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 Proposed Rule Summary (CMS-1803-P)

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I. Introduction

On June 26, 2024, the Centers for Medicare & Medicaid Services (CMS) placed the calendar year 2025¹ Home Health Prospective Payment System (HH PPS) proposed rule on public display. The proposed rule will be published in the *Federal Register* on July 3, 2024. The proposed rule updates the payment rates for home health agencies (HHAs), disposable negative pressure wound therapy (dNPWT) devices, and intravenous immune globulin (IVIG) items and services for 2025.

In addition, this proposed rule provides information on home health utilization trends to monitor the effect of the Patient-Driven Groupings Model (PDGM). CMS also proposes a permanent prospective behavior adjustment to the 2025 home health payment rate to account for the impact of the implementation of the PDGM. 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 proposes to adopt 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 seeks information on future HH QRP quality measure concepts. For the Expanded Home Health Value-Based Purchasing (HHVBP) Model, CMS includes a 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 the proposed policies would decrease Medicare payments to home health agencies (HHAs) in 2025 by -1.7 percent (-\$280 million). This decrease reflects the effects of the proposed +2.5 percent home health payment update, an estimated 3.6 percent decrease from the proposed permanent adjustment of -4.067 percent,² and an estimated 0.6 percent decrease from the proposed update to the fixed-dollar loss ratio (FDL) used in determining outlier payments.

The deadline for public comment is August 26, 2024.

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

² CMS proposes a permanent behavior adjustment of -4.067 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 -3.6 percent includes all 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 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

1. Routine PDGM Monitoring

Section 1895(b)(3)(D) of 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 may include 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 this proposed rule, CMS examines simulated data for 2018 and 2019 and actual data for 2020, 2021, 2022, and 2023 for 30-day periods of care. CMS refers readers to the 2022 HH PPS final rule³ for a discussion about the simulated data for 2018 and 2019.

a. Utilization

Tables 2, 3, and 4 in the proposed rule provide data on trends in utilization from 2018 to 2023.

- Table 2 shows the overall utilization of home health services, which shows declines in 30-day periods of care and unique beneficiaries. For example, the total number of 30-day periods of care decreased by 13% from 9.34 million to 8.13 million.
- Table 3 shows the average utilization of visits per 30-day period of care by home health discipline over time. Average utilization of visits per 30 days across all disciplines decreased 18.9% from 9.86 to 8.0. Each home health discipline (i.e., skilled nursing, physical therapy, occupational therapy, speech therapy, home health aide, social worker) showed a decrease from 2018 to 2023.
- Table 4 shows the proportion of 30-day periods of care that are LUPAs and the average number of visits per discipline of those LUPA 30-day periods of care over time. The average number of LUPA home health periods for skilled nursing declined from 1.15 to 0.99, while physical therapy increased from 0.43 to 0.51 during this period. Trends for occupational therapy, speech therapy, home health aide, and social worker remained about the same.

Table 2: Overall Utilization of Home Health Services, 2018-2023									
Volume of Periods and Number of Beneficiaries	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023			
30-Day Periods of Care (in millions)	9.34	8.74	8.42	9.27	8.59	8.13			
Unique Beneficiaries (in millions)	2.98	2.80	2.85	3.02	2.83	2.67			
Average Number of 30-Day Periods per Unique Beneficiary	3.13	3.12	2.95	3.07	3.04	3.05			

Source: CY 2018 and CY 2019 simulated PDGM data with behavior assumptions came from the Home Health LDS CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.

Note: All 30-day periods of care claims were included (for example LUPAs, partial payment adjustments, and outliers). There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in the analysis.

³ 86 FR 35881

D1 1 1	CY 2018	CV 2019		1		ne, 2018-2023
Discipline	(Simulated)	(Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Skilled Nursing	4.53	4.49	4.35	4.05	3.9	3.86
Physical Therapy	3.30	3.33	2.70	2.74	2.77	2.78
Occupational Therapy	1.02	1.07	0.79	0.78	0.77	0.76
Speech Therapy	0.21	0.21	0.16	0.15	0.14	0.14
Home Health Aide	0.72	0.67	0.54	0.48	0.43	0.41
Social Worker	0.08	0.08	0.06	0.05	0.05	0.05
Total (all disciplines)	9.86	9.85	8.59	8.25	8.06	8.00

Table 4: The Proportion	Table 4: The Proportion of 30-Day Periods of Care that are LUPAs and the Average Number of									
Visits by Home Health Discipline for LUPA Home Health Periods, CYs 2018-2023										
	CY 2018 CY 2019 CY 2020 CY 2021 CY 2022 CY 2									
	(Simulated)	(Simulated)								
Total LUPA % of Overall	6.7%	6.8%	8.7%	7.9%	7.8%	6.8%				
30-day Periods	0./70	0.870	0./70	7.9%	1.870	0.870				
Discipline (Average # visit	s for LUPA hor	ne health perio	ds)							
Skilled Nursing	1.15	1.14	1.19	1.12	1.08	0.99				
Physical Therapy	0.43	0.46	0.53	0.55	0.60	0.51				
Occupational Therapy	0.07	0.07	0.08	0.08	0.09	0.07				
Speech Therapy	0.02	0.02	0.02	0.02	0.02	0.02				
Home Health Aide	0.01	0.01	0.01	0.01	0.01	0.01				
Social Worker	0.01	0.01	0.01	0.01	0.01	0.01				
Total	1.69	1.71	1.84	1.79	1.81	1.61				
Source and Note: Same as Tab	ole 2.									

b. Analysis of 2022 Cost Report Data for 30-Day Periods of Care

CMS examined 2022 HHA Medicare cost reports (the most recent and complete cost report data available) and 2023 30-day period of care home health claims, to estimate 30-day period of care costs. CMS excluded LUPAs and visits with PEPs in the average number of visits. The 2022 average NRS cost per visit is \$4.38. CMS updated the estimated 30-day period of care costs, by multiplying the 2022 average costs per visit with NRS for each discipline by the 2023 home health payment update percentage of 1.04 percent. The amount for each discipline is then multiplied by the 2023 average number of visits by discipline to determine the 2023 estimated 30-day period costs.

Table 5, reproduced below, shows the estimated average costs for 30-day periods of care by discipline NRS and the total 30-day period of care costs with NRS for 2023.

Table 5: Estimated Costs for 30-Day Periods of Care in CY 2023									
Discipline	Discipline 2022 2023 2023 2023								
	Average Costs Market Basket Average Estimated 30-								
	per visit with	Update Factor	Number of	Day Period					
NRS Visits Costs									
Skilled Nursing	\$176.50	1.04	4.08	\$748.92					

Table 5: Estimated Costs for 30-Day Periods of Care in CY 2023									
Discipline	2022 Average Costs per visit with NRS	2023 Market Basket Update Factor	2023 Average Number of Visits	2023 Estimated 30- Day Period Costs					
Physical Therapy	\$176.71	1.04	2.95	\$542.15					
Occupational Therapy	\$172.48	1.04	0.81	\$145.30					
Speech Pathology	\$200.12	1.04	0.15	\$31.22					
Medical Social Services	\$302.17	1.04	0.05	\$15.74					
Home Health Aides	\$95.94	1.04	0.44	\$43.90					
Total \$1,527.23									
Source: 2022 Medicare cost rep 30- day periods of care with a th									

CMS notes the 2023 national, standardized 30-day period payment was \$2,010.69, which is approximately 32 percent more than the estimated 2023 30-day period average facility cost of \$1,527.23. Medicare Payment Advisory Commission (MedPAC) noted that for more than a decade, payments under the HH PPS have significantly exceeded HHA's costs because agencies reduced episode costs by reducing the average number of visits per episode.⁴

c. Clinical Groupings and Comorbidities

Each 30-day period of care is grouped into one of 12 clinical groups describing the primary reason patients are receiving home health services. The clinical grouping is based on the principal diagnosis reported on the HH claim. Table 6, reproduced below, shows the distribution of the 12 clinical groups over time.

Cable 6: Distribution of 30-Day Periods of Care by the 12 PDGM Clinical Groups, CYs 2018-2023Clinical GroupingCY 2018CY 2019CY 2020CY 2021CY 2022CY 2023										
CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023					
(Simulated)	(Simulated)									
1.7%	1.5%	2.3%	2.4%	2.3%	2.2%					
2.6%	2.5%	3.5%	3.3%	3.2%	3.1%					
16.5%	16.1%	18.9%	18.5%	17.9%	17.5%					
17.3%	17.4%	7.2%	6.9%	6.8%	7.0%					
2.2%	2.3%	4.7%	4.7%	4.9%	5.0%					
2.9%	2.7%	4.8%	4.6%	4.6%	4.7%					
4.7%	4.7%	3.1%	3.6%	3.5%	3.7%					
4.3%	4.1%	7.8%	8.0%	7.8%	7.2%					
1.8%	1.8%	3.6%	3.4%	3.4%	3.5%					
17.1%	17.3%	19.4%	19.8%	20.8%	21.2%					
14.4%	14.5%	10.5%	10.9%	11.0%	10.9%					
14.5%	15.1%	14.2%	13.9%	13.7%	14.0%					
	CY 2018 (Simulated) 1.7% 2.6% 16.5% 17.3% 2.2% 2.9% 4.7% 4.3% 1.8% 1.8% 17.1% 14.4%	CY 2018 (Simulated)CY 2019 (Simulated)1.7%1.5%2.6%2.5%16.5%16.1%17.3%17.4%2.2%2.3%2.9%2.7%4.7%4.7%4.3%4.1%1.8%1.8%17.1%17.3%14.4%14.5%	CY 2018 (Simulated) CY 2019 (Simulated) CY 2020 1.7% 1.5% 2.3% 2.6% 2.5% 3.5% 16.5% 16.1% 18.9% 17.3% 17.4% 7.2% 2.9% 2.3% 4.7% 4.7% 4.7% 3.1% 4.3% 4.1% 7.8% 18.8% 1.8% 3.6% 17.1% 17.3% 19.4%	CY 2018 (Simulated)CY 2019 (Simulated)CY 2020 CY 20211.7%1.5%2.3%2.4%2.6%2.5%3.5%3.3%16.5%16.1%18.9%18.5%17.3%17.4%7.2%6.9%2.2%2.3%4.7%4.7%2.9%2.7%4.8%4.6%4.7%4.7%3.1%3.6%4.3%4.1%7.8%8.0%1.8%1.8%3.6%3.4%17.1%17.3%19.4%19.8%14.4%14.5%10.5%10.9%	CY 2018 (Simulated)CY 2019 (Simulated)CY 2020 CY 2021CY 2021 CY 20221.7%1.5%2.3%2.4%2.3%2.6%2.5%3.5%3.3%3.2%16.5%16.1%18.9%18.5%17.9%17.3%17.4%7.2%6.9%6.8%2.2%2.3%4.7%4.7%4.9%2.9%2.7%4.8%4.6%4.6%4.7%4.7%3.1%3.6%3.5%4.3%4.1%7.8%8.0%7.8%1.8%1.8%3.6%3.4%3.4%17.1%17.3%19.4%19.8%20.8%14.4%14.5%10.5%10.9%11.0%					

Source: Same as Table 2.

Note: All 30-day periods of care claims were included (e.g., LUPAs, partial payment adjustments, and outliers). The average case mix weight for each clinical groups includes all 30-day periods regardless of other adjustments (for example admission source, timing comorbidities, etc.). MMTA is Medication Management, Teaching, and Assessment.

⁴ Report to Congress, Medicare Payment Policy. Home Health Care Services, Chapter 7. MedPAC. March 2024 https://www.medpac.gov/wp-content/uploads/2024/03/Mar24 Ch7 MedPAC Report To Congress SEC.pdf

Thirty-day periods of care receive a comorbidity adjustment based on the presence of certain secondary diagnoses reported on home health claims; the comorbidity adjustment can be low or a high comorbidity adjustment, or no comorbidity adjustment.⁵ Table 7, reproduced below, shows the distribution of 30-day periods of care by comorbidity adjustment category.

Table 7: Distribution of 30-Day Periods of Care by Comorbidity Adjustment Category for 30- Day Periods, CYs 2018-2023										
Comorbidity AdjustmentCY 2018 (Simulated)CY 2019 (Simulated)CY 2020 (CY 2021)CY 2021 (CY 2022)CY 2022 (CY 2023)										
None	55.6%	52.0%	49.1%	49.6%	37.3%	30.7%				
Low	Low 35.3% 38.0% 36.9% 36.9% 47.8% 52.6%									
High 9.2% 10.0% 14.0% 13.5% 14.9% 16.7%										
Source and Note: Sat	me as Table 2									

Source and Note: Same as Table 2.

d. Admission Source and Timing

Each 30-day period of care is classified into one of two admission source categories (community or institutional) depending on what healthcare setting was utilized in the 14 days prior to receiving home health care.⁶ Thirty-day periods of care are classified as "early" or "late" depending on when they occur within a sequence of 30-day periods of care. The first 30-day period of care is classified as early and all subsequent 30-day periods of care in the sequence are classified as late. A subsequent 30-day period of care would not be considered early unless there is a gap of more than 60 days between the end of one period of care and the start of another. The timing of a 30-day period of care comes from the HH claims data. Table 8, reproduced below, shows the distribution of 30-day periods of care by admission source and timing over time.

Table 8: Distri	bution of 30-I	Day Periods of	Care by Adm	ission Sour	ce and Perio	od Timing,	CYs
2018-2023							

Admission	Period	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023
Source	Timing	(Simulated)	(Simulated)				
Community	Early	13.5%	13.8%	12.4%	11.6%	11.7%	11.7%
Community	Late	61.1%	60.9%	61.8%	63.9%	63.2%	63.2%
Institutional	Early	18.6%	18.4%	20.0%	18.6%	19.1%	19.2%
Institutional	Late	6.8%	6.9%	5.8%	5.9%	6.0%	6.0%
Source and Note	: Same as Table	e 2.					

⁵ The comorbidity adjustment categories are discussed in the 2020 HH PPS final rule, 84 FR 60493.

⁶ Thirty-day periods of care for beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility stays, skilled nursing facility stays, inpatient rehabilitation facility stays, or long-term care hospital stays within 14 days prior to a HH admission are designated as institutional stays. The institutional source category also includes patients with an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted.

e. Functional Impairment Level

Each 30-day period of care is placed into a functional level based on responses to certain OASIS functional items associated with grooming, bathing, dressing, ambulating, transferring, and risk for hospitalization.^{7,8} The functional impairment level remains the same for the first and second 30-day periods of care unless here has been a significant change in condition that warranted an "other follow-up" assessment prior to the second 30-day period of care. Table 9, reproduced below, shows the distribution of 30-day periods by functional status.

Table 9: Distribution of 30-Day Periods of Care by Functional Impairment Level, CYs 2018-2023										
Functional Impairment Level	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023				
Low	33.9%	31.9%	25.7%	23.2%	28.1%	29.8%				
Medium	34.9%	35.5%	32.7%	32.6%	33.1%	31.8%				
High	31.2%	32.6%	41.7%	44.2%	38.9%	38.3%				
Source and Note: San	ne as Table 2.									

f. Therapy Visits

Prior to the implementation of the PDGM, HHAs could receive a payment adjustment based on the number of therapy visits provided during a 60-day episode of care.⁹ CMS examined the proportion of simulated 30-day periods with and without any therapy visits. Table 10, reproduced below, shows the proportion of 30-day periods of care for various therapy options. CMS also examined the proportion of 30-day periods of care by the number of therapy visits provided during 30-day periods of care (Figure 2 in proposed rule). CMS' analysis shows modest changes in the distribution of both therapy and non-therapy visits in 2023 compared to 2022. The proportion of 30-day periods of care with no therapy (37.1%) is trending downward towards pre-PDGM levels after peaking in 2020 (42.6%). CMS' comparison of therapy utilization before the PDGM (2018 and 2019) to after the implementation of the PDGM (2020-2023) shows a decline in therapy visits across all clinical groups (Table 11 in proposed rule).

Cable 10: Proportion of 30-Day Periods of Care With Only Therapy, At Least One Therapy Visit,						
	and No Th	erapy Visits fo	or CYs 2018	-2023		
30-day Period Visit	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023
Туре	(Simulated)	(Simulated)				
Therapy Only	13.5%	14.4%	15.2%	17.8%	19.4%	20.1%
Therapy + Non-therapy	48.2%	48.4%	42.2%	42.3%	42.7%	42.8%
No Therapy	38.3%	37.2%	42.6%	39.9%	38.0%	37.1%
Total 30-day periods	9,336,898	8,744,171	8,423,688	8,962,690	8,593,266	8,133,377
Source and Note: Same as '	Source and Note: Same as Table 2.					

⁷ The specific OASIS items used for the functional impairment level are listed in Table B7 in the 2020 HH PPS final rule, 84 FR 60490.

⁸ A detailed description of these response categories can be found in the technical report, "Overview of the HH Groupings Model" posted on the HHA web page (<u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM</u>)

⁹ Section 1895(b)(4)(B)(ii) of the Act eliminated the use of therapy thresholds in calculating payments for 2020 and subsequent years.

CMS also examined the proportion of 30-day periods of care with and without skilled nursing, social work, or home health aide visits for 2018-2023 (Tables 12 and 13, reproduced below).

Table 12: Proportion of 30-Day Periods of Care With Only Skilled Nursing, Skilled Nursing +Other Visit Type, and No Skilled Nursing Visits for CYs 2018-2023						
30-day Period Visit	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023
Туре	(Simulated)	(Simulated)				
Skilled Nursing Only	33.8%	33.1%	38.5%	36.2%	34.7%	34.1%
Skilled Nursing +	51.6%	51.5%	45.3%	44.9%	44.9%	44.7%
Other						
No Skilled Nursing	14.7%	15.5%	16.2%	18.9%	20.4%	21.2%
Total 30-day periods	9,336,898	8,744,171	8,423,688	8,962,690	8,593,266	8,133,377
Source and Note: Same a	ource and Note: Same as Table 2.					

Table 13: Proportion of 30-Day Periods of Care With and Without Home Health Aide or Social						
	Wo	rker Visits fo	r CYs 2018	-2023		
30-day Period Visit	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023
Туре	(Simulated)	(Simulated)				
Any home health aide or social worker	16.6%	15.9%	13.2%	12.2%	11.3%	10.8%
No home health aide or social worker	83.4%	84.1%	86.8%	87.8%	88.7%	89.2%
Total 30-day periods	9,336,898	8,744,171	8,423,688	8,962,690	8,593,266	8,133,377
Source and Note: Same a	Source and Note: Same as Table 2.					

g. Home Health Services Using Telecommunications Technology

In 2023, CMS began collecting data on the use of telecommunications technology used during a home health period using three new G-codes reported on home health claims. It began collecting this data on a voluntary basis on January 1, 2023 and then required this information to be reported starting on July 1, 2023. The three new G-codes help identify when home health services are furnished using synchronous telemedicine rendered via a real-time two-way audio and video telecommunications system (G0320); synchronous telemedicine rendered via telephone or other real-time interactive audio-only telecommunications system (G0321); and the collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency, that is, remote patient monitoring (G0322). CMS found that the use of telecommunications services reported on 2023 home health claims are low (roughly 1 percent of all 2023 claims) and are mainly associated with skilled nursing.

Table 14: Utilization of Telecommunications Technology Per 30-Day Periods of Care by HomeHealth Discipline as Indicated By G0320/G0321, CY 2023					
	Claims with at Least 1 Service Using Telecommunication	Number of Services Using Telecommunication	Unique Beneficiaries with at Least 1 Service Using Telecommunication	Unique Providers with at Least 1 Service Using Telecommunication	
Skilled Nursing	63,049	128,566	48,450	1,221	
PT	13,412	21,614	11,167	523	

OT	2,761	3,996	2,336	262	
SLP	740	1,176	558	107	
Aide	5	6	5	1	
MSS	1,812	2,052	1,691	195	
	Source: CY 2023 data was accessed from the CCW VRDC on March 19, 2024.				

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

Table 15: Utilization	Cable 15: Utilization of Remote Monitoring Per 30-Day Periods of Care by Home Health Discipline				
		cated by G0322, CY			
	Claims with at Least	Number of Services	Unique	Unique Providers	
	1 Service Using	Using	Beneficiaries with	with at Least 1	
	Telecommunication	Telecommunication	at Least 1 Service	Service Using	
			Using	Telecommunication	
			Telecommunication		
Skilled Nursing	19,084	337,194	11,615	494	
PT	380	6072	296	82	
OT	20	188	20	15	
SLP	53	966	41	7	
Aide	6	123	6	4	
MSS	271	4,480	145	2	
	Source: CY 2023 data was accessed from the CCW VRDC on March 19, 2024. Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).				

CMS states that it will continue to monitor the provision of home health services and overall home health payments to determine if refinements to the case-mix adjustment methodology or other policies may be needed in the future.

C. Proposed Payment Adjustments Under the HH PPS

1. Proposed 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(a) of the CAA, 2023, required CMS to present, to the extent practicable, a description of the actual behavior changes occurring under the HH PPS from CYs 2020-2026, the datasets underlying the simulated 60-day episodes, and provide for stakeholder input. It complied with these requirements by posting online the supplemental LDS and descriptive files and the description of actual behavior changes that affected the 2023 payment rate development. CMS also conducted a webinar on these issues on March 29, 2023.¹⁰

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 30day 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 is proposing to update two minor technical parts and proposing to add 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

¹⁰ These materials can be found at <u>https://www.cms.gov/medicare/medicare-fee-for-service-payment/homehealthpps/hh-pdgm</u>

(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 proposed 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 these 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 makes two proposals on assumptions to address the changes from the OASIS-D to the OASIS-E to continue to create simulated 60-day episodes from 30-day periods.

- If the simulated 60-day episode matches to a SOC or ROC assessment then CMS proposes not to impute the 13 items. If the simulated 60-day episode matches to a follow-up assessment, then CMS proposes to look back for the most recent 30-day period that is linked to a SOC or ROC assessment and impute the 13 responses for follow-up using the responses at the most recent SOC or ROC assessment. CMS states it would limit the look back period to the beginning of the calendar year that precedes the calendar year for the claim. For example, a simulated 60-day episode with a follow-up assessment on June 1, 2023, would have a look-back period for a 30-day period linked to a SOC or ROC assessment that began on or after January 1, 2022. If CMS cannot find a SOC or ROC assessment in that time period, it proposes to exclude the claim from analysis.
- If the simulated 60-day episode matches to an OASIS-D assessment, then CMS proposes to use the OASIS-D for responses. If the simulated 60-day episode matches to an OASIS-E assessment, CMS proposes to apply mapping for the therapies, vision, and pain items to impute responses as these responses are required for accurate payment calculation under the prior 153-group system. CMS also proposes to apply the look-back period as described in the assumption earlier when necessary.

Figures 5, 6, and 7 in the proposed rule details the mapping for therapies, vision, and pain response items from the OASIS-E to OASIS-D. **CMS solicits comments on these new proposed assumptions related to mapping of the OASIS-E items.**

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 estimated aggregate expenditures from all 30-day periods using the *recalculated* 30-day base payment rate, and
- The aggregate expenditures for all 30-day periods using the *actual* 30-day base payment rate for the same year.

The temporary adjustment is applied on a prospective basis and applies only with respect to the year for which such temporary increase or decrease is made. CMS refers readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis for CYs 2020 through 2022 claims.

d. 2023 Preliminary Claims Results

CMS notes that its 2023 analysis presented in the proposed rule is preliminary and will be updated 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 proposed rule included 6,494,947 actual 30-day periods of care and 3,845,954 simulated 60-day episodes of care for 2023.

e. 2025 Permanent and Temporary Adjustments

CMS determined that a permanent prospective adjustment of -1.125 percent to the 2023 30-day payment rate (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 \$965.88 million would be required to achieve budget neutrality. Table 16 (reproduced below) details these results.

Table 16: CY 2023 Final Permanent and Temporary Adjustments					
	Budget-neutral 30-day	Budget-neutral 30-day	Adjustment		
	Payment Rate with	Payment Rate with			
	Assumed Behavior	Actual Behavior			
	Changes	Changes			
Base Payment Rate	\$1,894.49*	\$1,873.17	Permanent		
			-1.125%		
Aggregate	\$15,982,282,880**	\$15,016,399,156	Temporary		
Expenditures	ψ1 <i>5</i> , <i>7</i> 02,202,000		-\$965,883,723		
Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW March 19, 2024					
Notes: * The \$1,894.49 is equal to the recalculated budget neutral 30-day base payment rate of \$1,839.10 for CY					
2022 (shown in Table 16) multiplied by the CY 2023 recalibration factor (0.9904), wage index budget neutrality					
factor (1.0001) and the CY 2023 home health payment update (1.040). ** The estimated aggregate expenditures					
	nges (\$16 billion) uses the act	ual CY 2023 payment rate of	\$2,010.69 as this is what		
CMS actually paid in CY 20)23.				

f. Proposed 2025 Permanent and Temporary Adjustments

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 C 2025 30-day payment rate, CMS

compares estimated aggregate expenditures under the PDGM and the prior system. Unlike the annual adjustments described in table 16, CMS does not assume the full adjustment from prior years had been taken.

As shown in table 17, a permanent prospective adjustment of -6.839 percent to the CY 2025 30day payment rate for CYs 2020 through 2023 would be required to offset for such increases in estimated aggregate expenditures in future years.

Table 17: Total Permanent Adjustment for CYs 2020, 2021, 2022, and 2023				
Recalculated CY 2023 Base Payment Rate (Actual Behavior)	Total Permanent Prospective Adjustment			
\$1,873.17	-6.839%*			
	Recalculated CY 2023 Base Payment Rate (Actual Behavior)			

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW March 19, 2024. *This is the total permanent adjustment based on CY 2023 data which includes the previous permanent adjustment of -3.925% applied. However, as described later, CMS recognizes for CY 2025 it must account for adjustment made in CY 2024.

Taking into account the permanent adjustment applied in CY 2024 of -2.890 percent, the current remaining permanent adjustment of **-4.067 percent** in 2025 would account for the permanent adjustments for CYs 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 -4.067 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 2023 Claims= -1.125% (Table 16)	

Accounting for the previous permanent adjustments applied to the 30-day payment rate in CYs 2023 and 2024, CMS simulates the permanent adjustment calculation with the simulated annual permanent adjustment percentage shown previously for CY 2025: (1-0.0652)(1-0.0142)(1-0.01767)(1-0.01125) = (1-0.03925)(1-0.0289)(1-x).

Solving, x = 4.067%.

Accordingly, CMS proposes to apply the full remaining permanent adjustment of -4.067 percent to the CY 2025 home health base payment rate, noting that it will update this percentage using more complete claims data in the final rule. CMS believes that it has been clear through notice and comment that the remainder of these permanent adjustments would be applied, thereby giving HHAs adequate notice to prepare for this year's proposed rate reduction.

Table 18 in the proposed rule (reproduced below) provides a summary of the permanent adjustments for prior years and the proposed year. 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 18: Summary of Permanent Adjustments for CYs 2020-2026					
Claims Analysis Year	Base Payment Rate for Assumed Behaviors (Actual Amount Paid to HHAs in the Claims Analysis Year)	Base Payment Rate that Reflects Actual Behavior Changes (As Determined After Later Claims Analysis)	Total Permanent Adjustment Between Assumed and Actual Behavior Rates*	Permanent Adjustment CMS Finalized and Implemented in Rulemaking	
CY 2020	\$1,864.03	\$1,742.52	-6.52%	n/a	
CY 2021	\$1,901.12	\$1,751.90	-7.85%	-3.925% 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	Proposec -4.067%	-4.067% proposed to be 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. * The total permanent adjustment accounts for prior adjustments that were finalized and implemented through rulemaking.

Given the magnitude of the temporary adjustment dollar amount (currently estimated at \$4.5 billion), CMS is not proposing to take the temporary adjustment in CY 2025. Table 19 (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.

Fable 19: 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 (as of proposed rule)	-\$965,883,723		
CY 2024	TBD		
CY 2025	TBD		

CY 2026	TBD
Total	-\$4,455,407,087

Source: CY 2020 Home Health Claims Data, periods that begin and end in CY 2020 accessed on the CCW July 12, 2021. CY 2021 Home Health Claims Data, periods that end in CY 2021 accessed on the CCW July 15, 2022. CY 2022 Home Health Claims Data, periods that end in CY 2022 accessed on CCW July 15, 2023. CY 2023 Home Health Claims Data, periods that end in CY 2023 accessed on CCW March 19, 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.

CMS seeks comments on the proposal to apply a -4.067 percent permanent adjustment to the CY 2025 base payment rate.

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

1. 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 proposes to update the LUPA thresholds using 2023 home health claims utilization data (as of March 19, 2024). The proposed 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 20 of the proposed rule. **CMS solicits comment on the proposed updates to the LUPA thresholds for 2025.**

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.

For 2025, CMS proposes 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 20 and 21, respectively. **CMS solicits comment on the updates to functional points and the functional impairment levels by clinical group.**

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 2024, CMS proposes 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 March 19, 2024). Using these data, CMS proposes to update the comorbidity subgroups to include 22 low comorbidity adjustment subgroups and 90 high comorbidity adjustment interaction subgroups as identified in Tables 22 and 23 in the proposed rule. CMS invites comment on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment interactions for 2024.

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 proposes to generate the recalibrated case-mix weights using 2023 home health claims data with linked OASIS assessment data (as of March 19, 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. These weights will be updated based on more complete 2023 claims data for the final rule.

Table 24 in the proposed 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 proposed 2024 case-mix weights are provided in Table 25 in the proposed 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 1.0035.

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.

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 first-quarter 2024 forecast for 2025 with historical data through fourth-quarter 2023, the proposed HH PPS market basket update is as follows:

Market Basket Update	Change (in %)
Market basket forecast	3.0
Total factor productivity	-0.5
Net update for HHAs reporting quality data	2.5
Net update for HHAs NOT reporting quality data	0.5

More recent forecasts for 2025 will be used for the final rule, if available. As noted below, the final update factor also includes budget neutrality adjustments for the wage index and case-mix recalibration.

2. Proposed 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 proposes 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 proposes 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 proposes to adopt the planning regions as county equivalents for wage index purposes. Table 26 provides a crosswalk of Connecticut county equivalents.

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

CMS' analysis shows that a total of 53 counties (and county equivalents) that are currently considered part of an urban CBSA would be considered located in a rural area, for HH PPS payment beginning in 2025, if its adopts the new OMB delineations (Table 27).

d. Rural Counties That Would 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 would be located in urban areas if it finalizes its proposal to implement the revised OMB delineations (Table 28).

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

Several urban counties would shift from one urban CBSA to another CBSA under its proposal to adopt the new OMB delineations. In other cases, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. Table 31 in the proposed 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 would involve a change only in CBSA name and/or number but no change to the counties that constitute the CBSA. Table 29 in the proposed rule details these CBSAs.

f. Proposed 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 proposed 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 CY 2025, to mitigate any potential negative impact, CMS proposes 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 proposes 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 CY 2025 wage index would not be less than 95 percent of the county's CY 2024 wage index value.

CMS notes that because of the proposal to calculate the 5-percent cap for counties that experience an OMB designation change, some counties would 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 proposes that beginning in CY 2025, counties that have a different wage index value than the CBSA or rural area into which they are designated after the application of the 5-percent cap would use a wage index transition code. The code would be five digits in length and begin with "50". CMS also proposes that the county would 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 32 in the proposed rule shows the counties that will use the transition code and the proposed code. The proposed HH PPS wage index file applicable for CY 2025 is available on the CMS website at: <u>https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center</u>.

3. CY 2025 Home Health Wage Index

CMS proposes 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 CY 2021 hospital cost report data as its source for the updated wage data. The proposed 2025 HH PPS wage index would not take into account any geographic reclassification of hospitals, but it would include the 5 percent cap on wage index decreases. In the 2023 HH PPS final rule (87 FR 66851 through 66853), CMS finalized for 2023 and subsequent years, the application of a permanent 5-percent cap on any decrease to a geographic area's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. In addition, if a geographic area's prior calendar year wage index is calculated based on the 5-percent cap, then the following year's wage index would not be less than 95 percent of the geographic area's capped wage index.

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 0.8608. For rural areas that do not have inpatient hospitals, CMS proposes to use the average wage index from all contiguous CBSAs as a reasonable proxy. As a result of the proposal to adopt the revised OMB delineations, rural North Dakota would now become a rural area without a hospital from which hospital wage data can be derived. Based on this approach, CMS calculates a proposed 2025 HH PPS wage index of 0.8334 for rural North Dakota. For Puerto Rico, CMS proposes 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 proposed wage 2025 wage index is available on the CMS website at: <u>https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center</u>.

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.¹¹ The labor portion is multiplied by the appropriate wage index based on the site of service and summed to the non-labor portion.

¹¹ A detailed description of how CMS rebased the HHA market basket and labor-related share is available in the CY 2024 HH PPS final rule (88 FR 77726 through 77742).

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 proposing to implement a permanent behavior adjustment of -4.067 percent in 2025 (that is, 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 proposes to apply 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 permanent behavior adjustment of -4.067 percent has the largest effect on the calculation of the proposed standardized amount. The proposed 2025 30-day payment amount would be -3.4 percent less than the 2024 30-day payment amount.

The following table shows the proposed standardized amounts, as displayed in Tables 34 and 35.

Proposed 2025 National, Standardized 30-Day Episode Payment Amount, for HHAs Submitting and Not Submitting Quality Data								
HHAs HHA								
	submitting	submitting						
	quality data	quality data						
2024 30-day budget neutral standardized amount	\$2,038.13							
Permanent behavior adjustment factor	x 0	.95933						
Case-mix weights recalibration neutrality factor	x 1	.0035						
Wage index budget neutrality factor x 0.9985								
HH payment update percentage x 1.025 x 1.005								
2025 30-day payment amount								

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

Computations are presented for the 2025 proposed per-visit amounts for each type of service. These amounts are used for LUPAs and in outlier calculations. The proposed per-visit amounts for those HHAs submitting the required quality data (Table 36 in the proposed rule) are as follows:

HH Discipline	CY 2024 Per-Visit Rates	Wage Index Budget Neutrality Factor	CY 2025 HH Payment Update Factor	CY 2025 Per- Visit Payment Amount
Home Health Aide	\$76.23	0.9991	1.025	\$78.07
Medical Social Services	\$269.87	0.9991	1.025	\$276.37
Occupational Therapy	\$185.29	0.9991	1.025	\$189.75
Physical Therapy	\$184.03	0.9991	1.025	\$188.46
Skilled Nursing	\$168.37	0.9991	1.025	\$172.42
Speech-Language Pathology	\$200.04	0.9991	1.025	\$204.86

HHAs that do not submit required quality data would have the payment update for per-visit services reduced from 2.5 percent to 0.5 percent, resulting in the following payment rates (Table 37 in the proposed rule):

HH Discipline	CY 2024 Per-Visit Rates	Wage Index Budget Neutrality Factor	CY 2025 HH Payment Update Factor	CY 2025 Per- Visit Payment Amount
Home Health Aide	\$76.23	0.9991	1.025	\$76.54
Medical Social Services	\$269.87	0.9991	1.025	\$270.98
Occupational Therapy	\$185.29	0.9991	1.025	\$186.05
Physical Therapy	\$184.03	0.9991	1.025	\$184.78
Skilled Nursing	\$168.37	0.9991	1.025	\$169.06
Speech-Language Pathology	\$200.04	0.9991	1.025	\$200.86

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 is proposing 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 proposes to use the same methodology used to establish the LUPA add-on amount for 2014, using updated claims data.

Specifically, CMS proposes to update the LUPA add-on factors by using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from 2023 claims data. Table 38 in the proposed 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 proposed LUPA add-on factors, and the percent change between the current and the proposed LUPA add-on factors. This table also shows the proposed OT LUPA add-on factor discussed below:

Table 38: Current and Proposed LUPA Add-on Factors									
Discipline	Current LUPA Add- on Factors	Proposed LUPA Add-on Factors Using Data from CY 2023	Change from	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	1.7227	-6.6%	30.00	41.51				
РТ	1.6700	1.6247	-2.7%	28.18	45.11				
SLP	1.6266	1.6703	+2.7%	31.59	47.13				
ОТ	1.6700	1.7266	+3.4%	33.40	45.97				

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 proposed add-on factors: 1.7227 for SN; 1.6247 for PT; and 1.6703 for SLP. CMS states that it will update these factors in the final rule based on more complete 2023 claims data in the final rule. **CMS solicits comments on the proposals to update the LUPA factors using the 2014 methodology and based on these updated numbers, the re-priced LUPA payment amounts.**

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 is now proposing 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 is proposing an add-on factor of 1.7266 for OT as described in Table 38 (reproduced above). This factor will be updated based on more complete 2023 claims data in the final rule. **CMS solicits comments on the proposed use of OT data to determine the OT LUPA add-on factor, as well as the proposed methodology**.

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 to be a proportion of the wage-adjusted estimated cost for the episode that surpasses the wage-adjusted threshold; this proportion is referred to as the loss-sharing ratio.

CMS notes that the FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the aggregate level of 2.5 percent of estimated total HH PPS payments, as required by statute. CMS has historically used a value of 0.80 for the loss-sharing ratio, meaning that Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount. No changes are proposed to the loss-sharing ratio for 2025.

For 2025 payment, CMS proposes an FDL ratio of 0.38 for 2025 based on analysis of 2023 claims data (as of March 19, 2024). CMS will update the FDL, if needed, in the final rule based on more complete 2023 claims data. In the proposed 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.¹²

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 (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.

¹² The per-unit amounts for 2023 are found in the November 10, 2022 HH PPS change request: <u>https://www.cms.gov/regulations-and-guidance/guidance/transmittals/transmittals/r11702cp</u>

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 of the Act (42 U.S.C. 1395m(s)) and mandated several amendments to the Medicare separate payment for dNPWT devices beginning in CY 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 (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 proposes 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. CMS notes that the CPI–U for the 12-month period ending in June of 2024 was not available at the time of this proposed rulemaking. Therefore, the 2025 payment amount, as well as the CPI–U for the 12-month period ending in June of 2024, and the corresponding productivity adjustment will be updated in the final rule.

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 QRP¹³ 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.¹⁴ 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 CY 2016 HH PPS final rule¹⁵ for considerations it uses for measure selection for the HH QRP quality, resource use, and other measures, and to the CY 2019 HH PPS final rule¹⁶ for the removal factors considered for removing HH QRP measures.

B. Overview of Proposals

Beginning with the 2027 HH QRP, CMS proposes (i) the addition of 4 new OASIS items and modification of one OASIS item, and (ii) an update to the removal of the suspension of OASIS all-payer data collection. CMS also seeks information on future HH QRP quality measure concepts.

If the proposals outlined in this section are finalized, CMS estimates that beginning with the January 1, 2027 OASIS assessments, in 2027 (as compared to the anticipated 2025 burden estimate), there would be an estimated net increase of 147,013 hours of clinician burden across all HHAs with an estimated net increase in clinician costs of \$12,604,895 in annualized cost across all HHAs. **CMS invites public comment** on all proposals under this section.

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, based on Table 39 of the rule.

¹⁵ 80 FR 68695 through 68696.

¹³ More information on the HH QRP can be found at <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits</u>. The HH QRP regulations are under 42 CFR 484.245 and 484.250.

¹⁴ 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.

¹⁶ 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)						
Ambulation						
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (CBE #0674)					
Application of Functional Assessment #	Application of Percent of HH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (CBE #2631)					
Bathing	Improvement in Bathing (CBE #0174)					
Bed Transferring	Improvement in Bed Transferring (CBE #0175)					
DRR	Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care (PAC) Home Health Quality Reporting Program					
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-	COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date					
19 Vaccine ##						
	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) ***					
РРН	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					
	<i>PH measure beginning with the CY 2023 HH QRP. The measures will be retired from public reporting beginning October 2024.</i>					
ННСА	AHPS-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.					

D. Proposal to Collect Four New Items as SPADEs and to Modify 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,¹⁷ 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 is data required with respect to the following categories: (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.¹⁸

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.¹⁹ 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. Proposal to Collect Four New Items as SPADEs

CMS proposes 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. ²⁰

¹⁷ 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.

¹⁸ These six categories are specified under section 1899B(b)(1)(B) of the Act.

¹⁹ See the 2020 HH PPS final rule (84 FR 60597-60608).

²⁰ See <u>https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures</u> for the following draft of the proposed items: <u>Draft SDOH Item Mockups (cms.gov)</u>.

a. One Living Situation Item Proposed

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 therefore proposes to adopt the Living Situation item, which would ask "What is your living situation today?" The proposed response options would 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 Proposed

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. Therefore, CMS proposes two new food items adapted from the Department of Agriculture 18-item Household Food Security Survey:

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

c. One Utilities Item Proposed

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

4. Proposal to Modify the Transportation Item

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.²¹ It currently asks "Has lack of transportation

²¹ Adopted in the 2020 HH PPS final rule (84 FR 60478).

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. The proposed modifications would 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.

Beginning with the 2027 HH QRP program year, therefore, CMS proposes to modify the Transportation item. The modified item would 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 would be: Yes; No; Patient declines to respond; and Patient unable to respond.

E. Proposed Updates to OASIS All-Payer Data Collection

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.²² There is a two-quarter voluntary phase-in during which HHAs will be able to start submitting this data for purposes of CMS making a compliance determination. Beginning with the 2027 program year, the new all-payer OASIS data reporting will be required, with data for the 2027 program year being required for patients discharge as the time point to identify the start of all-payer data collection.

CMS is proposing further details to clarify OASIS data collection and submission for non-Medicare and non-Medicaid patients. The agency proposes to change 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 would 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 would also ensure that baseline data is 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:

²² 2023 HH PPS final rule (87 FR 66862-66865).

- The period of voluntary data collection and submission will be for non-Medicare/non-Medicaid patients who are not exempt²³ 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,²⁴ 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.

F. Form, Manner, and Timing of Data Submission

1. Background

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

2. <u>Proposed Reporting Schedule for the Proposed New SPADEs and Modified Transportation</u> <u>Data Element</u>

- For the 2027 HH QRP program year, HHAs would be required to submit the 4 proposed new assessment items and the modified Transportation item using the OASIS beginning with patients admitted on January 1, 2027.
- Starting in 2027, HHAs would be required to submit data for the entire calendar year, corresponding to the 2028 HH QRP program year.
- 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) would be deemed to have submitted the items also with respect to discharge because 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

CMS seeks input on the importance, relevance, appropriateness, and applicability of each of the following four measure concepts for future years in the HH QRP:

• A composite measure of vaccinations, which could represent overall immunization status of patients.²⁵

²³ 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.

²⁴ 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.

²⁵ The Adult Immunization Status Measure in the Universal Foundation is provided as an example. <u>Centers for</u> <u>Medicare and Medicaid Services Measures Inventory Tool (cms.gov)</u>.

- The concept of depression, which may be similar to the Clinical Screening for Depression and Follow-up measure in the Universal Foundation.²⁶
- The concept of pain management.
- The concept of substance use disorders, such as the Initiation and Engagement of Substance Use Disorder Treatment measure in the Universal Foundation.

CMS will not respond to specific comments in the final rule, but intends to use input in response to this RFI for future measure development.

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

A. Background and Overview

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

The expanded HHVBP Model²⁷ began nationwide testing January 1, 2022, starting with a "preimplementation year" of 2022 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."

In the rule, CMS includes an 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.

B. RFI on Future Performance Measure Concepts

CMS requests 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: The TEP recommended that CMS consider development of a measure on caregivers' needs, not only the needs as they relate to the beneficiary. The agency notes that creating a measure based on an HHA's ability to meet caregiver needs would allow for measurement of changes in caregiver quality-of-life,

²⁶ See <u>Centers for Medicare and Medicaid Services Measures Inventory Tool (cms.gov)</u>.

²⁷ The expanded HHVBP Model regulations are under 42 CFR part 484, subpart F.

and that it intends to develop a patient-reported outcome performance measure in the Guiding an Improved Dementia Experience (GUIDE) model, which would assess caregiver burden.

- 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: The TEP raised concern that the DC Function measure does not include the full self-care/activities of daily living elements.

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.²⁸

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

²⁸ See the FY 2024 SNF PPS final rule (88 FR 53304-53316).

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.²⁹

F. Other Health Equity Measures

CMS is also considering other health equity measures to focus on disparities, such as:

- Measures for particular underserved communities, such as based on DES.
- Measures based on within-provider differences in performance for underserved communities.
- 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 2 years of performance data before incorporating any changes regarding health equity to the expanded Model.

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 home. Items may include the infusion set and tubing, and nursing services to complete an infusion of IVIG lasting on average three to five

²⁹ See 42 CFR 413.338(a).

hours. The demonstration ended December 31, 2023, after having been extended by the Consolidated Appropriations Act, 2021.³⁰

Effective January 1, 2024, the Consolidated Appropriation Act, 2023³¹ 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. Proposed 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 E1:

	Table E1: ICD-10-CM Codes Supporting Medical Necessity for Home IVIG					
Code	Description					
D80.0	Hereditary hypogammaglobulinemia					
D80.2	Selective deficiency of immunoglobulin A [IgA]					
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses					
D80.4	Selective deficiency of immunoglobulin M [IgM]					
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]					
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia					
D80.7	Transient hypogammaglobulinemia of infancy					
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis					
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers					
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers					
D81.5	Purine nucleoside phosphorylase [PNP] deficiency					
D81.6	Major histocompatibility complex class I deficiency					
D81.7	Major histocompatibility complex class II deficiency					
D81.82	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]					
D81.89	Other combined immunodeficiencies					
D81.9	Combined immunodeficiency, unspecified					
D82.0	Wiskott-Aldrich syndrome					
D82.1	Di George's syndrome					
D82.4	Hyperimmunoglobulin E [IgE] syndrome					
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					

³⁰ Division CC, section 104 of the CAA, 2021 CAA, 2021) (Pub. L. 115-63)

³¹ Division FF, section 4134 of the CAA, 2023 (CAA, 2023) (Pub. L. 117-328)

Through LCD L33610,³² 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. CMS is proposing these same HCPCS codes would apply to be eligible to receive items and services covered under the expanded IVIG benefit in the home.

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

2. <u>Home IVIG Items and Services and the Relationship to/Interaction with Home Health and</u> <u>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).³³ 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.

³² <u>LCD - Intravenous Immune Globulin (L33610) (cms.gov)</u>

³³ LCD - External Infusion Pumps (L33794) (cms.gov)

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. Home IVIG Administration Items and Services Supplier Type

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.

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. Proposed Payment Rate Update for Home IVIG Items and Services for 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 home health update percentage amount or \$420.48*1.025= \$430.99.

Apart from the update to the payment rate for the IVIG items and services bundle, in this proposed rule, CMS proposes no changes to the IVIG benefit as finalized in the CY 2024 final rule. Note that CMS is not seeking comment on the payment rate update.

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

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

CMS asserts that admission to home health is a critical step in the process of patients receiving timely, appropriate care to meet their needs. But the agency notes that the services provided by each HHA vary, creating challenges for individuals seeking to find the right HHA to meet their unique care needs. Thus, 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 is 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 this proposed rule, CMS proposes 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 proposes that the policy be reviewed annually and address, at minimum, the following criteria related to the HHA's capacity to provide patient care: the anticipated needs of the referred prospective patient, the HHA's case load and case mix, the HHA's staffing levels, and the skills and competencies of the HHA staff. CMS proposes that the patient acceptance to service policy be applied consistently to ensure that HHAs only accept those patients for whom there is a reasonable expectation that the HHA can meet the referred patient's needs.

Concurrently, CMS proposes 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 requests 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 requests comment regarding other ways to improve the referral process for referral sources, patients, and HHAs.

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.³⁴

³⁴ 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 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 seeks 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 seeks 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 seeks 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. CMS desires to understand how the services offered and business operations of an HHA may influence the development and implementation of care plans. The agency also asks for additional information on how HHAs communicate with patients' ordering physicians and allowed practitioners regarding the frequency and duration of services.

CMS also solicits 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. Specifically:

• What factors influence an HHA's decision on what services to offer as part of its business model and how often do HHAs change the service mix?

- What are the common reasons for an HHA to not accept a referral?
- How do physicians and allowed practitioners use their role in establishing and reviewing the plan of care to ensure patients are receiving the right mix, duration, and frequency of services to meet the measurable outcomes and goals identified by the HHA and the patient?
- To what extent do physicians rely on HHA clinician evaluations and reports in establishing the mix of services, service frequency, and service duration included in the plan of care?
- What are the patient and caregiver experiences in receiving nursing, aide, and therapy services when under the care of a home health agency?
- What additional evidence is available regarding negative outcomes or adverse events that may be attributable to the mix, duration, and service frequency provided by HHAs, including, but not limited to, avoidable hospitalizations?
- In what ways can referring providers and HHAs improve the referral process?
- What other factors may influence the provision of services that impact the timeliness of services and service initiation?
- What additional areas should CMS consider to address HHA patient health and safety concerns?

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.³⁵ Given the ongoing risk of LTC facilities' residents contracting COVID-19 or other respiratory diseases, in this proposed rule CMS proposes 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 builds on prior, temporary requirements for LTC facilities to report similar data since the onset of the COVID-19 PHE,³⁶ which were subsequently finalized in the CY 2022 Home Health PPS final rule.³⁷

³⁵ Sections 1819(d)(3) and 1919(d)(3) of the Social Security Act.

³⁶ *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).

³⁷ "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).

CMS asserts 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. Further, the benefits of these data stem from data collected at the facility, local, regional, state, and federal level, and reported through the CDC's National Healthcare Safety Network (NHSN).

Given the value of respiratory illness and vaccination reporting during the COVID-19 PHE in supporting resident health and safety, CMS is considering in this 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 respiratory illnesses as a means of guiding infection control interventions to keep LTC residents safe. Thus, the agency proposes to continue some of the reporting requirements it finalized in November 2021 that are set to expire in December 2024.

CMS proposes 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 proposes 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 proposes to continue weekly reporting through the CDC's NHSN. The data elements for which reporting would be required include all of the following:

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

CMS asserts that these proposals are scaled back and tailored from the current post-COVID-19 PHE requirements, but which would still continue the collection of the minimal necessary data to maintain a level of situational awareness that would protect resident health and safety in LTC facilities while reducing reporting burden on those facilities.

In soliciting comments on this proposal, CMS is particularly interested in comments that address 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 proposes that in the absence of a national PHE, LTC facilities would report the data elements specified above 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 proposes that additional data reporting would be required. Specifically, CMS proposes that during a declared national, state, or local PHE for a respiratory infectious disease (or if the Secretary determines a significant threat for one exists) the Secretary may require facilities to report:

- Data up to a daily frequency without additional notice and comment rulemaking.
- Additional or modified data elements relevant to the PHE, including relevant confirmed infections among staff, supply inventory shortages, staffing shortages, and relevant medical countermeasures and therapeutic inventories, usage, or both.
- If the Secretary determines that an event is significantly likely to become a PHE for an infectious disease, the Secretary may require LTC facilities to report additional or modified data elements without notice and comment rulemaking.

CMS provides estimates of the total annual burden of daily and weekly reporting of information addressing respiratory illnesses. Based on the assumption of a weekly reporting frequency and 1 hour of the infection preventionist's time to locate and electronically report the information, CMS estimates that total annual burden for all LTC facilities to comply would be a total cost of \$70.6 million or \$4,732 per facility annually (14,926 facilities). CMS estimates the cost of daily reporting frequency at \$495.8 million or \$33,215 per facility annually.

CMS solicits comments on if, during a PHE, there should be limits to the data the Secretary can require without notice and comment rulemaking, such as limits on the duration of additional reporting or the scope of the jurisdiction of reporting. CMS also asks for comments on whether and how the Secretary should still seek stakeholder feedback on additional elements during a PHE without notice and comment rulemaking and how HHS should notify LTC facilities of new required infectious disease data. CMS solicits 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 asks for comments on the utility and burden of specifically staffing and supply shortage data it proposes to collect during national, state, or local PHE (or imminent threat of such a PHE) for a respiratory infectious disease.

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 CY 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 this proposed rule, CMS discusses 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.³⁸ CMS proposes 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). CMS is here addressing this issue via rulemaking in proposed §424.527(a)(4). However, CMS strongly notes that it retains the authority under section 1866(j)(3)(B) of the Act to establish and implement PPEO procedures via sub-regulatory guidance.

VIII. Regulatory Impact Analysis

CMS estimates that the net impact of the HH PPS policies in this proposed rule is a decrease of 1.7 percent, or \$280 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 Proposed HH PPS Changes							
Dalian	2025 impact						
Policy	Percentage	Dollars					
HH PPS update	+ 2.5%	+\$415 million					
Permanent behavioral adjustment	-3.6%	-\$595 million					
Updated FDL	-0.6%	-\$100 million					
Net impact	-1.7%	-\$280 million					

Table 48, reproduced below from the proposed 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

³⁸ 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.

update, the 2025 update percentage, and the FDL update. The permanent behavior adjustment impact reflected in column 3 does not equal the proposed -4.067 percent permanent adjustment. CMS explains that the -3.6 percent reflected in column 3 includes all payments, while the proposed -4.067 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 decrease of payments of 1.5 percent. Voluntary/Non-profit HHAs would experience a 2.3 percent decrease.

CMS examined alternatives to the proposed -4.067 percent permanent payment adjustment, including halving the proposed adjustment (similar to its approach in 2024), a phase-in approach (spreading out over several years) or delaying the permanent adjustment to a future year. It believes, however, that a reduction, a phase-in approach, or delay in the permanent adjustment would not be appropriate as this would likely lead to the need for 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.

	Number of Agencies	Permanent Adjustment	CY 2025 Case- Mix Weights Recalibr ation	CY 2025 Updated Wage Index (with 5% cap and OMB Delineation)	On Factors Update	CY 2025 Proposed HH Payment Update %	Fixed- Dollar Loss (FDL)	Total
All Agencies	9,565	-3.6%	0.0%	0.0%	0.0%	2.5%	-0.6%	-1.7%
Facility Type and Control								
Free-Standing/Other Vol/NP	865	-3.5%	0.0%	-0.5%	0.0%	2.5%	-0.7%	-2.2%
Free-Standing/Other Proprietary	7,029	-3.7%	0.0%	0.2%	0.0%	2.5%	-0.5%	-1.5%
Free-Standing/Other Government	149	-3.6%	0.0%	0.3%	0.0%	2.5%	-0.7%	-1.5%
Facility-Based Vol/NP	429	-3.4%	0.0%	-0.4%	0.0%	2.5%	-0.9%	-2.2%
Facility-Based Proprietary	44	-3.6%	0.2%	0.6%	0.0%	2.5%	-0.5%	-0.8%
Facility-Based Government	137	-3.5%	0.0%	0.3%	0.0%	2.5%	-0.7%	-1.4%
Subtotal: Freestanding	8,043	-3.6%	0.0%	0.1%	0.0%	2.5%	-0.6%	-1.6%
Subtotal: Facility-based	610	-3.4%	0.0%	-0.2%	0.0%	2.5%	-0.8%	-1.9%
Subtotal: Vol/NP	1,294	-3.5%	0.0%	-0.5%	0.0%	2.5%	-0.8%	-2.3%
Subtotal: Proprietary	7,073	-3.7%	0.0%	0.2%	0.0%	2.5%	-0.5%	-1.5%
Subtotal: Government	286	-3.5%	0.0%	0.3%	0.0%	2.5%	-0.7%	-1.4%
Facility Type and Control: Rural								
Free-Standing/Other Vol/NP	205	-3.5%	0.1%	0.7%	0.0%	2.5%	-0.7%	-0.9%
Free-Standing/Other Proprietary	731	-3.7%	0.2%	1.5%	0.0%	2.5%	-0.4%	0.1%
Free-Standing/Other Government	101	-3.5%	0.2%	0.9%	0.0%	2.5%	-0.8%	-0.7%
Facility-Based Vol/NP	187	-3.4%	0.1%	0.8%	0.0%	2.5%	-0.9%	-0.9%
Facility-Based Proprietary	14	-3.8%	0.5%	-0.6%	0.0%	2.5%	-0.4%	-1.8%
Facility-Based Government	100	-3.5%	0.1%	0.4%	0.0%	2.5%	-0.9%	-1.4%
Facility Type and Control: Urban								

Table 48: Estimated HHA Impacts by Facility Type and Area of the Country, CY 2025

	Number of Agencies	Permanent Adjustment	CY 2025 Case- Mix Weights Recalibr ation	Updated Wage Index (with 5%	On Factors Update	ĤН	Fixed- Dollar Loss (FDL)	Total
Free-Standing/Other Vol/NP	660	-3.5%	0.0%	-0.7%	0.0%	2.5%	-0.7%	-2.4%
Free-Standing/Other Proprietary	6,290	-3.7%	0.0%	0.1%	0.0%	2.5%	-0.5%	-1.6%
Free-Standing/Other Government	48	-3.6%	-0.1%	-0.1%	0.0%	2.5%	-0.6%	-1.9%
Facility-Based Vol/NP	242	-3.4%	-0.1%	-0.6%	0.0%	2.5%	-0.9%	-2.5%
Facility-Based Proprietary	30	-3.6%	0.1%	0.9%	0.0%	2.5%	-0.6%	-0.7%
Facility-Based Government	37	-3.5%	-0.1%	0.2%	0.0%	2.5%	-0.7%	-1.6%
Facility Location: Urban or Rural								
Rural	1,338	-3.7%	0.2%	1.2%	0.0%	2.5%	-0.5%	-0.3%
Urban	7,307	-3.6%	0.0%	-0.1%	0.0%	2.5%	-0.6%	-1.8%
Facility Location: Region of the Country (Census Region)								
New England	298	-3.5%	-0.1%	-1.4%	0.0%	2.5%	-0.7%	-3.2%
Mid Atlantic	376	-3.6%	-0.1%	-1.2%	0.0%	2.5%	-0.6%	-3.0%
East North Central	1,418	-3.6%	0.0%	0.0%	0.0%	2.5%	-0.6%	-1.7%
West North Central	567	-3.5%	0.0%	0.9%	0.0%	2.5%	-0.8%	-0.9%
South Atlantic	1,546	-3.6%	0.0%	1.0%	0.0%	2.5%	-0.5%	-0.6%
East South Central	357	-3.7%	0.2%	2.2%	0.0%	2.5%	-0.4%	0.8%
West South Central	1,985	-3.7%	0.1%	1.3%	0.0%	2.5%	-0.6%	-0.4%
Mountain	702	-3.6%	-0.1%	1.3%	0.0%	2.5%	-0.7%	-0.6%
Pacific	2,273	-3.6%	0.0%	-1.9%	0.0%	2.5%	-0.6%	-3.6%
Outlying	43	-3.7%	0.5%	-1.2%	0.0%	2.5%	-0.5%	-2.4%
Facility Size (Number of 30- day Periods)								
< 100 periods	2,177	-3.6%	0.1%	0.1%	0.0%	2.5%	-0.7%	-1.6%
100 to 249	1,520	-3.6%	0.0%	-0.2%	0.0%	2.5%	-0.7%	-2.0%
250 to 499	1,693	-3.6%	0.0%	-0.1%	0.0%	2.5%	-0.6%	-1.8%
500 to 999	1,891	-3.6%	0.0%	0.0%	0.0%	2.5%	-0.6%	-1.7%
1,000 or More	2,284	-3.6%	0.0%	0.0%	0.0%	2.5%	-0.6%	-1.7%

Source: CY 2023 Medicare claims data for periods with matched OASIS records ending in CY 2023 (as of March 19, 2024).

Notes: The estimated 3.6 percent decrease related to the proposed permanent adjustment includes all payments, while the proposed -4.067 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 "Proposed Wage Index" column reflects updated hospital wage index data (reflecting 2021 cost report data) with the revised OMB delineations from OMB Bulletin No. 23-01 and a 5-percent cap on wage index decreases. The "Proposed LUPA Add-On Factors Update" column has an impact range of -0.01 percent to -0.035 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 to 0.38, from 0.27. 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 9,565): totals involving facility type or control only add up to 8,653 and totals involving urban/rural locations only add up to 8,645.