for HHAs reporting quality data | 2.7 |
| Net update for HHAs NOT reporting quality data | 0.7 |

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

Several commenters expressed concern that IGI's forecasted growth for the home health market basket has shown a consistent trend of under-forecasting actual market basket growth. 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. The cumulative forecast error since HH PPS inception (fiscal year 2002 to 2023, excluding 2019 and 2020 when the market basket was statutorily mandated) is -0.7 percent. It also noted that the recent forecast errors were largely a function of uncertainty in the overall economy and the health sector due to the nature of the public health emergency and the unforeseen rapidly accelerating inflationary environment.

2. Adoption of the CBSA Delineations for Wage Index

As discussed below, CMS uses hospital inpatient wage data in developing a wage index to be applied to HHAs. The applicable HH PPS wage index value is assigned based on the geographic area where the beneficiary receives the home health services rather than the provider's location. The Office of Management and Budget (OMB) provides the Core-Based Statistical Area (CBSA) delineations that are the basis of the labor market areas that CMS uses for the wage index adjustment.

For 2025, CMS finalizes its proposal to adopt the revised Office of Management and Budget (OMB) delineations identified in OMB Bulletin No. 23-01 for the wage index effective beginning in 2025. These revisions OMB published on July 21, 2023 contain a number of significant changes: a change to county equivalents in the state of Connecticut, new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would split apart. It believes that the delineations reflected in this update better reflect the local economies and wage levels of the areas in which HHAs are currently located.

CMS details the following changes related to adoption of these revised OMB geographic delineations.

a. Micropolitan Statistical Areas

CMS discusses how it uses the Micropolitan Statistical Area definition in the calculation of the wage index. OMB defines these areas as a CBSA associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000. Consistent with the treatment of Micropolitan areas under the IPPS, CMS finalizes its proposal to continue to treat Micropolitan Areas as "rural" and to include Micropolitan Areas in the calculation of the state's rural wage index.

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

In the June 6, 2022 Notice (87 FR 34235-34240), the Census Bureau announced that it was implementing the state of Connecticut's request to replace the eight counties in the state with nine new "Planning Regions." CMS adopts the planning regions as county equivalents for wage index purposes. Table 13 provides a crosswalk of Connecticut county equivalents.

c. Urban Counties That Will Become Rural Under the Revised OMB Delineations

CMS' analysis shows that a total of 54 counties (and county equivalents) that are currently considered part of an urban CBSA will be considered located in a rural area for HH PPS payment beginning in 2025 under the revised OMB delineations (Table 14).

d. Rural Counties That Will Become Urban Under the Revised OMB Delineations

CMS' analysis shows that a total of 54 counties (and county equivalents) that are currently located in rural areas will be located in urban areas under the revised OMB delineations (Table 15).

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

Several urban counties will shift from one urban CBSA to another CBSA under the new OMB delineations. In other cases, counties will shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. Table 18 in the final rule lists the 73 urban counties that would move from one urban CBSA to another urban CBSA under the new OMB delineations. For these counties, there may be impacts, both negative and positive, on their specific wage index values. There are also cases where adopting the revised OMB delineation will involve a change only in CBSA name and/or number but no change to the counties that constitute the CBSA. Table 16 in the final rule details these CBSAs.

Some commenters, including MedPAC, were generally supportive of the proposals to adopt the revised delineations from OMB Bulletin No. 23-01. A few commenters expressed concern with specific redesignations in their area, highlighting notable reductions in their wage index values.

In response, CMS notes these commenters only address the negative impact on certain areas but there are many geographic areas and home health providers that will experience positive impacts upon implementation of the revised CBSA designations. CMS also notes that its permanent 5-percent cap policy will provide an adequate safeguard against any significant payment reductions in 2025.

f. Transition Period

CMS discusses how it has used prior transition periods when adapting changes with significant payment implications, especially large negative impacts, in order to mitigate the potential impacts of policy changes.

For the changes related to the revised OMB delineations, CMS believes that the permanent 5-percent cap on wage index decreases would be sufficient to mitigate any potential negative impact on HHAs and no transition is necessary. However, for 2025, to mitigate any potential negative impact, CMS finalizes its proposal that in addition to the 5-percent cap being calculated for an entire CBSA or statewide rural area (the current policy), the cap could also be calculated at the county level, so that individual counties moving to a new delineation would not experience more than a 5 percent decrease in wage index from the previous CY. Specifically, CMS finalizes for 2025, the 5-percent cap would also be applied to counties that move from a CBSA or statewide rural area with a higher wage index value into a new CBSA or rural area with a lower wage index value, so that the county's 2025 wage index would not be less than 95 percent of the county's 2024 wage index value.

CMS notes that to calculate the 5-percent cap for counties that experience an OMB designation change, some counties will have a wage index value that is different than the wage index value assigned to the other constituent counties that make up the CBSA or statewide rural area. This presents a challenge for claims processing because each CBSA or statewide rural area can have only one wage index value assigned to that CBSA or statewide rural area.

CMS finalizes that beginning in 2025, counties that have a different wage index value than the CBSA or rural area into which they are designated after the application of the 5-percent cap will use a wage index transition code. The code will be five digits in length and begin with "50". CMS also adopts that the county will continue to use the assigned 50XXX transition code until the county's wage index value calculated for that CY is not less than 95 percent of the county's capped wage index from the previous CY. Table 19 in the final rule shows the counties that will use the transition code.

The final HH PPS wage index file applicable for 2025 is available on the CMS website at: https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center.

A few commenters recommended other changes to the finalized 5-percent cap policy. MedPAC recommended, for example, that the cap should be applied to both increases and decreases in a given year. Another commenter expressed support for the proposal to apply the 5-percent cap at the county level and that CMS provide a crosswalk in a CSV or Excel format of these changes.

CMS notes that any changes to the 5-percent cap policy is outside of the scope of the proposed rule as it did not propose to make any changes to this policy. CMS also notes that with respect to the 5-percent cap policy at the county level, it lists the counties that will require a transition code in 2025 in table 19 in the final rule and also includes this table in the 2025 wage index file.

3. 2025 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 2025, using 2021 hospital cost report data as its source for the updated wage data. The 2025 HH PPS wage index will not take into account any geographic reclassification of hospitals, but it will 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 will not be less than 95 percent of the geographic area's capped wage index.

CMS makes special provisions for geographic areas where there are no hospitals, and thus, no hospital wage data on which to base the calculation of the HH PPS wage index. For urban areas without inpatient hospitals, CMS uses the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For 2025, the only area without an inpatient hospital wage data is Hinesville, GA (CBSA 25980), and CMS calculates a proxy 2025 wage index value for this area of 0.8824. For rural areas that do not have inpatient hospitals, CMS uses the average wage index from all contiguous CBSAs as a reasonable proxy. As a result of its policy to adopt the revised OMB delineations, rural North Dakota will now become a rural area without a hospital from which hospital wage data can be derived. Based on this approach, CMS calculates a 2025 HH PPS wage index of 0.8503 for rural North Dakota. For Puerto Rico, CMS finalizes a wage index value of 0.3845 (5 percent cap adjusted), instead of the previously available wage index value of 0.4047. There is now a hospital in rural Puerto Rico from which hospital wage data can be derived.

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

Most commenters expressed concern with the updates to the home health wage index, with particular opposition related to wage index updates in rural areas. Commenters stated that utilizing hospital wage data does not adequately reflect HHA's costs of recruiting and retaining employees in rural areas, or the increased travel costs and lost productivity in serving rural areas. CMS states that it does not believe a population density adjustment is appropriate at this time and while rural areas cite the additional cost of traveling from one patient to another urban areas cite the added costs associated with needed security measures and traffic congestion. Thus, in the absence of home health specific data, the pre-floor, pre-reclassified hospital wage index is appropriate for the geographic adjustment of home health claims.

4. 2025 Annual Payment Update

a. 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. In the 2024 HHS PPS final rule (88 FR 77726), CMS finalized a rebasing of the home health market basket to reflect 2021 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 is finalizing implementing a permanent behavior adjustment of -1.975 percent in 2025 (half of the full current remaining permanent adjustment) 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.

b. 2025 National, Standardized 30-Day Period Payment Amount

To determine the 2025 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, and the home health payment update percentage. The final 2025 30-day payment amount would be 0.9 percent more than the 2024 30-day payment amount.

The following table shows the final standardized amounts, as displayed in Tables 21 and 22.

| 2025 National, Standardized 30-Day Episode Payment Amount, | | | | | |
|--|------------------------------------|--|--|--|--|
| for HHAs Submitting and Not Submitting Quality Data | | | | | |
| HHAs | HHAs not | | | | |
| submitting | submitting | | | | |
| quality data | quality data | | | | |
| 2024 30-day budget neutral standardized amount \$2,038.13 | | | | | |
| x 0.98025 | | | | | |
| Case-mix weights recalibration neutrality factor x 1.0039 | | | | | |
| | HHAs submitting quality data \$2,0 | | | | |

⁷ A detailed description of how CMS rebased the HHA market basket and labor-related share is available in the 2024 HH PPS final rule (88 FR 77726 through 77742).

| Wage index budget neutrality factor | x 0.9988 | | |
|-------------------------------------|------------|------------|--|
| HH payment update percentage | x 1.027 | x 1.007 | |
| 2025 30-day payment amount | \$2,057.35 | \$2,017.28 | |

c. 2025 National Per-Visit Rates for 30-Day Periods of Care

Computations are presented for the 2025 final per-visit amounts for each type of service. These amounts are used for LUPAs and in outlier calculations. The final per-visit amounts for those HHAs submitting the required quality data (Table 23 in the final rule) are as follows:

| HH Discipline | 2024 Per- Visit Rates | Wage Index Budget Neutrality Factor | 2025 HH Payment Update Factor | 2025 Per-Visit Payment Amount |
|------------------------------|--------------------------|--|-------------------------------------|-------------------------------------|
| Home Health Aide | \$76.23 | 0.9989 | 1.027 | \$78.20 |
| Medical Social Services | \$269.87 | 0.9989 | 1.027 | \$276.85 |
| Occupational Therapy | \$185.29 | 0.9989 | 1.027 | \$190.08 |
| Physical Therapy | \$184.03 | 0.9989 | 1.027 | \$188.79 |
| Skilled Nursing | \$168.37 | 0.9989 | 1.027 | \$172.73 |
| Speech-Language Pathology | \$200.04 | 0.9989 | 1.027 | \$205.22 |

HHAs that do not submit required quality data would have the payment update for per-visit services reduced from 2.7 percent to 0.7 percent, resulting in the following payment rates (Table 24 in the final rule):

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

d. 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 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.

In an effort to enhance the accuracy and relevance of LUPA add-on factors to reflect current healthcare practices and costs, CMS finalizes its proposal to update the LUPA add-on factors for PT, SN, and SLP. These factors have not been revised since the 2014 HH PPS final rule, during

which 2012 data was used. CMS uses the same methodology used to establish the LUPA add-on amount for 2014, using updated claims data.

Specifically, CMS updates the LUPA add-on factors by using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from 2023 claims data. Table 25 in the final rule (reproduced here) shows the average excess minutes for the first visit in LUPA periods, the average minutes for all non-first visits in non-LUPA episodes, as well as the current LUPA add-on factors, the final LUPA add-on factors, and the percent change between the current and the final LUPA add-on factors. This table also shows the OT LUPA add-on factor discussed below:

| Table 25: Current and Final LUPA Add-on Factors | | | | | | | | |
|---|------------------------------------|--|--------------------------------------|---|---|--|--|--|
| Discipline | Current LUPA Add- on Factors | LUPA Add-on Factors Using Data from 2023 | Percent Change from Old to New | Average Excess of Minutes for the First Visit in LUPA Periods | Average Minutes for All Non-First Visits in Non- LUPA Episodes | | | |
| SN | 1.8451 | 1.7200 | -6.8% | 29.91 | 41.54 | | | |
| PT | 1.6700 | 1.6225 | -2.8% | 28.08 | 45.11 | | | |
| SLP | 1.6266 | 1.6696 | +2.6% | 31.57 | 47.15 | | | |
| OT | 1.6700 | 1.7238 | +3.2% | 33.28 | 45.98 | | | |

To determine the LUPA add-on factors for each discipline, CMS calculates the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. It then adds one to these ratios to obtain the final add-on factors: 1.7200 for SN; 1.6225 for PT; and 1.6696 for SLP.

e. Occupational Therapy LUPA Add-On Factor

In the 2022 HH PPS final rule, CMS finalized changes to regulations at §§484.55(a)(2) and 484.55(b)(3) to implement requirements of CAA, 2021. 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. At the time of implementation, CMS did not have sufficient data to establish an OT-specific add-on factor and thus used the PT LUPA add-on factor of 1.6700 as a proxy.

With sufficient claims data available, CMS finalizes its proposal to establish a definitive OT-specific LUPA add-on factor and discontinue the temporary use of the PT LUPA add-on factor as a proxy. CMS is using the same methodology described above for the SN, PT, and SLP add-on factors. Specifically, CMS is updating the analysis using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from 2023 claims data. The analysis shows that the average excess of minutes for the first OT visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods is 33.40 minutes for the first visit. The average

number of minutes for all non-first visits in non-LUPA periods is 45.97 minutes for OT. CMS finalizes an add-on factor of 1.7238 for OT as described in Table 25 (reproduced above).

Many commenters raised concerns regarding proposed payment rate reductions specific to occupational therapy services. CMS notes that many commenters conflated the OT LUPA add-on factor proposal with the proposed permanent adjustment to the national, standardized 30-day payment rate. To clarify, in the 2025 HH PPS proposed rule (89 FR 55377) CMS did not propose any OT-specific payment rate cuts. In fact, with the proposal to establish a definitive OT LUPA add-on factor and discontinue the use of the PT LUPA add-on factor as a proxy, the add-on factor for OT services has increased by 3.2 percent.

f. 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 as 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 2025.

For 2025 payment, CMS finalizes an FDL ratio of 0.35 for 2025 based on analysis of 2023 claims data (as of July 11, 2024). In the final rule, 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 2025 in the rate update change request to be issued after the publication of the 2025 HH PPS final rule.⁸

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

1. Background

Negative pressure wound therapy (NPWT) is a medical procedure in which a vacuum dressing is used to enhance and promote healing in acute, chronic, and burn wounds. The therapy can be administered using the conventional NPWT system, classified as durable medical equipment

⁸ The per-unit amounts for 2025 are found in the November 7, 2024 HH PPS change request: https://www.cms.gov/files/document/r12911cp.pdf

(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.

2. Payment Policies for dNPWT Devices

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

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

3. 2025 Separate Payment Amount for dNPWT Device

For 2025, CMS finalizes that the separate payment amount for a dNPWT device would be set equal to the 2024 payment amount of \$270.09 updated by the CPI-U for June 2024, minus the productivity adjustment, as mandated by the CAA, 2023. For this final rule, the CPI-U for the 12 month period ending in June of 2024 is 3.0 percent and the corresponding productivity adjustment is 0.6 percent based on IHS Global Inc.'s third-quarter 2024 forecast of the 2025 productivity adjustment. Thus, the final update percentage is 2.4 percent (3.0 percent reduced by

the 0.6 percentage point). The final 2025 separate payment amount for a dNPWT device will be \$276.57. which reflects the 2024 payment amount of \$270.09 updated by the final update percentage of 2.4 percent.

For 2026 and subsequent years, CMS does not intend to propose changes to its established methodology for calculating dNPWT payments; payment rates will be updated using CMS' established methodology via the Home Health Prospective Payment System Rate Update Change Request and posted on the HHA Center website.

III. Home Health Quality Reporting Program (HH QRP)

A. Statutory Authority and Background

The HH QRP⁹ 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.¹⁰ 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).

For the 2023 program year, 820 of the 11,549 HHAs (approximately 7.1 percent) did not receive the full annual percentage increase for failing to meet assessment submission requirements.

CMS refers readers to the 2016 HH PPS final rule¹¹ for considerations it uses for measure selection for the HH QRP quality, resource use, and other measures, and to the 2019 HH PPS final rule¹² for the removal factors considered for removing HH QRP measures.

B. Overview

Beginning for the 2027 HH QRP, CMS finalizes (i) the addition of 4 new OASIS items and modification of one OASIS item, and (ii) an update to the reinstatement of OASIS all-payer data collection. The agency also summarizes feedback on future HH QRP quality measure concepts.

C. Measures Currently Adopted for the 2024 HH QRP

The HH QRP for 2024 currently includes 21 measures. The table below lists the current HH QRP measures adopted for the 2024 HH QRP, based on Table 26 of the rule.

⁹ More information on the HH QRP can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits. The HH QRP regulations are under 42 CFR 484.245 and 484.250.

¹⁰ 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.

¹¹ 80 FR 68695 through 68696.

¹² 83 FR 56548 through 56550.

Measures Adopted for 2024 HH QRP

| 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 | Application of Percent of HH Patients with an Admission and Discharge Functional | | | | | |
| Assessment # | 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 | | | | | |
| DC Function | Discharge Function Score | | | | | |
| 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 | | | | | |
| Patient/Resident COVID- 19 Vaccine ## | COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date | | | | | |
| | Assessment will be retired from public reporting beginning January 2025. Home Health PPS final rule beginning with CY 2025 HH QRP | | | | | |
| | 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 | 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 20 | 022 HH PPS Rate Update Final Rule (86 FR 62340-62344), the ACH and ED Use measures | | | | | |
| | H measure beginning with the CY 2023 HH QRP. The measures will be retired from public reporting beginning October 2024. | | | | | |
| 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 | | | | | |
| | components (all listed) that together are used to represent one measure. | | | | | |
| | 1 / J | | | | | |

D. Collection of Four New Items as SPADEs and Modification of One Item Collected as a SPADE Beginning with the 2027 HH QRP

1. Definition of Standardized Patient Assessment Data

HHAs are statutorily required, as a post-acute care (PAC) provider, ¹³ to submit standardized patient assessment data under the HH QRP with respect to the admission and discharge of an individual (or more frequently as specified by the Secretary) using a standardized patient assessment instrument, which for HHAs is OASIS. Standardized patient assessment data includes data on: (1) functional status, such as mobility and self-care at admission to and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow; and (6) other categories deemed necessary and appropriate by the Secretary.¹⁴

2. Social Determinants of Health (SDOH) Collected as SPADEs

Under the "other categories deemed necessary and appropriate" authority, CMS created the social determinants of health (SDOH) category. The agency currently collects seven items in the SDOH category of SPADEs: ethnicity, race, preferred language, interpreter services, health literacy, transportation, and social isolation. The agency states that standardized data relating to SDOH on national levels allows it to assess the data's appropriateness as risk adjustors or in future quality measures. The adopted SDOH items use common standards and definitions across the PAC provider settings to facilitate care coordination, continuity in care planning, and discharge planning from PAC settings. CMS further explains that health-related social needs (HRSNs) are adverse social conditions that negatively affect a person's health or health care, such as lack of access to food, housing, or transportation, and are associated with poorer health outcomes and higher health care costs.

3. Collection of Four New Items Finalized as SPADEs

CMS is finalizing its proposal to require HHAs to submit, beginning for the 2027 HH QRP program year, the following four new items as SPADEs under the SDOH category using the OASIS, all selected from the Accountable Health Communities (AHC) HRSN Screening Tool developed for the AHC Model. ¹⁶

¹³ Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit standardized patient assessment data required under section 1899B(b)(1) of the Act, which requires PAC providers to submit such data under applicable reporting provisions.

¹⁴ These six categories are specified under section 1899B(b)(1)(B) of the Act.

¹⁵ See the 2020 HH PPS final rule (84 FR 60597-60608).

¹⁶ See https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures for the following draft of the items: Draft SDOH Item Mockups (cms.gov).

a. Living Situation Item

CMS describes the potential negative impacts that housing instability may have on health and believes that HHAs can use information from the Living Situation item during a patient's initial assessment and discharge planning, including to refer patients to community resources and better coordinate with other PAC providers during transitions of care.

CMS finalizes adoption of the Living Situation item, which will ask "What is your living situation today?" The response options will be: (1) I have a steady place to live; (2) I have a place to live today, but I am worried about losing it in the future; (3) I do not have a steady place to live; (4) Patient unable to respond; and (5) Patient declines to respond.

b. Two Food Items

CMS describes food insecurity, which is not having enough food or having a diet that is not nutritious, as a factor for negative health outcomes and health disparities. The agency believes HHAs could use data on food insecurity at home to help them with patient transitions of care and referrals, including to federal and other assistance initiatives.

CMS finalizes two new food items adapted from the Department of Agriculture 18-item Household Food Security Survey:

- The first will state: "Within the past 12 months, you worried that your food would run out before you got money to buy more."
- The second will state: "Within the past 12 months, the food you bought just didn't last and you didn't have money to get more."
- The response options for each will be: (1) Often true; (2) Sometimes true; (3) Never true; (4) Patient declines to respond; and (5) Patient unable to respond.

c. Utilities Item

CMS describes a lack of utility security as an inability to adequately meet basic household energy needs. The effects of a lack of utility security include vulnerability to environmental exposures which impact a person's health. The agency believes HHAs could use information on utility security collected at the start or resumption of care in HHAs to help identify patients who can benefit from referrals to utility assistance programs for paying for their home energy costs.

CMS finalizes adoption of the Utilities item, which will ask "In the past 12 months has the electric, gas, oil, or water company threatened to shut off services in your home?" The response options will be: (1) Yes; (2) No; (3) Already shut off; (4) Patient unable to respond; and (5) Patient declines to respond.

d. Selected Comments/Responses

Many commenters supported the proposals, but some also expressed concerns about implementing the changes, including concerns that vendors needed time to prepare for the changes, that HHAs needed time and resources to educate staff on the changes, and that OASIS

revisions are too frequent and burdensome for HHAs. In response, CMS states (i) the data elements are being finalized for inclusion beginning January 1, 2027, which is to ensure vendors and HHAs have sufficient time; (ii) the agency will make training available to HHAs on the changes to the OASIS; and (iii) CMS intends to propose revisions to the OAIS no more frequently than every two years.

4. Modification of the Transportation Item

Background. The Transportation item is one of seven items HHAs began collecting as of January 1, 2023 on the OASIS as SPADEs under the SDOH category.¹⁷ It currently asks "Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?" The response options are: Yes, it has kept me from medical appointments or from getting my medications; Yes, it has kept me from non-medical meetings, appointments, work, or from getting things I need; No; Patient unable to respond; and Patient declines to respond.

As part of routine monitoring, CMS has determined that the Transportation item could be improved by revising the look-back period to a defined 12-month period (as opposed to the current look-back period of 6 to 12 months) and by simplifying the response options to reduce burden.

Final Action. CMS finalizes, as proposed, beginning with the 2027 HH QRP program year, modifications to the Transportation item. The modified item will ask: "In the past 12 months, has a lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?" The proposed response options will be: Yes; No; Patient declines to respond; and Patient unable to respond. The modifications align the item with a Transportation item collected on the AHC HRSN Screening Tool, which is a tool available to the Inpatient Psychiatric Facility Quality Reporting and Hospital Inpatient Quality Reporting programs.

E. Updates to OASIS All-Payer Data Collection

Background. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 temporarily suspended OASIS requirements for collection of data on non-Medicare and non-Medicaid patients. CMS finalized in the 2023 HH PPS final rule that, beginning with the 2027 program year, the agency will end the temporary suspension of OASIS data collection on non-Medicare/non-Medicaid HHA patients and on the requirement for HHAs to submit all-payer OASIS data for purposes of the HH QRP. There is a two-quarter voluntary phase-in during which HHAs will be able to start submitting this data for patients discharged between January 1, 2025, through June 30, 2025, but the data will not be used for purposes of CMS making a compliance determination. Beginning with the 2027 program year, all-payer OASIS data reporting will be required, with data for the 2027 program year being required for patients discharged between July 1, 2025, and June 30, 2026. The 2023 HH PPS final rule referenced discharge as the time point to identify the start of all-payer data collection.

¹⁷ Adopted in the 2020 HH PPS final rule (84 FR 60478).

¹⁸ 2023 HH PPS final rule (87 FR 66862-66865).

<u>Final Action</u>. CMS finalizes, as proposed, further details to clarify OASIS data collection and submission for non-Medicare and non-Medicaid patients beginning January 1, 2025. The agency is changing the time point at which data collection begins from the OASIS discharge time point to instead be the start of care (SOC) time point. The agency will use the M0090 Date Assessment Completed date of the SOC assessment to identify non-Medicare/non-Medicaid patient assessments during both the voluntary phase-in and mandatory periods, ensuring that agency demographics and patient demographics are collected at the start of all-payer OASIS data collection. This is to ensure that baseline data are available for use in calculating or risk-adjusting quality measures and or linking to prior OASIS assessments.

Specifically, CMS outlines the following for the voluntary phase-in and mandatory periods:

- The period of voluntary data collection and submission will be for non-Medicare/non-Medicaid patients who are not exempt¹⁹ from OASIS data collection and who begin receiving home health care services with an OASIS SOC M0090 date from January 1, 2025, through June 30, 2025. When OASIS data collection and submission is started for such a patient, HHAs may complete all subsequent SOC OASIS assessments related to the patient's home health stay,²⁰ including assessments on or after July 1, 2025.
- Mandatory data collection and submission to the Internet Quality Improvement
 Evaluation System (iQIES) will begin for patients with any pay source (who are not
 exempt from OASIS data collection) and who begin receiving home health care services
 with an OASIS SOC M0090 date on or after July 1, 2025. This will include the SOC
 OASIS and any subsequent OASIS time point assessments relevant to the patient's home
 health stay.

<u>Selected Comments/Responses</u>. Some commenters expressed concern about how CMS will use the data in the HHQRP and HHVBP. The agency expects to use the data to gain a better understanding of the overall quality of care furnished by Medicare providers, regardless of payor source. Some commenters opposed the proposal because of an increase in burden, including on limited staff who would need to meet the expanded data collection requirement.

F. Form, Manner, and Timing of Data Submission²¹

Reporting Schedule for the New SPADEs and Modified Transportation Data Element. CMS finalizes that for the 2027 HH QRP program year, HHAs will be required to submit the four new assessment items and the modified Transportation item using the OASIS beginning with patients admitted on January 1, 2027. HHAs that submit the new items (Living Situation, Food, and Utilities) and the modified Transportation item with respect to start or resumption of care (and not discharge) will be deemed to have submitted the items also with respect to discharge because

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¹⁹ Patients exempt from OASIS data collection include patients under 18 years of age, patients receiving maternity services, and patients receiving only personal care, housekeeping or chore services.

²⁰ Subsequent OASIS time point assessments relevant to a patient's home health stay include resumption of care, recertification, other follow up, transfer, discharge, and death at home.

²¹ See regulatory text at 42 CFR 484.45 for information regarding the policies for reporting HH QRP data.

it is unlikely the status for those items would change between the time of the start or resumption of care and the time of discharge.

G. RFI - HH QRP Quality Measure Concepts under Consideration for Future Years

In the 2025 HH PPS proposed rule, CMS sought input on the importance, relevance, appropriateness, and applicability of four measure concepts for future years in the HH QRP. Those four measure concepts include a composite measure of vaccinations, the concept of depression, the concept of pain management, and the concept of substance use disorders (SUD).

Selected Comments: Most commenters did not support the composite vaccination concept for reasons that included concerns about various burdens on HHAs and about populations with vaccine hesitancy. The majority of commenters supported the depression measure concept, some noting that individuals needing home health care may be likely to develop depression for a number of reasons and the effect of depression on patients' abilities to care for themselves. Commenters supported a pan management measure concept because of the relevance of pain management for home health, though several commenters asked for clarification regarding the intent of having this type of concept given a pain management measure had been retired from the HHQRP in 2020. Most commenters did not support the SUD measure concept, noting that management of SUD is outside of the scope of home health.

CMS does not in the final rule respond to specific comments received but intends to use the feedback for future measure development.

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

A. Background

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 as well as an average TPS increase of 4.6 percent, without evidence of adverse outcomes. 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 Model²² began nationwide testing January 1, 2022, with 2022 designated a "pre-implementation year" during which agencies could familiarize themselves with the expanded model and their performance 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. The first payment year is 2025 based on 2023 (the first 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."

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²² The expanded HHVBP Model regulations are under 42 CFR part 484, subpart F.

B. RFI on Future Performance Measure Concepts

In the 2025 HH PPS proposed rule, CMS requested public comments on the following performance measures, and any other potential performance measures, that may be considered for future inclusion in the expanded HHVBP Model. The specific measures are based on input from the HHVBP Technical Expert Panel (TEP).

- A family caregiver measure.
- A claims-based measure of falls with injury.
- The Medicare spending per beneficiary (MSPB) measure, which is a cross-setting measure that is part of the HH QRP and reported on Care Compare.
- Function measures to complement the existing cross-setting Discharge (DC) Function measure included in the measure set.

<u>Selected Comments</u>: Commenters generally supported the caregiver burden assessment measure concept, but some expressed concerns about how to identify caregivers and how the data would be used. Commenters also generally supported the measures to complement the DC Function measure and suggested CMS use a single set of function items. Both the MSPB measure and falls with major injury measure received mixed comments. Regarding the MSPB measure, supporters believed it would provide information on the efficiency of home health providers and help identify costs associated with furnishing high-quality nursing services; while commenters not in support raised concerns about the focus on spending over quality. Regarding the falls with major injury measure, some stated falls are outside of a HHA's control.

CMS does not respond to comments but states the comments will be reviewed with stakeholders and the HHVBP TEP and that any changes to the measure set would be made through future rulemaking.

C. Future Approaches to Health Equity

CMS has been considering potential approaches for integrating health equity concepts into the expanded HHVBP model and is using the following considerations for evaluating those approaches: (1) Effectiveness, including if the approach furthers the model test and its impact on underserved communities; (2) Feasibility, including how long it would take to implement, if the necessary data are currently collected, and how many HHAs would be included; (3) Reliability, including if the approach allows for reliable measurement of health equity within HHAs; and (4) Alignment, including if the approach aligns with other Medicare quality and VBP programs.

D. Social Risk Factors

CMS is exploring potential definitions to use for defining historically underserved communities. The agency identifies the following proxies as the social risk factors on which it has focused to identify the underserved: (i) dual eligible status (DES), (ii) area deprivation index (ADI), and (iii) Medicaid as a sole payment source.

E. Approaches to a Potential Health Equity Adjustment

CMS has considered for the Expanded HHVBP the Health Equity Adjustment (HEA) that was adopted for the Skilled Nursing Facility (SNF) VBP starting with the FY 2027 program year. That HEA is calculated by considering the SNF's performance on the SNF VBP quality measures as well as the proportion of the SNF's residents with DES. SNFs that perform well on the measures and serve a higher proportion of residents with DES will earn HEA bonus points that are added to a normalized sum of all points the SNF is awarded for each measure, which produces the final SNF performance score.²³

The agency used the SNF VBP HEA methodology to simulate how application of that methodology under the Expanded HHVBP model would impact the model. For the simulation, CMS used the current measure set for the model and the July 2023 Interim Performance Report (IPR) data. The simulation found that before applying the HEA, the average TPS was higher for HHAs in the highest decile of share of beneficiaries with DES than for HHAs in any other decile. After application of the HEA, the TPS primarily increased for these HHAs that were already high performing, increasing the gap in the average payment adjustment for these HHAs and the average payment adjustment for HHAs with a lower share of beneficiaries with DES. Because of this finding, CMS does not believe that it should apply for home health the HEA, as designed for the SNF VBP, using DES as the proxy for the underserved. In contrast, the agency found that average TPS was lower for HHAs serving a high share of beneficiaries living in a neighborhood with a high ADI, and that HHAs in the highest ADI and highest DES quintile had lower average TPS than other groups. This suggests that using ADI or a combination of ADI and DES (and not DES alone) as an indicator for the underserved would alter the effects of the HEA.

CMS also plans to consider how the effects of the HEA in the home health setting would be altered if the changes to the definition of the underserved population codified for the SNF VBP were applied.²⁴

F. Other Health Equity Measures

CMS is also considering other health equity measures to focus on disparities, such as (i) Measures for particular underserved communities (such as DES); (ii) Measures based on within-provider differences in performance for underserved communities; and (iii) Measures based on the worst performing group, such as by calculating performance or different groups and setting the performance equal to the score for the worst performing group. However, the agency's analyses have suggested that many HHAs may not have a sufficient number of DES beneficiaries for these measures to be calculated (with about 25 percent of HHAs serving fewer than 12 beneficiaries with DES) and that therefore the impact and reportability of a potential HHVBP HEA needs more analysis. CMS will look into other measures using other proxies for identifying the underserved and adjusting the scoring mechanism and continues to plan to gather at least two years of performance data before incorporating any changes regarding health equity to the expanded Model.

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²³ See the FY 2024 SNF PPS final rule (88 FR 53304-53316).

²⁴ See 42 CFR 413.338(a).

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 did not also authorize payment for "items and services" related to the administration of IVIG in the patient's home.

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 ended December 31, 2023, after having been extended by the Consolidated Appropriations Act, 2021.²⁵

Effective January 1, 2024, the Consolidated Appropriation Act, 2023²⁶ 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. Standard 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.

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 diagnosis codes listed in Table 27 of the final rule, reproduced below:

| | Table 27: ICD-10-CM Codes That Support Medical Necessity for Home IVIG | | | | | | |
|-------|--|--|--|--|--|--|--|
| Code | Description | | | | | | |
| D80.0 | Hereditary hypogammaglobulinemia | | | | | | |
| D80.2 | Selective deficiency of immunoglobulin A [IgA] | | | | | | |
| D80.3 | Selective deficiency of immunoglobulin G [IgG] subclasses | | | | | | |
| D80.4 | Selective deficiency of immunoglobulin M [IgM] | | | | | | |
| D80.5 | Immunodeficiency with increased immunoglobulin M [IgM] | | | | | | |
| D80.6 | Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia | | | | | | |
| D80.7 | Transient hypogammaglobulinemia of infancy | | | | | | |
| D81.0 | Severe combined immunodeficiency [SCID] with reticular dysgenesis | | | | | | |
| D81.1 | Severe combined immunodeficiency [SCID] with low T- and B-cell numbers | | | | | | |

²⁵ Division CC, section 104 of the CAA, 2021 CAA, 2021) (Pub. L. 115-63)

²⁶ Division FF, section 4134 of the CAA, 2023 (CAA, 2023) (Pub. L. 117-328)

| | Table 27: ICD-10-CM Codes That Support Medical Necessity for Home IVIG | | | | | | |
|--------|--|--|--|--|--|--|--|
| Code | Description | | | | | | |
| D81.2 | Severe combined immunodeficiency [SCID] with low or normal B-cell numbers | | | | | | |
| D81.5 | Purine nucleoside phosphorylase [PNP] deficiency | | | | | | |
| D81.6 | Major histocompatibility complex class I deficiency | | | | | | |
| D81.7 | Major histocompatibility complex class II deficiency | | | | | | |
| D81.82 | Activated Phosphoinositide 3-kinase Delta Syndrome [APDS] | | | | | | |
| D81.89 | Other combined immunodeficiencies | | | | | | |
| D81.9 | Combined immunodeficiency, unspecified | | | | | | |
| D82.0 | Wiskott-Aldrich syndrome | | | | | | |
| D82.1 | Di George's syndrome | | | | | | |
| D82.4 | Hyperimmunoglobulin E [IgE] syndrome | | | | | | |
| D83.0 | Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function | | | | | | |
| D83.1 | Common variable immunodeficiency with predominant immunoregulatory T-cell disorders | | | | | | |
| D83.2 | Common variable immunodeficiency with autoantibodies to B- or T-cells | | | | | | |
| D83.8 | Other common variable immunodeficiencies | | | | | | |
| D83.9 | Common variable immunodeficiency, unspecified | | | | | | |
| G11.3 | Cerebellar ataxia with defective DNA repair | | | | | | |

Through LCD L33610,²⁷ the DME Medicare Administrative Contractors (MACs) specify the Healthcare Common Procedure Coding System (HCPCS) codes for IVIG derivatives that a beneficiary must be receiving to qualify to receive home administration of IVIG.

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) will also apply.

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 prior IVIG demonstration. 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.

²⁷ LCD - Intravenous Immune Globulin (L33610) (cms.gov)

2. <u>Home IVIG Items and Services and the Relationship to/Interaction with Home Health and Home Infusion Therapy Services</u>

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).²⁸ 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 be 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.

C. Home IVIG Administration Items and Services Payment

1. <u>Home IVIG Administration Items and Services Supplier Type</u>

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 (42 CFR 424.57(c), including subpart A of part 424). The DMEPOS supplier may subcontract with a provider for professional nursing services specified above.

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.

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²⁸ LCD - External Infusion Pumps (L33794) (cms.gov)

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. Hospitals, critical access hospitals, or skilled nursing facilities cannot be defined as an individual's home.

D. Home IVIG Items and Services Payment Rate

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

Pursuant to Section 1842(o) of the Social Security Act, 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 prior IVIG 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 was annually updated based on the nursing LUPA rate for such year.

In its CY 2024 final rule, CMS based the home IVIG items and services payment rate on LUPA without a wage index adjustment as there is no statutory requirement for geographic adjustments; therefore, CMS also finalized a policy of not applying the wage index budget neutrality factor to the LUPA. CMS finalized a policy of annually updating the per visit payment by the home health update percentage amount for such year. Under this policy, the home IVIG items and services payment rate for 2025 would be the LUPA for 2024 updated by the final home health update percentage amount or \$420.48*1.027= \$431.83.

Apart from the update to the payment rate for the IVIG items and services bundle, in the proposed rule, CMS did not propose any changes to the IVIG benefit as finalized in the CY 2024 final rule, nor did CMS seek comment on the payment rate update. However, a few comments addressed the payment rate update, suggesting that the methodology for calculating the update undervalues nursing and pharmacy services involved in the provision of home-administered IVIG. **CMS** is nevertheless finalizing the payment rate of \$431.83.

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

A. Home Health Agency CoP Changes

1. Background and Statutory Authority

CMS has broad statutory authority to establish health and safety standards for most Medicareand Medicaid-participating provider and supplier types. Sections 1861(o) and 1891 of the Act authorize the Secretary to establish the requirements that an HHA must meet to participate in the Medicare Program, and these conditions of participation (CoPs) are set forth in regulations at 42 CFR part 484.

2. <u>Updates to the Home Health Agency CoPs to Require HHAs to Establish an Acceptance to Service Policy (§484.105(i))</u>

In the 2025 HH PPS proposed rule, CMS asserted that admission to home health is a critical step in the process of patients receiving timely, appropriate care to meet their needs. Accordingly, CMS has codified at §484.60 a CoP stating that patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's needs in his or her place of residence. CMS was particularly concerned about patients who are self-referrals, or referred by a community practitioner (*i.e.*, patients without a preceding hospital stay), who are more likely to be dually eligible for Medicare and Medicaid, have cognitive impairments, and have more social vulnerability compared to HH patients admitted from acute care. The agency contends that these patients may have particular difficulty in finding a home health agency that meets their needs, and that they are more likely to end up in an HHA that actually cannot meet their needs.

Therefore, in the proposed rule, CMS proposed to add a new standard at §484.105(i) that would require HHAs to develop, implement, and maintain an acceptance to service policy that is applied consistently to each prospective patient referred for home health care. CMS proposed that the policy would be reviewed annually and address, at minimum, the following criteria related to the HHA's capacity to provide patient care: the anticipated needs of the referred prospective patient, the HHA's case load and case mix, the HHA's staffing levels, and the skills and competencies of the HHA staff. CMS argued that this policy will ensure that HHAs only accept those patients for whom there is a reasonable expectation that the HHA can meet the referred patient's needs.

Concurrently, CMS proposed at §484.105(i)(2) that HHAs make public accurate information regarding the services offered by the HHA and any limitations related to the types of specialty services, service duration, or service frequency, as well as the geographic boundaries of the HHA's service area, and that HHAs review that information annually or as necessary. Under this proposal, HHAs could post this information on their websites, or in response to requests from prospective patients.

CMS requested comment on these proposals, specifically on alternative ways to address the delay of home health care initiation, barriers for patients with complex needs to find and access

HHAs, and other opportunities to improve transparency regarding home health patient acceptance policies to better inform referral sources. The agency also requested comment regarding other ways to improve the referral process for referral sources, patients, and HHAs.

CMS indicated that the agency received 78 comments in response to these specific proposals. Comments on the proposed acceptance-to-service policy were mixed, with some supporting, but others opposing the proposals. Those opposing the proposals asserted that HHAs already use these criteria in making admissions determinations (but documenting them as proposed would add administrative burden), and would not admit to service a patient that they could not adequately care for. Some commenters were concerned that CMS did not discuss how HHAs would be evaluated for compliance with the proposed acceptance-to-service policy. However, after consideration of public comments, CMS is finalizing the acceptance-to-service policy at §484.105(i)(1) as proposed.

As with the acceptance-to-service policy, comments on the proposal to make public information about offered services and service limitations (§484.105(i)(2)) were also mixed. Supporters asserted that such public information would expedite connecting beneficiaries with HHAs capable of providing the post-acute care they need. Others, however, were concerned about the administrative burden of keeping this information up-to-date, especially in light of volatile, day-to-day variations in staffing (which affect service offering capabilities). Others opposed this reporting as redundant, given that some HHAs already report this information on their public websites, and comparable information is available on the Medicare Care Compare website.

After consideration of these comments, CMS is finalizing the public information component of the acceptance-to-service policy with revisions. Specifically, CMS is revising §484.105(i)(2), to require HHAs to review the publicly facing information as frequently as services are changed, but no less often than annually.

3. Requests for Information

a. RFI for the Initial and Comprehensive Assessment

The current HHA CoPs at §484.55(a)(1) require that a registered nurse conduct an initial assessment visit to determine the immediate care and support needs of the patient within 48 hours of referral, within 48 hours of the patient's return home, or on the start of care date. Section 484.55(b) further requires that a comprehensive assessment must be completed by a registered nurse, no later than 5 calendar days after the start of care. However, when therapy services are the sole services ordered by the clinician ordering home health care, the initial and comprehensive assessments can be conducted by rehabilitation professionals (specifically occupational therapists (OTs), physical therapists (PTs), or speech-language pathologists (SLPs)), subject to certain limitations, as specified by §484.55(a)(2) and (b)(3). During the COVID-19 public health emergency, CMS waived these requirements and allowed rehabilitation

professionals to conduct the initial and comprehensive assessments in instances when both nursing and therapy services were ordered.²⁹

CMS notes that some stakeholder groups advocate for the agency to permanently allow therapists to perform the initial and comprehensive assessment in the home health setting when both therapy and nursing services are ordered. However, CMS indicates that different types of rehabilitative therapists have different education requirements for entry into practice, which may affect the ability of a therapist to conduct these patient assessments. Therefore, CMS sought information to inform whether the agency should shift its longstanding policy and permit all classes of rehabilitative therapists (PTs, SLPs, and OTs) to conduct the initial assessment and comprehensive assessment for cases that have both therapy and nursing services ordered as part of the plan of care. Specifically, CMS sought information on:

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

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

In light of both an increase in demand for home health care and an increasing complexity in the patients receiving this kind of care, CMS sought public comment on policies designed to achieve the goals of improving the HHA referral process, ensuring the timely delivery of home health care, and ensuring that home health care is delivered in a manner that meets patient needs and achieves the measurable outcomes and goals set forth in each patient's individualized plan of care. The agency also asked for additional information on how HHAs communicate with patients' ordering physicians and allowed practitioners regarding the frequency and duration of services.

²⁹ Subsequently, the Consolidated Appropriations Act, 2021 (Pub. L. 116-260), permitted OTs to conduct the initial and comprehensive assessments only when OT is on the home health plan of care with either PT or speech therapy, and skilled nursing services are not initially on the plan of care.

CMS also solicited public comments on factors that influence the services HHAs provide, the referral process, limitations on patients being able to obtain HHA service, such as rural location and availability of staff, plan of care development, and the HHA's communication with patients' ordering physicians and allowed practitioners. (See HPA's summary of the HH PPS proposed rule for 2025 for a detailed listing of the questions CMS asked in this RFI.)

In this final rule, CMS discusses in very general terms the responses to the RFI the agency received, noting that the majority of comments either overlapped with comments related to other parts of the proposed rule, or fell into one of three general themes: alternative ways to address delays, improved referral process, and overall plan of care development/scope of service. CMS does not respond to any of the information it received, other than to note that the agency may use this feedback to inform future rulemaking.

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

LTC facilities (SNFs and NFs) must meet Medicare's participation requirements. Among these are statutory requirements that LTC facilities develop and maintain an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the public.³⁰ Given the ongoing risk of LTC facilities' residents contracting COVID-19 or other respiratory diseases, in the 2025 HH PPS proposed rule CMS proposed to establish the ongoing collection of a proposed set of data elements necessary to quickly identify threats to resident health and safety and initiate requisite responses. This proposal built on prior, temporary requirements for LTC facilities to report similar data since the onset of the COVID-19 PHE,³¹ which were subsequently finalized in the 2022 Home Health PPS final rule.³² CMS asserted that given the prevalence of COVID-19 and other respiratory diseases among the LTC population, there is still a pressing public health need for information on these illnesses and associated vaccinations.

Given the value of respiratory illness and vaccination reporting during the COVID-19 PHE in supporting resident health and safety, CMS considered in the proposed rule the continued utility of LTC facility respiratory illness data to monitor and protect residents against respiratory illnesses and the ongoing need for such data in the "new normal" of diverse respiratory disease threats. CMS believes it is vital to maintain national surveillance of these emerging and evolving

³⁰ Sections 1819(d)(3) and 1919(d)(3) of the Social Security Act.

³¹ E.g., Interim Final Rules: "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (85 FR 27550); "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (85 FR 54873); "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff" (86 FR 26306).

³² "CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long- Term Care Facilities" (86 FR 62421).

respiratory illnesses as a means of guiding infection control interventions to keep LTC residents safe. Thus, the agency proposed to continue some of the reporting requirements it finalized in November 2021 that are set to expire in December 2024.

CMS proposed to revise the infection prevention and control requirements for LTC facilities to extend reporting in NHSN for a limited subset of the current COVID-19 elements and also require reporting for data related to influenza and RSV. Specifically, CMS proposed to replace the existing reporting requirements for LTC facilities at §483.80(g)(1)(i) through (ix) and (g)(2) with new requirements to report information addressing respiratory illnesses. Beginning on January 1, 2025, facilities would be required to electronically report information about COVID-19, influenza, and RSV in a standardized format and frequency specified by the Secretary. CMS proposed to continue weekly reporting through the CDC's NHSN. The data elements for which reporting would be required would include all of the following:

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

In soliciting comments on this proposal, CMS was particularly interested in comments that addressed the ways these additional data elements could be used to better protect resident and community health and safety both during and outside of a declared PHE, and in comments on how to protect resident privacy within demographic groups and how to best use the data to inform public health efforts without stigmatizing demographic groups.

CMS proposed that in the absence of a national PHE, LTC facilities would report the required data elements on a weekly basis through the CDC's NHSN; this reporting requirement would be ongoing and not tied to the declaration of a specific PHE.

During a declared PHE, however, or after the Secretary's determination that a significant threat of one exists, CMS proposed that additional data reporting would be required. Specifically, CMS proposed that during a declared national, state, or local PHE for a respiratory infectious disease (or if the Secretary determines a significant threat for one exists) the Secretary could require facilities to report:

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

• If the Secretary determines that an event is significantly likely to become a PHE for an infectious disease, the Secretary may require LTC facilities to report additional or modified data elements without notice and comment rulemaking.

CMS solicited comments on if, during a PHE, there should be limits to the data the Secretary could require without notice-and-comment rulemaking, such as limits on the duration of additional reporting or the scope of the reporting. CMS also asked for comments on whether and how the Secretary should seek stakeholder feedback on additional elements during a PHE without notice-and-comment rulemaking and how HHS should notify LTC facilities of new required infectious disease data. CMS solicited comments on the evidence HHS should provide to demonstrate that (1) an event is "significantly likely to become a PHE;" or (2) the increased scope of required data will be used to protect resident and community health and safety. The agency also asked for comments on the utility and burden of specifically staffing and supply shortage data it proposed to collect during national, state, or local PHE (or imminent threat of such a PHE) for a respiratory infectious disease.

In response to the proposed rule, CMS indicates the agency received 73 total comments from industry commenters, such as national associations, leadership, and facility staff. It received very few comments from advocacy organizations and no comments from anyone identifying themselves as residents or family advocates. CMS states that many commenters supported the proposed extension of respiratory illness reporting requirements for LTC facilities, although some commenters suggested reducing the frequency of required reporting to minimize administrative burden, and other commenters suggesting that reporting be required only in the event of a disease outbreak. However, CMS indicates that "many" commenters opposed the extension of the current reporting requirements, and recommended that CMS allow these reporting requirements to end on December 31, 2024, as scheduled. Administrative burden and redundancy were two major concerns raised by such commenters. Others raised concerns about the technical challenges of reporting data through the CDC's NHSN.

Regarding CMS' proposal to require additional data elements to be reported during a PHE, the agency indicates that many commenters opposed such a requirement, given the vague nature of terms such as "significantly likely," and even "public health emergency." Commenters asserted that rapidly changing reporting requirements during a PHE could lead to unintentional compliance issues, and create additional administrative burden without demonstrable benefit.

In light of comments received, CMS is finalizing its proposal to require ongoing respiratory illness reporting in a modified form as proposed. LTC facilities, in a standardized format and frequency specified by the Secretary, must electronically report information on acute respiratory illnesses, including influenza, SARS-CoV-2/COVID-19, and RSV, facility census (defined as the total number of residents occupying a bed at this facility for at least 24 hours during the week of data collection), resident vaccination status, confirmed resident cases, and hospitalized residents with confirmed cases.

With respect to requiring LTC facilities to report additional data elements during a PHE, CMS is finalizing as proposed its proposal to require additional reporting during a declared national, State, or local PHE for an acute infectious illness. However, CMS in this final rule

withdraws its proposal to require additional reporting if the Secretary determines that an event is "significantly likely" to become a PHE for an infectious disease. During a declared national, State, or local PHE for an acute infectious illness the Secretary may require reporting of data elements relevant to confirmed infections for staff, supply inventory shortages, staffing shortages, and relevant medical countermeasures and therapeutic inventories, usage, or both.

VII. Provider Enrollment – Provisional Period of Enhanced Oversight (PPEO)

A. Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. One requirement in this process is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS-855, either on paper or through the Provider Enrollment, Chain, and Ownership System (PECOS) process. PECOS is used to process initial enrollments, changes in ownership, revalidations, reactivations, and other changes of information.

B. Provisions – Provisional Period of Enhanced Oversight (PPEO)

Section 1866(j)(3)(A) of the Act states that the Secretary shall establish procedures to provide for a provisional period of between 30 days and 1 year during which new providers and suppliers—as the Secretary determines appropriate, including categories of providers or suppliers—will be subject to enhanced oversight. This is referred to as a provisional period of enhanced oversight (PPEO). CMS has typically executed PPEOs through sub-regulatory guidance, but the agency has in the past used notice and comment rulemaking to effect provisions related to provider enrollment. For example, in the 2024 HH PPS final rule, CMS codified at §424.527(a)(1) through (3) definitions of "new" providers that would be subject to a PPEO.

In the HH PPS proposed rule for 2025, CMS discussed the program integrity rationale for applying PPEOs to providers whose Medicare status has been "deactivated" (as opposed to revoked), effectively treating them as "new" providers.³³ CMS proposed to add a new paragraph (a)(4) to §424.527 that includes providers and suppliers that are reactivating their enrollment and billing privileges under §424.540(b). While CMS indicated that the agency was addressing this issue via rulemaking in proposed §424.527(a)(4), it strongly noted that it retains the authority under section 1866(j)(3)(B) of the Act to establish and implement PPEO procedures via sub-regulatory guidance.

CMS indicates that a number of commenters supported its proposed change to apply PPEO to "deactivated" providers re-entering the Medicare program. Interestingly, the agency indicates

³³ A provider's Medicare status can be deactivated for a number of reasons, such as ceasing to bill the Medicare program for a period that exceeds six months or failing to report a change in ownership. Providers whose Medicare status is deactivated can be reactivated if they meet all applicable requirements. This is in contrast to providers whose status is revoked, in which case they cannot re-enroll in Medicare for a period of 1 to 10 years.

that most of the comments it received in response to this proposal were "outside the scope of this final rule."

After considering the comments received, CMS is finalizing its proposed change to §424.527(a)(4) without modification.

VIII. Regulatory Impact Analysis

CMS estimates that the net impact of the HH PPS policies in this final rule is an increase of 0.5 percent, or \$85 million, in Medicare payments to HHAs for 2025. The overall impact of the changes in the HH PPS system on payments to HHAs in 2025 is summarized in the following table.

| Summary of Overall Impact of Final HH PPS Changes | | | | | | | |
|---|-------------|----------------|--|--|--|--|--|
| Dallar | 2025 impact | | | | | | |
| Policy | Percentage | Dollars | | | | | |
| HH PPS update | + 2.7% | +\$460 million | | | | | |
| Permanent behavioral adjustment | -1.8% | -\$305 million | | | | | |
| Updated FDL | -0.4% | -\$70 million | | | | | |
| Net impact | +0.5% | +85 million | | | | | |

Table 35, 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. The table breaks out the payment effects of the permanent behavioral adjustment, the case-mix weights recalibration budget neutrality factor, the 2025 wage index update, the LUPA add-on factors update, the 2025 update percentage, and the FDL update. The permanent behavior adjustment impact reflected in column 3 does not equal the final -1.975 percent permanent adjustment. CMS explains that the -1.8 percent reflected in column 3 includes all payments, while the final -1.975 percent 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 74 percent of all facilities) would experience an average increase in payments of 0.7 percent. Voluntary/Non-profit HHAs would experience a 0.1 percent decrease. Government-based facilities would experience a 1.1 percent increase.

CMS examined alternatives to how to implement the permanent payment adjustment. One alternative to the -1.975 percent permanent adjustment, as finalized in this rule, including taking the full adjustment of -3.95 percent. Other alternatives included taking the remaining permanent adjustment not taken in the 2024 HH PPS final rule, which resulted in -2.890 percent, a phase-in approach (spreading out over several years) or delaying the permanent adjustment to a future year. However, the agency did not implement the full adjustment of -3.95 percent as to be responsive to commenters' concerns about the on-going permanent adjustments to the payment rate. It believes, however, that a phase-in approach, or delay in the permanent adjustment would not be appropriate as this would likely lead to the need for a larger reduction to the payment rate in future years to maintain budget neutrality. It also considered proposing to implement the one-time temporary adjustment to reconcile retrospective overpayments in 2020, 2021, 2022 and 2023. It remains concerned, however, that implementing both the permanent and temporary

adjustments to the 2025 payment rate may adversely affect HHAs given the potentially large reduction in payments in one year.

Table 35: Estimated HHA Impacts by Facility Type and Area of the Country, CY 2025

| | Number of Agencies | Permanent Adjustment | 2025 Case- Mix Weights Recalibr ation | | 2025 LUPA Add-On Factors Update | 2025 Final HH Payment Update % | Fixed- Dollar Loss (FDL) | Total |
|--|--------------------------|-------------------------|--|---------------|---|---|-----------------------------------|---------------|
| All Agencies | 9,638 | -1.8% | 0.0% | 0.0% | 0.0% | 2.7% | -0.4% | 0.5% |
| Facility Type and Control | | | | | | | | |
| Free-Standing/Other Vol/NP | 866 | -1.7% | 0.0% | -0.6% | 0.0% | 2.7% | -0.5% | -0.1% |
| Free-Standing/Other Proprietary | 7,049 | -1.8% | 0.0% | 0.2% | 0.0% | 2.7% | -0.4% | 0.7% |
| Free-Standing/Other Government | 149 | -1.7% | 0.0% | 0.6% | 0.0% | 2.7% | -0.5% | 1.1% |
| Facility-Based Vol/NP | 429 | -1.7% | -0.1% | -0.3% | 0.0% | 2.7% | -0.6% | 0.0% |
| Facility-Based Proprietary | 44 | -1.8% | 0.1% | 0.6% | 0.0% | 2.7% | -0.4% | 1.2% |
| Facility-Based Government | 137 | -1.7% | 0.0% | 0.6% | 0.0% | 2.7% | -0.5% | 1.1% |
| Subtotal: Freestanding | 8,064 | -1.8% | 0.0% | 0.1% | 0.0% | 2.7% | -0.4% | 0.6% |
| Subtotal: Facility-based | 610 | -1.7% | -0.1% | -0.2% | 0.0% | 2.7% | -0.6% | 0.1% |
| Subtotal: Vol/NP | 1,295 | -1.7% | 0.0% | -0.5% | 0.0% | 2.7% | -0.5% | 0.0% |
| Subtotal: Proprietary | 7,093 | -1.8% | 0.0% | 0.2% | 0.0% | 2.7% | -0.4% | 0.7% |
| Subtotal: Government Facility Type and Control: Rural | 286 | -1.7% | 0.0% | 0.6% | 0.0% | 2.7% | -0.5% | 1.1% |
| Free-Standing/Other Vol/NP | 205 | -1.7% | 0.1% | 0.7% | 0.0% | 2.7% | -0.5% | 1.3% |
| Free-Standing/Other Proprietary | 731 | -1.8% | 0.3% | 1.5% | 0.0% | 2.7% | -0.3% | 2.4% |
| Free-Standing/Other Government | 101 | -1.7% | 0.2% | 1.2% | 0.0% | 2.7% | -0.6% | 1.8% |
| Facility-Based Vol/NP | 187 | -1.6% | 0.1% | 0.9% | 0.0% | 2.7% | -0.7% | 1.4% |
| Facility-Based Proprietary | 14 | -1.8% | 0.5% | -0.5% | 0.0% | 2.7% | -0.3% | 0.6% |
| Facility-Based Government Facility Type and Control: | 100 | -1.7% | 0.1% | 0.3% | 0.0% | 2.7% | -0.6% | 0.8% |
| Urban E. C. I. (O.I. V. I/NID. | 661 | 1.70/ | 0.0% | 0.70/ | 0.00/ | 2.70/ | 0.50/ | 0.20/ |
| Free-Standing/Other Vol/NP Free-Standing/Other Proprietary | 6,310 | -1.7% -1.8% | 0.0% | -0.7% 0.1% | 0.0% | 2.7% | -0.5% -0.4% | -0.2% 0.6% |
| Free-Standing/Other Government | 48 | -1.8% | -0.1% | 0.0% | 0.0% | 2.7% | -0.4% | 0.4% |
| Facility-Based Vol/NP | 242 | -1.7% | -0.1% | -0.6% | 0.0% | 2.7% | -0.6% | -0.3% |
| Facility-Based Proprietary | 30 | -1.8% | 0.0% | 0.9% | 0.0% | 2.7% | -0.5% | 1.3% |
| Facility-Based Government | 37 | -1.7% | -0.1% | 0.8% | 0.0% | 2.7% | -0.4% | 1.3% |
| Facility Location: Urban or Rural | | | | | | | - | - |
| Rural | 1,338 | -1.8% | 0.2% | 1.3% | 0.0% | 2.7% | -0.4% | 2.0% |
| Urban | 7,328 | -1.8% | 0.0% | -0.1% | 0.0% | 2.7% | -0.4% | 0.4% |
| Facility Location: Region of the Country (Census Region) | | | | | | | | |
| New England | 300 | -1.7% | -0.1% | -1.6% | 0.0% | 2.7% | -0.5% | -1.2% |
| Mid Atlantic | 379 | -1.7% | -0.1% | -1.4% | 0.0% | 2.7% | -0.4% | -0.9% |
| East North Central | 1,427 | -1.8% | 0.0% | 0.1% | 0.0% | 2.7% | -0.4% | 0.6% |
| West North Central | 569 | -1.7% | -0.1% | 0.7% | 0.0% | 2.7% | -0.5% | 1.1% |
| South Atlantic | 1,566 | -1.8% | -0.1% | 1.3% | 0.0% | 2.7% | -0.4% | 1.7% |
| East South Central | 357 | -1.8% | 0.2% | 2.4% | 0.0% | 2.7% | -0.3% | 3.2% |
| West South Central | 1,996 | -1.8% | 0.2% | 1.2% | 0.0% | 2.7% | -0.4% | 1.9% |
| Mountain | 705 | -1.7% | -0.1% | 1.2% | 0.0% | 2.7% | -0.5% | 1.6% |

| | Number of Agencies | Permanent Adjustment | 2025 Case- Mix Weights Recalibr ation | 2025 Updated Wage Index (with 5% cap and OMB Delineation) | Factors Update | 2025 Final HH Payment Update % | Fixed- Dollar Loss (FDL) | Total |
|--|--------------------------|-------------------------|--|---|-------------------|---|-----------------------------------|-------|
| Pacific | 2,296 | -1.8% | 0.0% | -2.0% | 0.0% | 2.7% | -0.4% | -1.5% |
| Outlying | 43 | -1.8% | 0.5% | -1.2% | 0.0% | 2.7% | -0.4% | -0.2% |
| Facility Size (Number of 30-day Periods) | | | | | | | | |
| < 100 periods | 2,178 | -1.8% | 0.1% | 0.0% | 0.0% | 2.7% | -0.5% | 0.5% |
| 100 to 249 | 1,504 | -1.7% | 0.0% | -0.4% | 0.0% | 2.7% | -0.5% | 0.1% |
| 250 to 499 | 1,702 | -1.8% | 0.0% | -0.2% | 0.0% | 2.7% | -0.5% | 0.2% |
| 500 to 999 | 1,909 | -1.8% | 0.0% | 0.0% | 0.0% | 2.7% | -0.4% | 0.5% |
| 1,000 or More | 2,345 | -1.8% | 0.0% | 0.0% | 0.0% | 2.7% | -0.4% | 0.5% |

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

Notes: The estimated 1.8 percent decrease related to the finalized permanent adjustment includes all payments, while the -1.975 percent permanent adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The "CY 2025 Updated Wage Index (with 5% cap and OMB delineations)" column reflects updated hospital wage index data (reflecting 2022 cost report data) with the revised OMB delineations from OMB Bulletin No. 23-01 and a 5-percent cap on wage index decreases. The "CY 2025 LUPA Add-On Factors Update" column has an overall impact of -0.02 percent which is reflected in the table as 0.0 percent due to rounding. The "Fixed Dollar Loss (FDL) Update" column reflects a change in the FDL from 0.27 to 0.35. Due to missing Provider of Services file information (from which home health agency characteristics are obtained), some subcategories in the impact tables have fewer agencies represented than the overall total (of 9,638): totals involving facility type or control only add up to 8,674 and totals involving urban/rural locations only add up to 8,666.