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Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-term Care Hospital Quality Reporting Program Requirements Summary of Proposed Rule

(CMS-1747-P)

On June 28, 2021, the Centers for Medicare & Medicaid Services (CMS) put on public display a proposed rule that would expand nationwide the Home Health Value-Based Purchasing (HHVBP) Model, address routine updates to the Home Health Prospective Payment System (HH PPS) rates and the home infusion therapy services payment rates for calendar year 2022,[1] among other proposals. The proposed rule would provide for a 1.7 percent update to the HH PPS rates. Among other provisions, CMS proposes to make permanent selected regulatory blanket waivers related to home health aide supervision and the use of telecommunication that were issued to Medicare participating home health agencies during the COVID-19 public health emergency (PHE). In addition, this proposed rule codifies survey and enforcement requirements for hospice programs that were required to implement provisions of the Consolidated Appropriations Act (CAA) of 2021. **The deadline for public comment is August 27, 2021.**

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

I. Payment Under the Home Health Prospective Payment System

A. Overview

CMS reviews the statutory and regulatory history of the HH PPS from 1997. Most recently, beginning on or after January 1, 2020, Medicare makes payment under the HH PPS based on a national, standardized 30-day period payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 30-day period rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS), previously paid through a separate adjustment, 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 Patient Driven Groupings Model (PDGM), also implemented beginning January 1, 2020, 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, and level of functional impairment to case-mix adjust payments resulting in 432 unique case-mix groups. Patient characteristics and other clinical information is drawn from Medicare claims and the Outcome and Assessment Information Set (OASIS). In the proposed rule, CMS details how timing, admission source, clinical grouping, functional impairment level, and comorbid conditions are used to establish the PDGM case-mix weights.

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.

For 2020 through 2022, payment for home health services provided to beneficiaries residing in rural counties will be increased based on rural county classification (high utilization; low population density; or all other categories (section 50208 of the Bipartisan Budget Act (BBA) of 2018).

B. Proposing Provisions for Payment Under the HH PPS

1. Monitoring the Effects of the Implementation of PDGM

The PDGM made several changes to the HH PPS, including replacing 60-day episodes of care with 30-day periods of care, removing therapy volume for directly determining payment and developing 432 case-mix adjusted payment groups in place of 153 groups. In the CY 2020 HH PPS final rule[2], CMS stated it would continue to monitor how the PDGM, including the variables that determine the case-mix weights, affect the provision of home health care and would implement any future refinements, if needed.

CMS believes that stakeholders want information about how home health utilization patterns may have changed under the PDGM. CMS notes that adjusting to the new payment system takes time and that any emergent trends from implementation of the PDGM may be impacted by the COVID-19 PHE. Preliminary utilization patterns are discussed below.

a. Claims Data Overview used in PDGM Monitoring

CMS discusses the analysis it performed for monitoring PDGM implementation. CMS used 2018 home health data to divide 60-day episodes of care into two simulated 30-day periods of care that were used to set payment rates in the 2020 HH PPS final rule.[3] CMS also used 2019 home health data (used for routine rate setting updates for 2021) to divide 60-day episodes of care into two simulated 30-day periods of care. The simulated data in these analytical files represent pre-PDGM utilization. CMS refers readers to the 2019 HH PPS proposed rule for a detailed description of how these analytical files were created.[4] CMS used 2020 claims data as of March 30, 2021, to analyze changes post-implementation of the PDGM and the 30-day unit of payment.

b. 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, but not be limited, to analyzing: overall total 30-day periods of care and average periods of care per HHA user; the distribution of visits in a

[2] 84 FR 60513
[3] 84 FR 60518
[4] 83 FR 32382 – 32388.

30-day period of care; the percentage of periods that receive a low-utilization payment adjustment (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.

CMS notes the beginning of 2020 included ongoing 60-day episodes of care that began in 2019 and ended in 2020. Depending on the length of the remainder of the episode, these 60-day episodes were simulated into one or two 30-day periods of care and are included in the analysis. Approximately 6.1 percent of the 30-day periods of care in 2020 data were simulated because the original 60-day episode of care began in 2019 and ended in 2020.

(1) Utilization. To evaluate utilization CMS compared the simulated 30-day periods in its analytical files to actual 2020 PDGM claims. CMS examined utilization for 2018 simulated 30-day periods of care, 2019 simulated 30-day periods of care, and 2020 actual 30-day periods of care.

CMS notes this preliminary data indicates the number of 30-day periods of care decreased between 2018 and 2020, while the average number of 30-day periods of care per unique HHA user is similar. In addition, on average, the total number of visits decreased by 1.27 visits per 30-day period of care between 2018 and 2020. The percentage of 30-day periods of care that are LUPAs increased from 6.7% in 2018 to 8.6% in 2020. Tables 2, 3, and 4 reproduced below, provide additional information.

Table 2: Overall Utilization of Home Health Services, CYs 2018-2020

	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020
30-Day Periods of Care	9,336,898	8,744,171	8,165,402
Unique HHA Users	2,980,385	2,802,560	2,786,662
Average Number of 30-Day Periods of Care per Unique HHA User	3.13	3.12	2.93

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH Limited Data Set (LDS) file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the Chronic Conditions Data Warehouse (CCW) Virtual Research Data Center (VRDC) on March 30, 2021.

Notes: There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in this analysis. All 30-day periods of care claims were included (e.g., LUPAs, PEPs, and outliers).

Table 3: Utilization of Visits Per 30-Day Periods of Care by Home Health Discipline, CYs 2018-2020

Discipline	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020
Skilled Nursing	4.53	4.49	4.35
Physical Therapy	3.30	3.33	2.71
Occupational Therapy	1.02	1.07	0.78
Speech Therapy	0.21	0.21	0.16
Home Health Aide	0.71	0.67	0.54
Social Worker	0.08	0.08	0.06
Total (all disciplines)	9.86	9.85	8.59

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH LDS file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the CCW VRDC on March 30, 2021.
Notes: There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in this analysis. All 30-day periods of care claims were included (e.g., LUPAs, PEPs, and outliers).

Table 4: The Proportion of 30-Day Periods of Care That Are LUPAs and The Average Number of LUPAs and the Average Number of Visits by Home Health Discipline for LUPA Home Health Periods, CYs 2018-2020

Discipline	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020
Total percentage of overall 30-day periods of care that are LUPAs	6.7%	6.8%	8.6%
Discipline (Average # of visits for LUPA home health periods			
Skilled Nursing	1.15	1.14	1.19
Physical Therapy	0.43	0.46	0.53
Occupational Therapy	0.07	0.07	0.08
Speech Therapy	0.02	0.02	0.02
Home Health Aide	0.01	0.01	0.01
Social Worker	0.01	0.01	0.01
Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH LDS file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the CCW VRDC on March 30, 2021.			
Notes: The average (CY 2018 to CY 2020) number of visits per 30-day periods of care across all claims for skilled nursing is 4.46, for PT is 3.13, for OT is 0.97, for SLP is 0.19, for aide is 0.65, and for social worker is 0.07. There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in this analysis. All 30-day periods of care claims were included (e.g., LUPAs, PEPs, and outliers).			

(2) Analysis of 2019 Cost Report Data for 30-Day Periods of Care. CMS examined 2019 HHA Medicare cost reports (the most recent and complete cost report data available) and 2020 30-day period of care home health claims, to estimate 30-day period of care costs. CMS excluded LUPAs and PEPs in the average number of visits. Table 5, reproduced below, shows the estimated average costs for 30-day periods of care by discipline with non-routine supplies (NRS) and the total 30-day period of care costs with NRS for 2020.

Table 5: Estimated Costs for 30-Day Periods of Care in CY 2020

Discipline	2019 Average Costs Per Visit with NRS	2020 Average Number of Visits	2020 Market Basket Update	2020 Estimated 30-Day Period Costs
Skilled Nursing	$142.75	4.66	1.026	$682.51
Physical Therapy	$160.85	2.92	1.026	$481.89
Occupational Therapy	$160.14	0.85	1.026	$139.66
Speech Therapy	$181.27	0.17	1.026	$31.62
Home Health Aide	$238.66	0.06	1.026	$14.69
Social Worker	$72.20	0.59	1.026	$44.31
Total (all disciplines)				$1,394.68
Source: 2019 Medicare cost report data obtained on January 26, 2021. Home health visit information came from episodes ending or on before December 31, 2019 (obtained from the CCW VRDC on July 13, 2020).				
Note: The 2020 average number of visits excludes LUPAs and PEPs				

CMS notes the 2020 national, standardized 30-day period payment was $1,864.03, which is approximately 34 percent more than the estimated 2020 30-day period cost of $1,394.68. In addition, using the actual 2020 claims data, the average number of visits in a 30-day period was 9.25 visits – a decrease of approximately 10.5 from the estimated number of visits for a 30-day period of care in 2017. CMS acknowledges that with the PHE, the 2019 data on the Medicare cost reports may not reflect the associated changes such as increased telecommunications technology costs and personal protective equipment costs. CMS will update the estimated 30-day period of care costs in 2020 in future rulemaking.

(3) 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. Table 6, reproduced below, shows the distribution of the 12 clinical groups over time. The average case-mix weight for each clinical group includes all possible comorbidity adjustments, admission source and timing, and functional impairment levels.

Table 6: Distribution of 30-Day Periods of Care by the 12 PDGM Clinical Groups, CYs 2018-2020

Clinical Grouping	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	Average Case-mix Weight for Each Group
Behavioral Health	1.7%	1.5%	2.3%	0.8243
Complex	2.6	2.5	3.5	0.8574
MMTA - Cardiac	16.5	16.1	19.0	0.9202
MMTA - Endocrine	17.3	17.4	7.2	1.0161
MMTA – GI/GU	2.2	2.3	4.7	0.9793
MMTA - Infectious	2.9	2.7	4.8	0.9805
MMTA - Other	4.7	4.7	3.1	0.9711
MMTA - Respiratory	4.3	4.1	7.8	0.9906
MMTA – Surgical Aftercare	1.8	1.8	3.5	1.0701
MS Rehab	17.2	17.3	19.4	1.1174
Neuro	14.4	14.5	10.5	1.1603
Wound	14.5	15.1	14.2	1.1923

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH LDS file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the CCW VRDC on March 30, 2021.

Note: The average case mix weight for each clinical group includes all 30-day periods regardless of other adjustments (for example admission source, timing, comorbidities, etc.)

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. Table 7, reproduced below, shows the distribution of 30-day periods of care by comorbidity adjustment category. The average case-mix weight for each comorbidity adjustment includes all possible clinical groupings, admission source and timing, and functional impairment levels.

Table 7: Distribution of 30-Day Periods of Care by Comorbidity Adjustment Category for 30-Day Periods, CYs 2018-2020				
Comorbidity Adjustment	**CY 2018 (Simulated)**	**CY 2019 (Simulated)**	**CY 2020**	**Average Case-mix Weight for Each Group**
None	55.6%	52.0%	49.2%	1.0058
Low	35.3	38.0	36.9	1.0446
High	9.2	10.0	114.0	1.1683
Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH LDS file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the CCW VRDC on March 30, 2021.				
Note: The average case mix weight for each clinical group includes all 30-day periods regardless of other adjustments (for example admission source, timing, comorbidities, etc.)				

(4) Admission Source and Timing. Each 30-day period of care is classified into one of two admission source categories depending on what healthcare setting was utilized in the 14 days prior to receiving home health care. 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. Table 8, reproduced below shows the distribution of 30-day periods of care by admission source and timing over time. The average case-mix weight for each admission source and period timing includes all possible clinical groupings, comorbidity adjustment, and functional impairments.

Table 8: Distribution of 30-Day Periods of Care by Admission Source and Period Timing. CYs 2018-2020					
Admission Source	**Period Timing**	**CY 2018 (Simulated)**	**CY 2019 (Simulated)**	**CY 2020**	**Average Case-mix Weight for Each Group**
Community	Early	13.5%	13.8%	12.5%	1.2584
Community	Late	61.1	60.9	61.9	0.8504
Institutional	Early	18.6	18.4	19.9	1.4234
Institutional	Late	6.8	5.8	5.8	1.3303
Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH LDS file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the CCW VRDC on March 30, 2021.					

(5) 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. 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. The average case-mix weight for each functional impairment level includes all possible clinical groupings, comorbidity adjustments, admission source, and period timing.

Table 9: Distribution of 30-Day Periods of Care by Functional Impairment Level, CYs 2018-2020				
Functional Impairment Level	**CY 2018 (Simulated)**	**CY 2019 (Simulated)**	**CY 2020**	**Average Case-mix Weight for Each Group**
Low	33.9%	31.9%	25.6%	0.8392
Medium	34.9	35.5	32.7	1.0373
High	31.2	31.6	41.7	1.1724
Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH LDS file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the CCW VRDC on March 30, 2021.				

The functional impairment level is currently determined by responses to OASIS items M1800-M1860 and M1032. Section 1899B(b)(1)(A) of the Act requires the Secretary to require HHAs to report standardized patient assessment data beginning no later than January 1, 2019. The standardized patient assessment data categories include functional status; CMS finalized adding the functional items, Section GG, "Functional Abilities and Goals" to the OASIS data set, effective January 1, 2019. Although CMS does not yet have the data to determine the effect of these newly added items on resource cost utilization during a home health period of care, it examined the correlation between the current functional items used for payment and the analogous GG items (see Figure 2 in the proposed rule). CMS' preliminary analysis shows there is a correlation between the current responses to the M1800-1860 items and the GG items. CMS will continue to monitor the GG items to determine the correlation between the current functional items used to case-mix home health payments and the GG items.

(6) Therapy Visits. Beginning in CY 2020, section 1895(b)(4)(B)(ii) of the Act eliminated the use of therapy thresholds in calculating payments for 2020 and subsequent years. CMS examined the proportion of simulated 30-day periods with and without any therapy visits for 2018 and 2019, prior to the removal of therapy thresholds. CMS also examined the proportion of actual 30-day periods of care with and without therapy visits for 2020, after the removal of therapy thresholds. 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 (see Figure 3 in the proposed rule). CMS' preliminary analysis shows there have been changes in the distribution of both therapy and non-therapy visits in 2020.

Table 10: Proportion of 30-Day Periods of Care with Only Therapy, At Least One Therapy Visits, and No Therapy Visits for CYs 2018-2020			
30-Day Period Visit Type	**CY 2018 (Simulated)**	**CY 2019 (Simulated)**	**CY 2020**
Therapy Only	13.5%	14.4%	15.2%
Therapy + Non-therapy	48.2%	48.4%	42.2%
No Therapy	38.3%	37.2%	42.6%
Total 30-Day Periods	9,336,898	8,744,171	8,165,402
Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH LDS file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the CCW VRDC on March 30, 2021.			

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, 2019, and 2020 (see Tables 11 and 12, reproduced below).

Table 11: Proportion of 30-Day Periods of Care with Only Skilled Nursing, Skilled Nursing + Other Visit Type, and No Skilled Nursing Visits for CYs 2018-2020			
30-Day Period Visit Type	**CY 2018 (Simulated)**	**CY 2019 (Simulated)**	**CY 2020**
Skilled Nursing Only	33.8%	33.1%	38.6%
Skilled Nursing + Other	51.6%	51.5%	45.2%
No Skilled Nursing	14.7%	15.5%	16.2%
Total 30-Day Periods	9,336,898	8,744,171	8,165,402
Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH LDS file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the CCW VRDC on March 30, 2021.			

Table 12: Proportion of 30-Day Periods of Care with and without Home Health Aide and/or Social Worker Visits for CYs 2018-2020			
30-Day Period Visit Type	**CY 2018 (Simulated)**	**CY 2019 (Simulated)**	**CY 2020**
Any HH Aide and/or social worker	16.6%	15.9%	13.1%
No HH aide and/or social worker	83.4%	51.5%	86.9%
Total 30-Day Periods	9,336,898	8,744,171	8,165,402
Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data comes from the HH LDS file. CMS applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was assessed from the CCW VRDC on March 30, 2021.			

CMS 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 may be needed in the future. **CMS invites comments on this preliminary data and whether there are other analyses that should be conducted to examine the effect of the PDGM on home health expenditures and utilization.**

2. Comment Solicitation on the Annual Determination of the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Payment Expenditures under the HH PPS

a. Background

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

Section 1895(b)(3)(A)(iv) of the Act requires CMS to make a prospective adjustment for 2020 to maintain budget neutrality while section 1895(b)(3)(D)(i) of the Act requires CMS to revisit the adjustment retrospectively for each year beginning with 2020 and ending with 2026. If CMS'

retrospective review reveals that behavioral changes were different than assumed in the prospective adjustment, CMS is required to make both permanent and temporary adjustments to the home health rate to ensure aggregate spending neither increased or decreased as a result of the new unit of payment and elimination of therapy thresholds. The temporary adjustment is made to either recoup or repay past over or underspending while the permanent adjustment ensures that future spending neither increased nor decreased relative to continuing the prior policies.

CMS applied a prospective budget neutrality adjustment including its behavior assumption of -4.36 percent when setting the 2020 30-day payment rate of $1,864.03.

b. Methodology and Estimate of Additional Adjustment

The proposed rule provides a detailed explanation of CMS' methodology and assumptions to determine whether further budget neutrality adjustments are needed for the change to a 30-day unit of payment. In summary, CMS simulated home health payments for a 60-day episode of care with 153 payment groups and compared it to actual payments using a 30-day episode of care with 432 payment groups using actual 2020 data as of March 30, 2021—the most recent, complete data available. Actual rates from 2020 were used to make the comparison. The proposed rule details the exclusions and assumptions that CMS needed to make to undertake this analysis. After all exclusions and assumptions were applied, the final dataset included 7,441,602 actual 30-day periods of care and 4,378,823 simulated 60-day episodes of care for 2020.

CMS determined the 2020 30-day base payment rate was approximately 6 percent higher than it should have been to maintain budget neutrality. Temporary retrospective adjustments for 2020 and subsequent years will be necessary until a permanent prospective adjustment can be implemented in future rulemaking. A change in case-mix between the two systems is driving the increase in payment. The average case-mix weight for the 30-day periods of care used to construct the simulated 60-day of care episodes was 1.0310; compared to the average case-mix weight for the simulated 60-day of care episodes was 0.9657, a difference of 0.0653.

The law provides CMS with flexibility for when and how to make prospective adjustments based on retrospective behavior. CMS anticipates further change to its analysis as more claims become available from 2020 and subsequent years. It is also further considering that the COVID-19 PHE is still ongoing. For these reasons, it intends to propose a methodology and, if appropriate, a temporary and permanent payment adjustment in future rulemaking. However, by not proposing any adjustment for 2022, future adjustments could be larger.

The proposed rule indicates that there may other ways to analyze the data to determine the difference between assumed versus actual behavior change such as analysis of nominal case-mix growth or calculating the percent difference and percent change of payments between simulated 30-day periods of care and actual 30-day periods of care. **CMS solicits comments on its methodology and alternative approaches to determining how behavior changes affect Medicare spending for home health services.**

3. 2020 PDGM Low-Utilization Payment Adjustment (LUPA) Thresholds and PDGM Case-Mix Weights

a. 2022 PDGM LUPA Thresholds.

Low utilization payment adjustments (LUPAs) are paid when a certain visit threshold for a payment group during a 30-day period of care is not met.[5] LUPA thresholds are set at the 10th percentile value of visits or 2 visits, whichever is higher for each payment group. That is, the LUPA threshold for each 30-day period of care varies based on the PDGM payment group to which it is assigned. If the LUPA threshold is met, the 30-day period of care is paid the full 30-day period payment. If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment is made using the per-visit payment amount.

CMS adopted a policy that the LUPA thresholds would be updated each year based on the most current utilization data available. However, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID-19 PHE, CMS proposes to maintain the thresholds adopted for 2020, as shown in Table 16 of the HH PPS final rule for 2020 (84 FR 60522). Those thresholds were based on 2018 Medicare home health claims as of July 31, 2019, linked to OASIS assessment data. CMS believes this is the best approach because it mitigates any potential fluctuations in the thresholds caused by changes due to the PHE. It will repost these thresholds on its HHA center webpage.[6]

b. 2022 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 2022, CMS proposes to use the 2020 claims data to update the functional points and functional impairment levels by clinical group and the same methodology previously finalized to update the functional impairment levels for CY 2022. The updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2022 are listed in Tables 13 and 14, respectively. **CMS solicits public comments on the updates to functional points and the functional impairment levels by clinical group.**

c. 2022 Comorbidity Groups

Thirty-day periods of care receive a comorbidity adjustment based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home

[5] The thresholds previously in place for 60-day episodes of care resulted in LUPAs accounting for about 7 to 8 percent of episodes, and CMS set 30-day thresholds to achieve about the same percentage of LUPA episodes under the PDGM.

[6] https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center

health list of clinically and statistically significant secondary diagnosis subgroups with similar resource use. A comorbidity adjustment is applied to the 30-day period of care when there is the following: (1) low comorbidity adjustment – a reported secondary diagnoses on the health-specific comorbidity subgroup list that is associated with higher resource use; or a (2) high comorbidity adjustment – two or more secondary diagnoses on the home health-specific comorbidity subgroup list.

For 2022, CMS proposes to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using 2020 home health data. Using these data, CMS propose to update the comorbidity subgroups to include 20 low comorbidity adjustment subgroups and 85 high comorbidity adjustment interaction subgroups as identified in Tables 15 and 16 in the proposed rule. **CMS invites comment on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment interactions for 2022.**

d. 2022 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 and complete utilization data available at the time of annual rulemaking. For 2022, CMS proposes to generate the recalibrated case-mix weights using 2020 home health claims data with linked OASIS assessment data (as of March 2021). CMS believes that recalibrating the case-mix weights using actual 30-day periods under the PDGM rather than using simulated claims data of 60-day episodes grouped under the old system is preferrable.

Table 17 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 2022 case-mix weights are provided in Table 18 in the proposed rule and will also be posted on its HHA Center webpage.

4. Proposed 2022 Home Health Payment Rate Updates

a. CY 2022 Home Health Market Basket Update for HHAs

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 2021 forecast for 2022 with historical data through fourth-quarter 2020, the proposed HH PPS market basket update is as follows:

Market Basket Update	**Change (in %)**
Market basket forecast	2.4
Multifactor productivity	-0.6
Net update for HHAs reporting quality data	**1.8**
Net update for HHAs NOT reporting quality data	**-0.2**

More recent forecasts for 2022 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.

b. CY 2022 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 2022, using FY 2018 hospital cost report data as its source for the updated wage data. Consistent with its longstanding policy of adopting OMB delineation updates, CMS proposes to adopt the updates set forth in OMB Bulletin No. 20-01, though it notes that specific wage index updates would not be necessary for 2022 as a result of adopting these OMB updates.[7]

The proposed wage 2022 wage index is available on the CMS website at: https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.

c. CY 2022 Annual Payment Update

(1) Background. CMS discusses the methodology it uses to compute the case-mix and wage-adjusted 30-day period rates as set forth in §484.215. 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 (76.1 percent) and non-labor (23.9 percent) portions. The labor portion is multiplied by the appropriate wage index based on the site of service and summed to the non-labor portion.

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, for 2022 CMS is not proposing to make any additional changes to the 30-day payment rate other than the routine updates described further below.

(2) 2022 National, Standardized 30-Day Period Payment Amount. To determine the 2022 national, standardized 30-day period payment rate, CMS proposes to apply a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor and the home health payment update percentage. To account for changes between the previous year's PDGM case-mix weights and the recalibrated weights, CMS proposes to apply a case-mix weights budget

[7] OMB Bulletin No. 20-01 made minor updates including one new Micropolitan Statistical Area and changes to New England City and Town Area (NECTA) delineations.

neutrality factor for 2022 of 1.0344. CMS notes that for the wage index budget neutrality factor, it explored whether it should utilize 2019 data instead of 2020 data for its calculation because of the potential impact of the COVID-19 PHE. Its analysis, however, showed small differences and thus CMS decided to continue to use the most recent data available for this calculation – 2020 claims data for the 2022 payment rate updates.

The following table shows the proposed standardized amounts, as displayed in Tables 19 and 20.

Proposed 2022 National, Standardized 30-Day Episode Payment Amount, for HHAs Submitting and Not Submitting Quality Data		
	HHAs submitting quality data	HHAs not submitting quality data
2021 30-day budget neutral standardized amount	$1,901.12	
Case-mix weights recalibration neutrality factor	x 1.0390	
Wage index budget neutrality factor	x 1.0013	
HH payment update percentage	x 1.018	x 0.998
2022 30-day payment amount	**$2,013.43**	**$1,973.88**

(3) 2022 National Per-Visit Rates for 30-Day Periods of Care. Computations are presented for the 2022 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 21 in the proposed rule) are as follows:

Proposed 2022 National, Per-Visit Payment Amounts for HHAs that Submit Quality Data				
HH Discipline	**CY 2021 Per-Visit Rates**	**Wage Index Budget Neutrality Factor**	**CY 2022 HH Payment Update**	**CY 2022 Per-Visit Payment**
Home Health Aide	$69.11	X 1.0014	X 1.018	$70.45
Medical Social Services	$244.64	X 1.0014	X 1.018	$249.39
Occupational Therapy	$167.98	X 1.0014	X 1.018	$171.24
Physical Therapy	$166.83	X 1.0014	X 1.018	$170.07
Skilled Nursing	$152.63	X 1.0014	X 1.018	$155.59
Speech-Language Pathology	$181.34	X 1.0014	X 1.018	$184.86

HHAs that do not submit required quality data would have the payment update for per-visit services reduced from 1.8 percent to -0.2 percent, resulting in the following payment rates (Table 22 in the proposed rule):

Proposed 2022 National, Per-Visit Amounts for HHAs that Do Not Submit Quality Data				
HH Discipline	**CY 2021 Per-Visit Rates**	**Wage Index Budget Neutrality Factor**	**CY 2022 HH Payment Update Minus 2 Percentage Points**	**CY 2022 Per-Visit Rates**
Home Health Aide	$69.11	X 1.0014	X 0.998	$69.07
Medical Social Services	$244.64	X 1.0014	X 0.998	$244.49
Occupational Therapy	$167.98	X 1.0014	X 0.998	$167.88
Physical Therapy	$166.83	X 1.0014	X 0.998	$166.73
Skilled Nursing	$152.63	X 1.0014	X 0.998	$152.54
Speech- Language Pathology	$181.34	X 1.0014	X 0.998	$181.23

CMS reminds stakeholders that as adopted in the 2020 HH PPS final rule (84 FR 60544), for 2021 all HHAs (both existing and newly-enrolled HHAs) must submit a "no-pay" Request for Anticipated Payment (RAP) at the beginning of each 30-day period. This will establish the home health period of care in the common working file and also trigger the consolidated billing edits. A payment reduction is applied if the HHA does not submit the RAP within 5 calendar days from the start of care. The reduction equals one-thirtieth of the wage and case-mix adjusted 30-day period payment amount, including any outlier payment, for each day from the home health start of care date until the date the HHA submitted the RAP. For LUPA 30-day periods for which an HHA fails to submit a timely RAP, no LUPA payments will be made for days that fall within the period from the start of care prior to submission of the RAP. These days would be a provider liability; the payment reduction cannot exceed the total payment of the claim; and the provider may not bill the beneficiary for these days. Beginning in 2022, HHAs will submit a one-time Notice of Admission (NOA) that includes similar information to the 2021 RAP. The NOA will establish the home health period of care and covers all contiguous periods of care until the patient is discharged from Medicare home health services. Similar penalties for failure to timely submit the NOA will apply. There are certain exceptions to the timely filing consequences of the RAP requirements, which include fires, floods, earthquakes, and other damaging events; issues with CMS or Medicare contractor systems; and other situations CMS determines to be out of the HHA's control.

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

CMS proposes proposing conforming changes to regulations at §§ 484.55(a)(2) and 484.55(b)(3) to implement requirements of CAA 2021. These revisions will 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 proposes to establish a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled OT visit in LUPA periods that occurs as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods

of care. Because CMS does not have sufficient data to estimate a OT specific LUPA add-on factor, CMS proposes to utilize the PT LUPA add-on factor of 1.6700 as a proxy until it has CY 2022 data. **CMS invites comments on this proposal.**

d. Rural Add-On Payments for 2022.

Section 50208(a)(1)(D) of the BBA of 2018 provides rural add-on payments for episodes and visits ending during 2019 through 2022. In the 2019 HH PPS final rule (83 FR 56443), CMS finalized policies for 2019 through 2022 for these rural add-on payments. The three categories for purposes of rural add-on payments are: (1) High utilization category: rural counties and equivalent areas in the highest quartile of all counties and equivalent areas based on the number of Medicare home health episodes furnished per 100 individuals; (2) Low population density category: rural counties and equivalent areas with a population density of six individuals or fewer per square mile of land area; and (3) All other category: rural counties and equivalent areas not in the above categories.[8]

The HH PRICER module within CMS' claims processing system applies the rural add-on amounts prior to applying any case-mix and wage index adjustments. Table 23 of the proposed rule lists the 2019 through 2022 rural add-on payments outlined in law.

Table 23: HH PPS Rural Add-On Percentages, 2019-2022

Category	2019	2020	2021	2022
High utilization	1.5%	0.5%	None	None
Low population density	4.0%	3.0%	2.0%	1.0%
All other	3.0%	2.0%	1.0%	None

e. 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 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 2021.

[8] The data used to categorize each county or equivalent area and an Excel file containing the rural county or equivalent area name, its Federal Information Processing Standards (FIPS) state and county codes, and its designation into one of the three rural add-on categories is available on the CMS webpage for this proposed rule: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html

For 2022 payment, CMS proposes a FDL ratio of 0.41 for 2022 based on analysis of 2020 claims data (as of March 30, 2021). In the proposed rule, CMS 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 2022 in the rate update change request to be issued after the publication of the 2022 HH PPS final rule.[9]

5. Conforming Regulations Text Changes Regarding Allowed Practitioners

In the May 2020 COVID-19 interim final rule with comment period (85 FR 27550), CMS amended the regulations at parts 409, 424, and 484 to implement section 3708 of the CARES Act. This included defining a nurse practitioner, a clinical nurse specialist, and a physician's assistant. This means that in addition to a physician an allowed practitioner may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit. CMS also amended the regulations so that the allowed practitioner could also perform the face-to-face encounter for the patient for whom they are certifying eligibility. These regulations text changes are not time limited to the period of the COVID-19 PHE.

When implementing plan of care changes in the CY 2021 HH PPS final rule (85 FR 70298), CMS inadvertently deleted from the regulation text the term "allowed practitioner" at §409.43. Thus, CMS proposes conforming regulation text changes at §409.43 to reflect that allowed practitioners, in addition to physicians, may establish and periodically review the plan of care.

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

A. Proposal to Expand the HHVBP Model Nationwide

1. Background

The HHVBP Model was established in the 2016 HH PPS final rule (80 FR 68624) as a five-year test by the Center for Medicare and Medicaid Innovation (the Innovation Center) in which payments to participating HHAs are adjusted upward or downward based upon performance on a set of pre-defined quality measures.[10] The adjustment percentage increased annually over the course of the model test. Participation has been mandatory for all Medicare-certified HHAs providing services in nine randomly selected states who meet data minimums.[11]

[9] The per-unit amounts for 2021 are found in the November 13, 2020 HH PPS change request: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10464cp [10] Modifications were made to the measure set for performance years 2018 and 2019.
[11] The nine states are AZ, FL, IA, MD, MA, NE, NC, TN, and WA.

On January 8, 2021, CMS announced that the HHVBP Model had been certified for expansion through rulemaking under section 1115(a) of the Act. The certification for expansion was based upon the model's performance over its first three performance years (CY 2016-2018) and expansion was set to occur to occur no earlier than CY 2022. The model was found to improve the quality of care provided by HHAs, shown by higher performance scores in HHVBP states versus non-HHVBP states, and to reduce Medicare expenditures through decreased Emergency Department (ED), inpatient hospital, and skilled nursing facility (SNF) utilization. This HH PPS proposed rule for CY 2022 presents the agency's plan for implementing the model nationwide.

More information about the HHVBP model test is available at https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model and the most recent formal evaluation of the model (performance year 4, issued in May 2021) is available for download https://innovation.cms.gov/data-and-reports/2021/hhvbp-fourthann-rpt.

2. Overview of the Expanded HHVBP Model (§§484.34 through 484.375)

Participation in the model. The expanded model would be tested using the Innovation Center's waiver authority (section 1115A of the Act) and would undergo periodic formal evaluation of cost and quality results. Modifications of the model could be adopted through rulemaking. CMS proposes to begin the model test on January 1, 2022. All HHAs certified for Medicare participation before January 1, 2021 who receive payments from CMS for providing services in the 50 states, District of Columbia, and the territories – a total of 55 distinct model test locations – would be required to participate and would be termed "competing" HHAs. Participants would be assigned to cohorts for performance and payment adjustment purposes.

Payment Adjustments. CMS proposes to make adjustments ranging from 0 percent up to a maximum of ± 5 percent to participants' payments based on their performances relative to their peers.[12] Performance scoring for each HHA would include achievement and improvement points on specified quality measures in comparison to a baseline year, aggregated into a Total Performance Score (TPS). Like the original model, payment adjustments under the expanded model would lag performance results by 2 years. Thus, CY 2022 would be performance year 1 (PY 1) of the Expanded HHVBP model, and payment adjustments based on PY 1 results would be made during CY 2024, payment year 1, and so forth for subsequent PYs. TPSs and payment adjustments would be calculated and applied at the CMS Certification Number (CCN) level. **CMS requests comment on the proposed payment adjustment percentage.**

Baseline year. The baseline year would serve as the basis against which measure performance in a performance year (PY) would be compared and used for setting quality measure benchmarks. CMS proposes setting CY 2019 as the baseline year for HHAs certified on or before January 1, 2019. For HHAs certified thereafter, CMS proposes that the baseline year would be the first full CY beginning after the certification date and the first PY would be the first full CY following the baseline year. Out of concern for potential impacts of the COVID-19 PHE on HH quality data,

[12] CMS notes that while the original HHVBP model was certified for expansion based on results using a 3 percent payment adjustment, the Medicare Chief Actuary's certification memo indicated a belief that savings also would be achieved at higher adjustment percentages. The memo is available at https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf.

CMS proposes an exception for HHAs certified during 2019 and specifies for this group a baseline year of CY 2021 rather than CY 2020. Like the original HHVBP model, the applicable baseline year would be fixed for each HHA for all model test years unless changed through rulemaking.[13] Table 25 illustrates the proposed baseline, first PY and first payment years for participant HHAs according to their Medicare certification dates, reproduced below from the rule.

TABLE 25: Proposed HHA Baseline, Performance and Payment Year Based on Medicare Certification Date through December 31, 2021

Certification Date	Baseline (CY)	Performance (CY)	Payment (CY)
Prior to January 1, 2019	2019	2022	2024
On January 1, 2019 - December 31, 2019	2021	2022	2024
On January 1, 2020 - December 31, 2020	2021	2022	2024
On January 1, 2021 - December 31, 2021	2022	2023	2025

Baseline years would be specifically identified during rulemaking for any quality measures added to the model for PY 2 or subsequent PYs. **CMS requests comment on the proposed baseline years.**

Waivers. No waivers of Medicare or Medicaid fraud and abuse laws are being proposed at this time by the Secretary. Further, CMS has determined that the CMS-sponsored model arrangements safe harbor under the anti-kickback statute will not be available to protect remuneration under the expanded HHVBP model.

Definitions. CMS proposes definitions at §484.345 for the following terms used during quality performance scoring and payment adjustment calculations: *achievement threshold*, *applicable measure*, *applicable percent*, *baseline year*, *benchmark*, *competing HHA*, *HH PPS*, *improvement threshold*, *larger-volume cohort*, *linear exchange function*, *nationwide*, *payment adjustment*, *payment year*, *performance year*, *smaller-volume cohort*, and *total performance score (TPS*).

3. Defining Cohorts under the Expanded HHVBP Model

The original HHVBP model utilizes peer grouping (cohorts) for setting quality measure benchmarks and for making the performance comparisons that determine payment adjustments. CMS proposes to continue cohorting within the expanded model but with modifications. Under both models, it is essential for each cohort to include enough HHAs to ensure validity and reliability of performance scoring within the cohort.

a. Original model cohorts

Under the original model, cohort assignment depends in part on HHA service volume. Each HHA is assigned to a larger-volume or smaller-volume cohort based on whether it is required to report HH Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) experience

[13] For example, the baseline year would be fixed as CY 2019 for an HHA certified in December 2018 and would be fixed as CY 2021 for an HHA certified in December 2020.

of care survey measures. HHAs having fewer than 60 eligible, unique, HHCAHPS survey patients for a CY who submit their patient counts to CMS are exempted from survey measure reporting for that CY and assigned to smaller-volume cohorts. Volume-based cohorting is done at the state level, as all nine participating states have sufficient numbers and sizes of HHAs to populate both larger- and smaller-volume cohorts within each state. Analyses performed by CMS prior to beginning the original model found that a minimum of 8 HHAs in a cohort was sufficient to protect the cohort from outlier effects on payment adjustments, and this minimum was reached within all 18 cohorts of the original model (9 states x 2 cohorts per state).

b. Proposed expanded model cohorts

HHVBP model expansion to all 50 states, the District of Columbia, and the territories required CMS to reexamine its approach to cohorting, as expansion brought with it numerous small model locations and greater heterogeneity in model participants' service volumes. CMS favored an approach that allowed prospective grouping, maintained separation by service volumes, and used HHCAHPS reporting status to differentiate larger from smaller service volumes.

To guide cohort definition, CMS undertook detailed examinations of HHA size and geographic dispersion, as described in the rule's preamble.[14] Simulations using service volume and HHCAHPS status established the expanded model's minimum number of HHAs per cohort for outlier protection and buffering of HHA attrition during the model test to be 20. CMS first explored cohort assignment by expanded model location, similar to the original model's state-level assignment. Roughly 55 percent of the potential 110 cohorts (55 locations x 2 cohorts per location) failed to contain 20 or more HHAs.

CMS proposes, therefore, to create two national cohorts, one larger-volume and one smaller-volume, with assignment based on HHCAHPS survey reporting status. This approach produces a larger-volume cohort with 7,084 HHAs and a smaller-volume cohort with 485 HHAs. Comparisons within the cohorts would be likely to be internally consistent since most of the smaller-volume cohort members would not be scored on HHCAHPS measures while most larger-volume cohort members would receive HHCAHPS measure scores.

c. Alternatives considered for expanded model cohorts

First, CMS also discusses using model location-based cohorts without subdivision into larger- and smaller-volume groups. The agency's analysis showed that 11 of the 55 (20%) potential cohorts would fail to meet the 20-HHA minimum threshold for cohort scoring reliability. Second, CMS explored a variation of this alternative in which the HHAs assigned to cohorts with fewer than 20 members would simply be excluded entirely from participation in the expanded model. This option would maintain scoring reliability for the remaining larger-volume cohorts, but also would markedly reduce the intended national footprint of the model. Third, CMS considered consolidating model locations with fewer than 20 HHAs into a single larger-volume cohort. The consolidated cohort, however, would embed greater internal heterogeneity than that

[14] For example, Table 24 provides HHA counts by state or other model locations, and by volume, as used by CMS in considering cohorting options.

seen in the model's other cohorts, raising concerns of inequitable scoring. CMS ends by noting the operational simplicity of its preferred approach (two national cohorts) compared to the inherent complexity of the alternatives considered.

CMS requests comments on the alternative of cohorting only by state or other jurisdiction, without consideration of HHA volumes. CMS states that based on comments received, this alternative may be finalized in lieu of the national, volume-based, two-cohort proposal.

4. Quality Measures Proposed for the Expanded HHVBP Model

CMS proposes the applicable measure set for the expanded model for PY 1 and subsequent model years; the agency states that future measure additions would occur through rulemaking. Policies for measure addition, removal, modification, and suspension are proposed, as well as those for the form, manner, and timing of measure submission. CMS also proposes policies for an appeals process, extraordinary circumstances exceptions, and public reporting of performance data.

Under the original HHVBP model, participant HHAs were required to report data on three measures, termed "New Measures", for which data submission was not required by HHAs located in states excluded from the model. HHAs were not scored on the New Measures. CMS does not propose to continue the New Measures as part of the expanded HHVBP model test nor to create replacements for the New Measures.

a. Proposed Quality Measures for PY 1 (CY 2022)

CMS states the measures proposed for inclusion in the expanded model's initial measure set were chosen based on the following considerations: alignment with measures of the Home Health Quality Reporting Program (HH QRP); endorsement by the National Quality Forum (NQF); measure availability; and collection burden for providers. CMS notes that the authority available to the Innovation Center under section 1115A of the Act allows the agency wide discretion to explore a broad range of measure types and topics for future addition to the model, including those lacking NQF endorsement. The proposed initial measures are listed in the table below, modified from Table 26 of the rule.

TABLE 26 (modified): Proposed Measure Set for the Expanded HHVBP Model

Short Name	Measure Name & Data Source
Currently in HH QRP and Original HHVBP Model PY 4 Measure Sets	
OASIS	
Dyspnea	Improvement in Dyspnea
DTC	Discharged to Community[a]
Oral Medications	Improvement in Management of Oral Medication (NQF #0176)
Claims	
ACH	Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171)[b]
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of Home Health (NQF #0173)[b]

Short Name	Measure Name & Data Source
Currently in HH QRP and Original HHVBP Model PY 4 Measure Sets	
HHCAHPS (NQF #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
Currently in Original HHVBP Model PY 4 Measure Set	
OASIS	
TNC Mobility	Total Normalized Composite Change in Mobility[c]
TNC Self-Care	Total Normalized Composite Change in Self-Care[c]
[a] Table 26 specifies reporting via OASIS M2420 rather than claims-based DTC measure NQF #3477	
[b] Proposed for replacement beginning with CY 2023 HH QRP	
[c] Composite score	

CMS notes that the design of the two OASIS composite measures (TNC Mobility and TNC Self-Care) adjusts for patients with inherently limited goals for improvement by using a very broad set of risk-adjustment factors (e.g., cognitive function, living arrangements) to recalibrate expectations for improvement.[15] More detailed information about these measures is available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20computing%20the%20hhvbp%20composite%20measures.pdf.
CMS clarifies that HHAs would not be required to report HHCAHPS data twice – once under the HH QRP and again under the expanded HHVBP model.
CMS requests comments on the proposed measure set.

b. Proposed Policies for Measure Modifications/Updates, Removal, or Suspension

Measure Updates. CMS notes that information pertinent to potential measure updates arises from many sources (e.g., new clinical guidelines, NQF committee reports). CMS proposes to adapt the HH QRP's bifurcated process for use in the expanded HHVBP model: substantive changes would occur through rulemaking, while non-substantive changes would be made through a subregulatory process in which the CMS website would be used to inform stakeholders and the public of the changes. Determination of substantive versus non-substantive changes would be made by CMS on a case-by-case basis. For example, routine updates of diagnosis codes would generally be considered non-substantive changes while changing the care setting for a measure from inpatient to outpatient would generally be judged as substantive.

Measure Removal. CMS proposes a list of factors it would consider when identifying measures for proposed removal from the expanded model. These factors are similar to those in use already in other quality programs (e.g., the hospital inpatient quality reporting program). CMS notes that the applicability of one or more removal factors to a measure does not mandate that measure's removal if the measure still serves a valuable purpose (e.g., measure removal would create a

[15] For example, a cognitively impaired patient is unable to improve in self-care to the same extent as a cognitively intact patient.

significant quality gap). CMS also notes that unforeseen reasons for measure removal could occur that are not well-described by the removal factors below.

1) Measure performance is so high and unvarying that meaningful distinctions in improvements can no longer be made (measure is "topped out").
2) Performance or improvement on a measure does not result in better patient outcomes.
3) A measure does not align with current clinical guidelines or practice.
4) A more broadly applicable measure (e.g., across settings) is available.
5) A measure more proximal in time to the desired patient outcome is available.
6) A measure more strongly associated with the desired patient outcome is available.
7) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
8) The costs associated with a measure outweigh the benefit of its continued use.

CMS also provides a list of types of costs it has identified for consideration in association with Factor 8, such as provider burden associated with measure submission to CMS and costs accruing to CMS for measure maintenance. CMS proposes that measure removal based on Factor 8 would be done on a case-by-case basis.

Measure Suspension. CMS proposes to proceed immediately with suspension of a measure if continued measure data collection raises potential patient safety concerns. The measure's suspension would be announced through multiple CMS communication channels and the measure would be proposed for removal or modification during the next rulemaking cycle.

c. Future Measure Considerations

In the expanded HHVBP model's PY 1 measure set (see modified Table 26 above) CMS proposes to include two claims-based measures Acute Care Hospitalization During the First 60 Days of Home Health (ACH) and Emergency Department Use without Hospitalization During the First 60 Days of Home Health (ED Use). However, later in this rule, CMS also proposes to remove these same two measures from the HH QRP measure set for CY 2023, replacing them with a new measure – Home Health Within-Stay Potentially Preventable Hospitalization. **CMS requests comment on whether the measures of the expanded HHVBP model should be aligned with the HH QRP measure set by proposing removal of the ACH and ED Use measures from the HHVBP measure set in a future year.**

CMS requests comment on the challenges unique to value-based purchasing frameworks in terms of promoting health equity, and ways in which the agency could incorporate health equity goals into the expanded HHVBP model. CMS notes this comment request is separate from the broader request for information in section VIII.B. of this rule concerning the agency's efforts to close the health equity gap in its quality programs for post-acute settings, including the HH QRP.

d. Proposed Data Submission

CMS proposes to evaluate the performances of participating HHAs on a specified set of quality measures (see modified Table 26 above), for which purpose HHAs would be required to submit quality measure data to CMS in the form and manner, and at a time, specified by the agency. CMS also proposes to require participant HHAs to collect and submit information throughout the model's test period for utilization in monitoring and evaluation of the model.

OASIS measures. HHAs must complete and electronically submit OASIS assessments at specified intervals via the Internet Quality Evaluation System (iQIES) to comply with the HH Conditions of Participation (COPs). CMS proposes that expanded HHVBP model participants would be required to submit OASIS data in accordance with the COPs. The model would not require any additional OASIS data submission. CMS also proposes that OASIS-based HHVBP model measures would be scored using data extracted from the iQIES for the applicable model performance year.[16]

HHCAHPS survey measures. To successfully report under the HH QRP, HHAs already are required to contract with a CMS- approved, independent survey vendor to administer the survey. CMS proposes to adopt the survey requirements of the HH QRP into the expanded HHVBP model (e.g., a survey vendor is subject to CMS oversight, including site visits). Included in this proposal is the patient count exemption, under which HHVBP model participants having fewer than 60 eligible, unique, HHCAHPS survey patients for a CY who submit their survey patient counts to CMS are exempted from survey measure reporting for that CY. (As described earlier, exempted HHAs would be assigned to the proposed smaller-volume cohort of the model.) Under the HHVBP, each of the five required survey components is treated as a separate measure.

Claims-based measures. CMS proposes that the expanded model's two claims-based utilization measures would be scored by CMS using claims data extracted for the applicable performance year.

e. Proposed Waiver of Pre-rulemaking Process

CMS proposes to use the Innovation Center's waiver authority (section 1115A of the Act) to waive performance under the expanded HHVBP model of all but one of the otherwise required steps of the pre-rulemaking process (e.g., NQF review) for quality and efficiency measures.[17] The retained step would be the requirement that measures being considered by the Secretary be posted publicly before December 1 of each year – the Measures Under Consideration (MUC) list. CMS states that the established pre-rulemaking process would impede timely testing of new and innovative measures under the model. CMS further states that the flexibility gained would also allow rapid adaptation of the model to unpredictable changes caused by beneficiary care preference changes (e.g., age-in-place), industry trends (e.g., demographic shifts), and events that disproportionately affect the HHA beneficiary population (e.g., the COVID-19 PHE).

[16] A "complete quality episode" is necessary to calculate measure scores from OASIS data. The complete episode contains both a Start of Care or Resumption of Care OASIS assessment and a Transfer or Discharge assessment.
[17] For more information on the pre-rulemaking process, see https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking

5. Proposed Performance Scoring Methodology for the Expanded HHVBP Model

a. Background

CMS proposes a performance scoring methodology for the expanded model that builds on the original model's methodology. Four proposed changes from the original methodology are highlighted: 1) no New Measures are included in the expanded model and therefore would no longer be part of the scoring process; 2) minor modifications would be made to the achievement and improvement score formulas to simplify calculations; 3) benchmarks and achievement thresholds would be calculated based on the proposed national volume-based cohorts; and 4) to facilitate measure alignment and to simplify score calculations, the achievement score range for the TNC Mobility and TNC Self-Care measures would change to 1-10 points each and the improvement score range would become 0-9 points each.

The goal of the performance scoring methodology is to produce a TPS for each HHA participant based on its raw measure scores for subsequent translation into its payment adjustment percentage. Guiding principles for methodology development were:

- The methodology is straightforward and transparent to HHAs and beneficiaries.
- The methodology is aligned with those for other Medicare VBPs.
- Score differences must reflect true differences in performance.
- Both achievement and improvement scores are produced and are weighted appropriately.
- The methodology is designed to use the most recently available data for all measures.

b. Overview of the Proposed Methodology

CMS proposes to calculate an achievement score for each HHA for each measure as well as an *improvement score*, and to assign a *performance score* for each measure, defined as the higher of each HHA's achievement or improvement score. Measure performance scores would be weighted within their data source categories (OASIS, claims, or HHCAHPS). The category scores are weighted then summed to produce the Total Performance Score (TPS). The OASIS and claims categories would each be weighted at 35 percent and the HHCAHPS category at 30 percent.[18] The TPS would be translated into a payment adjustment percentage using a linear exchange function (LEF).

c. Benchmarks and Thresholds

Achievement and improvements points are determined using benchmarks and thresholds. CMS proposes to calculate the benchmark as the mean of the top decile of all HHAs' performance scores on the specified quality measure during the baseline year. It would be calculated separately for the proposed larger- and smaller-volume cohorts, and the achievement and

[18] These weights apply if the minimum number of measures are reported in all three categories. Category reweighting is applied when measures are lacking in one or two categories, described later in the rule and this summary.

improvement benchmarks would be the same. See Table 25 of the rule (reproduced earlier in this summary) for the applicable baseline years. CMS further proposes to define the achievement threshold to mean the median of all HHAs' performance scores for a measure during the baseline year. Additionally, CMS proposes to set an HHA's improvement threshold for a measure to its baseline year performance score. Achievement and improvement thresholds would be set separately for the proposed larger- and smaller-volume cohorts.

d. Achievement and Improvement Scores

Using the achievement threshold and benchmark, the achievement score quantifies the HHA's current year performance on a measure versus its baseline performance as compared to its cohort members. CMS proposes to set an achievement score range of 1-10 points for each measure, capping the score at 10 points. The points earned for each measure would be rounded up or down to the third decimal point. The proposed achievement score formula would be:

$$\text{Achievement Score} = 10 \times \left(\frac{\textit{HHA Performance Score} - \textit{Achievement Threshold}}{\textit{Benchmark} - \textit{Achievement Threshold}} \right)$$

Finally, CMS proposes scoring rules based on each HHA's raw quality measure score; a score that is:

- at or above the benchmark would accrue the maximum allowable 10 points for the HHA;
- above the achievement threshold but below the benchmark would accrue greater than 0 but less than 10 points for the HHA; and,
- at or below the achievement threshold would accrue 0 points for the HHA.

Using the improvement threshold and benchmark, the improvement score quantifies the HHA's current performance on a measure versus its own baseline performance. CMS proposes to set an improvement score range of 1-9 points for each measure, capping the score at 9 points. The points earned for each measure would be rounded up or down to the third decimal point. The proposed improvement score formula would be:

$$\text{Improvement Score} = 9 \times \left(\frac{\textit{HHA Performance Score} - \textit{HHA Improvement Threshold}}{\textit{Benchmark} - \textit{HHA Improvement Threshold}} \right)$$

Finally, CMS proposes scoring rules based on each HHA's raw quality measure score; a score that is:

- at or above the benchmark would accrue the maximum allowable 9 points for the HHA;
- above the improvement threshold but below the benchmark would accrue greater than 0 but less than 9 points for the HHA; and,
- at or below the improvement threshold would accrue 0 points for the HHA.

CMS provides three illustrative examples of achievement and improvement score calculations as Figures 4 and 5 of the rule. Actual 2019 data and hypothetical 2022 data are used to simulate the baseline and performance years, respectively.

e. Measure and TPS Score Thresholds

Measure scoring thresholds. CMS proposes that to receive a measure score for an OASIS or claims-based measure for a PY, an HHA must have provided at least 20 home health episodes of care during that PY (i.e., have at least 20 cases in the measure's denominator). The corresponding minimum for each of the five HHCAHPS component measures is 40 completed surveys. A measure for which an HHA meets the case minimum threshold is termed an *applicable measure*.

TPS score threshold. CMS proposes that an HHA must meet the case or survey minimum threshold for at least five of the model's 12 measures during a PY in order to receive a TPS score for that PY. The distribution of the five applicable measures across measure categories is not prescribed by CMS. CMS notes that over 97 percent of claims for HH services during 2019 were submitted by HHAs that reported on at least five applicable measures.

For the rare HHA that fails the TPS score threshold, no HHVBP payment adjustment percentage would be applied and the HHA would be paid at an amount equivalent to the HH PPS rate absent the HHVBP model. The failing HHA would receive performance feedback for any applicable measures it reported and would remain eligible to return to expanded HHVBP model participation in future PYs.

f. Proposed Measure Weights and Reweighting

Measure Category Weights and Reweighting. For TPS score calculations, when no applicable measure is available to be scored in one measure category, CMS proposes to reweight the remaining categories according to their original proportional relationships, as shown in Table 29 of the rule, reproduced in part below. When no applicable measure is available to be scored in two measure categories, the remaining category is weighted at 100 percent of the TPS.

TABLE 29 (modified): Proposed Quality Measure Category Weighting and Reweighting Schedule for TPS Scoring

	Measure Reporting Scenario			
Category Measure Minimum Met	All Measures	No HHCAHPS	No Claims	No Claims or HHCAHPS (OASIS only)
TPS Weights by Measure Category				
Weight OASIS measures	35.00%	50.00%	53.85%	100%
Weight Claims measures	35.00%	50.00%	0%	0%
Weight HHCAHPS survey component measures	30.00%	0%	46.15%	0%

Within Category Weights and Reweighting. Within the HHCAHPS survey measure category, CMS proposes to weight all five measures equally. Reweighting is not applicable since a completed survey includes responses to all five measures, so there are no missing measure values that would trigger reweighting. Within the claims measure category, CMS proposes to weight the ACH and ED measures at 75 percent and 25 percent of the total category weight, respectively. Reweighting within this category is not necessary since the 20 or more HH service episode

claims required for scoring the ACH measure would also suffice for scoring the ED measure, so that reweighting would never be triggered by a missing measure value. Within the OASIS measure category, CMS proposes to weight TNC Self Care and TNC Mobility measures at 25 percent each. Weights for the remaining measures (Dyspnea, Discharged to Community, and Oral Medications) would each be set at 16.67 percent. If any measures are missing in the OASIS category, the remaining measures would be reweighted to maintain their original proportional relationships, shown for all missing measure potential combinations in Table 29 of the rule.

CMS provides two examples of TPS scoring calculations calculated using the proposed TPS methodology, one without and one with missing measure values. The latter example includes the use of reweighting.

6. Proposed Payment Adjustment Methodology under the Expanded HHVBP Model

CMS proposes to translate HHAs' TPSs to payment adjustments using a linear exchange function (LEF); LEFs are similarly used in other Medicare VBPs (e.g., the SNF VBP). By setting the proposed LEF's intercept to 0, the payment adjustment would be 0 percent for an HHA whose TPS equals the average TPS value of its cohort. CMS further proposes to set the LEF's slope for each PY using the maximum payment adjustment percentage for that PY in such a way that the estimated aggregate payment adjustments for all HHAs are equal to the product of the PY's adjustment percentage and the estimated aggregate operating payment amount for all HHAs. CMS also proposes to determine separate LEF slopes for the two volume-based HHA cohorts. (To set the LEF for payment year 1 (CY 2024), CMS assumes the maximum adjustment percentage of 5 percent as proposed earlier in the rule.). The estimated aggregate payment amount would be based on HH PPS claims data from the year preceding the performance year and three years prior to the payment year (e.g., based on CY 2021 claims for PY 1 – CY 2022 – and its associated payment year 1 – CY 2024).

CMS describes a 7-step calculation process by which the LEF slopes would be set for the two proposed national cohorts and which would produce a final percent payment adjustment for each HHA, to be applied to each claim's final payment amount. In Table 32 (reproduced at the end of this summary section), CMS provides an example in which the 7-step process is applied for eight HHAs across a broad range of hypothetical TPS scores and prior year HH PPS payments. For each HHA example, CMS begins at Step 1 with the prior CY's aggregate payment amount to the HHA; uses the HHA's TPS to determine the HHA's TPS-adjusted payment reduction amount at Steps 2 and 3; applies the LEF at Steps 4 and 5; and converts the payment adjustment from dollars to yield the HHA's actual payment adjustment percentage at Steps 6 and 7.

Table 32: 5-Percent Reduction Sample Calculation

		Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
	TPS	Prior Year Aggregate HHA Payment Amount	5-Percent Payment Reduction Amount (C2*5%)	TPS Adjusted Reduction Amount (C1/100)* C3	LEF (Sum of C3 / Sum of C4)	Final TPS Adjusted Payment Amount (C4*C5)	Quality Adjusted Payment Rate (C6/C2)	Final Percent Payment Adjust-ment (C7-5%)
Step Result	(C1)	(C2) (in $)	(C3) (in $)	(C4) (in $)	(C5)	(C6) (in $)	(C7) (%)	(C8) (%)
HHA1	38	100,000	5,000	1.900	1.931	3,669	3.669	-1.331
HHA2	55	145,000	7,250	3,988	1.931	7,701	5.311	0.311
HHA3	22	800,000	40,000	8,800	1.931	16,995	2.124	-2.876
HHA4	85	653,222	32,261	27,762	1.931	53,614	8.208	3.208
HHA5	50	190,000	9,500	4,750	1.931	9,173	4.828	-0.172
HHA6	63	340,000	17,000	10,710	1.931	20,683	6.083	1.083
HHA7	74	660,000	33,000	24,420	1.931	47,160	7.146	2.146
HHA8	2	564,000	28,200	7,050	1.931	13,615	2.414	-2.586
Sum			172,611	89,379		172,611		

TPS = Total Performance Score; LEF = Linear Exchange Function

7. Performance Feedback Reports under the Expanded HHVBP Model

a. Interim Performance Report (IPR)

CMS proposes to provide HHAs with quarterly performance feedback based on the 12 most recent months of data available, with reports made available through a CMS data platform (e.g., iQIES). Initial reports issued for each quarter would be preliminary and final reports issued after CMS completes processing of all reconsideration requests (the appeals process is discussed later in the rule and below in this summary). The agency estimates releasing the first IPRs in July 2022, in which Q1 2022 would be included.

The IPR would include the HHA's TPS and other model-specific performance results and comparisons to the results of its cohort members, along with an estimated relative rank within its cohort. The report also would provide a "TNC Change Reference" with results for the individual OASIS measures that are consolidated into the two TNC composite measures (TNC Mobility and TNC Self Care).[19] Also provided would be a "Scorecard" designed to facilitate an HHA's understanding of contributions to the TPS by each of the expanded model's quality measures. CMS notes that HHAs can access additional, detailed results through iQIES-generated reports and HHCAHPS Data Submission reports, available at https://iqies.cms.gov/ and under the "For HHAs" tab of https://homehealthcahps.org, respectively.

[19] TNC Mobility measure includes toilet transferring, bed transferring, and ambulation/locomotion. The TNC Self Care measure includes grooming, bathing, upper body dressing, lower body dressing, toilet hygiene, and eating.

b. Annual TPS and Payment Adjustment Report

CMS proposes to provide each HHA with an Annual TPS and Payment Adjustment Report via a CMS data platform, with an expected release date of August 2023 for the first annual report. The report would be confidential and designed to provide information about an HHA's payment adjustment percentage for the upcoming CY. The annual report would first be provided as a Preview Annual Report for review by the HHA, at which point it could request recalculation (see the proposed appeals process later in this rule and this summary). An HHA not requesting recalculation would next receive its Final Annual Report. An HHA requesting recalculation would next receive for review a Preliminary Annual Report with CMS' response to the recalculation request, after which the HHA could request reconsideration. A Final Annual Report would not be provided until CMS has completed processing of all reconsideration requests. CMS provides a sample timeline for the various reports for PY 1/payment year 1 (CY 2022/CY 2024) n Table 33, reproduced below with modifications.

Table 33 (modified): Sample Timeline for CY 2022 Performance Year and CY 2024 Payment Year by Report Type and Data Type

Report Type (Approximate Date Issued)	OASIS-based Measures	Claims-based and HHCAHPS-based Measures
July 2022 IPR (July 2022)	12 months ending 3/31/2022	Baseline data only
October 2022 IPR (October 2022)	12 months ending 6/30/2022	12 months ending 3/31/2022
January 2023 IPR (January 2023)	12 months ending 9/30/2022	12 months ending 6/30/2022
April 2023 IPR (April 2023)	12 months ending 12/31/2022	12 months ending 9/30/2022
July 2023 IPR (July 2023)	12 months ending 3/31/2023	12 months ending 12/31/2022
Annual TPS/Payment Adjustment Report – Preview (August 2023)	12 months ending 12/31/2022	12 months ending 12/31/2022
Annual TPS/Payment Adjustment Report – Final (On or before December 31, 2023)	12 months ending 12/31/2022	12 months ending 12/31/2022

8. Appeals Process under the Expanded HHVBP Model

Building on the appeals process for the original HHVBP model, CMS proposes a process for the expanded model, with key steps outlined below.

a. Recalculation Request Process

This process would be applicable to both the Preliminary IPR and the Preview Annual Report when an HHA identifies a potential discrepancy due to a CMS calculation error (both reports) or a potential error in the application of the payment adjustment formula (annual report only).

- HHA submits recalculation request within 15 days of report receipt, per CMS directions.
    - Requests must include the specific data or calculation being questioned.

- As soon as administratively feasible, CMS sends a formal response with findings and decisions.
    - If recalculation by CMS changes a performance measure score, CMS will review all pertinent data and, if an error is found, will recalculate the TPS.
- CMS will provide corrected information in the Final IPR for the quarter under review or the Preliminary Annual Report, as applicable.

b. Reconsideration Process

This process would be applicable only to the Preview Annual Report and when CMS denies an HHA's request for recalculation or the HHA disagrees with a result of a recalculation by CMS.

- HHA sends of CMS' reconsideration request within 15 days of the CMS response to the antecedent recalculation request, submitted per CMS directions.
    - Request must include the specific data or calculation being questioned.
    - Reconsideration is conducted by a CMS official not involved with the antecedent recalculation.
    - For CMS to change scores or payment adjustment percentages, the HHA must prove its case by a preponderance of evidence with respect to issues of fact.
- CMS will provide corrected information in the HHA's Final Annual Report.
    - All Final Annual Reports to all HHAs will be released at the same time.
    - Final Annual Reports will be made available no later than 30 days before the effective date of the payment adjustment for the PY.
    - Final data files will be provided by CMS to its administrative contractors for updating payment adjustment percentages for the upcoming payment year in their provider files.

9. Public Reporting under the Expanded HHVBP Model

For each PY, CMS proposes to publicly report the applicable measure benchmarks and achievement thresholds for each cohort. CMS further proposes to report all of the following for each HHA that qualified for a payment adjustment during the PY: TPS, the HHA's TPS percentile ranking among all HHAs, payment adjustment percentage; and applicable measure results and improvement thresholds. CMS states that this broader range of publicly reported data for the expanded model compared to the original model is intended to align the HHVBP with the SNF and hospital value-based VBPs.

CMS acknowledges that there would be duplicate display on *Care Compare* of measures common to the HH QRP and the expanded HHVBP model (i.e., all measures of the expanded model's PY 1 quality measure data set) but notes that the results would differ between the programs for some measures since the public reporting periods used for the HH QRP and the expanded model may differ. CMS states that explanatory text will be provided for the differing results of the duplicated measures, along with definitions and descriptions related to the TPS and payment adjustment processes. CMS also notes that new measures may be added to the expanded model that are not also part of the HH QRP. CMS anticipates making PY 1 (CY

2022)performance data public on or after December 1, 2023 and following a similar timeline annually.

10. Extraordinary Circumstances Exception (ECE) Policy for the Expanded HHVBP Model

CMS proposes to adopt an ECE policy related to the data reporting requirements of the HHVBP model for circumstances beyond the control of HHAs, building on the existing HH QRP policy. An HHA could make an individual exception request to CMS within 90 days of the occurrence of the extraordinary circumstance, to which CMS would strive to respond formally within 90 days of the request. CMS also proposes to grant exceptions to one or more HHAs in the absence of requests from them should CMS determine that an extraordinary circumstance has affected an entire region or locale (e.g., the COVID-19 PHE). CMS would communicate such determinations to HHAs and vendors through routine channels (e.g., PAC QRP listserv). Broad-based exceptions could also be issued should CMS data collection systems become inaccessible.

11. Estimated Impact of Expanded HHVBP Model

For the expanded HHVBP model, CMS does not provide an estimate of burden because section 1115A(d)(3) of the Act exempts the testing and evaluation of Innovation Center models from the provisions of the PRA. By design, if proposals for the expanded model are finalized as described further in this section, the aggregate payment reductions to lower-performing HHAs would approximate closely the aggregate payment increases to higher-performing HHAs. Somewhat higher positive payment adjustment percentages are seen for HHAs serving populations in rural locations or have higher proportions of dually-eligible beneficiaries. Net savings to Medicare aggregated over the duration of the expanded model are estimated at $3.154 billion (CYs 2002-2006). Savings are primarily derived from anticipated reductions in service utilization including hospital and SNF admissions.

B. Proposed Changes to the Original HHVBP Model

1. PY 5 Performance Data and Payment Year 5 Adjustment Percentages

The original HHVBP model was designed to end after five performance years were completed (December 31, 2020). PY 5 performance data were to be used to adjust participant HHAs' payments for payment year 5 (CY 2022), with the maximum payment adjustment percentage set at ± 8 percent for that year. However, one element of the CMS response to the COVID-19 PHE was a waiver of quality data reporting requirements for Q1 and Q2 2020 applicable to multiple Medicare quality programs including the original HHVBP model. CMS reports having reviewed the available data from those quarters for the nine states included in the model,[20] and finding evidence of significant changes in utilization patterns of home health services: OASIS assessments decreased 8.9 percent and HH services claims fell by 20.2 percent. The changes occurred throughout Q1 and Q2 and involved all nine states, though varied in their extent both within and across those states.

[20] The states included in the original HHVBP model were AZ, FL, IA, MD, MA, NE, NC, TN, and WA.

CMS states its concern that using the available but anomalous Q1 and Q2 2020 performance data to calculate TPSs and payment adjustments for payment year 2022 could fail to accurately reflect HHA performance and unfairly penalize some HHAs. CMS considered the alternative of using only Q3 and Q4 2020 data to generate TPSs and adjustment percentages for 2022 but rejected this approach, being concerned that COVID-19 impacts on HHA care delivery and quality reporting persisted into the second half of 2020 and even into 2021.

Given the foregoing, CMS proposes not to use CY 2020 data for TPS and payment adjustment calculations that would be applicable to original HHVBP model participants in payment year 2022. Instead, CMS proposes to terminate the original model early, so that the model's final performance year would have been 2019 and final payment year would be 2021. Final evaluation of the model would include four rather than five PYs. CMS states that not using anomalous 2020 data for payment adjustments is consistent with changes proposed for other Medicare VBP programs due to COVID-19 PHE effects (e.g., measure suppression in the hospital VBP program).

2. Public Reporting

Under the original HHVBP model, both TPS results and HHA percentile rankings according to their TPS results are publicly reported after CMS releases final annual reports to HHA participants. Due to concerns about COVID-19 PHE effects and anomalous performance data similar to those just described, CMS proposes not to publicly report 2020 data and associated performance results. As proposed elsewhere in this rule, public reporting of HHA performance data would continue as part of the expanded HHVBP model, starting with CY 2022 results.

III. HH Quality Reporting Program (HH QRP) and Other HH Related Provisions

A. Vaccinations for Home Health Agency Health Care Personnel

In this section of the rule, CMS reviews the ongoing risks of COVID-19 infection transmission between and among health care providers and patients. CMS states its belief that HHA efforts to assess and reduce COVID-19 transmission should include programs for staff member education and vaccination and that such programs potentially would limit staff work absences and related patient care disruptions. CMS further states that, in general, vaccinated providers are more likely to recommend vaccination to patients and expresses its belief that vaccinated HHA staff could increase vaccination rates among HH patients. CMS does not make any specific proposals at this time for requirements related to staff member education or vaccination, though has proposed health care worker vaccination measures for other CMS quality programs.

B. Advancing Health Information Exchange

In this section of the rule, CMS reviews several initiatives underway to further interoperability in post-acute care (PAC) settings including the work of the PAC Interoperability Workgroup (PACIO), updates to the CMS Data Element Library, and the adoption of robust information blocking provisions by CMS and the Office of the National Coordinator for Health Information Technology (ONC). CMS emphasizes the work of the PACIO and encourages PAC providers,

including HHAs, to participate and the agency generally encourages the HHA community to closely follow improvements in interoperability as they continue to evolve. CMS does not make any specific proposals at this time for requirements related to the interoperability capabilities of HHAs.

C. Home Health Quality Reporting Program (HH QRP)

CMS reviews the legislative and regulatory history of the HH QRP, a pay-for-reporting program implemented in 2007. Under this program the annual market basket percentage increase is reduced by 2 percentage points for HHAs that do not report required quality data. The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, P.L. 113-185) imposed new reporting requirements, including standardized patient assessments, for the PAC providers including HHAs. The new assessments require electronic reporting of information through OASIS entries known as standardized patient assessment data elements (SPADE) that are organized into several data categories. Some SPADEs transmit data in the category of social determinants of health (SDOH): race, ethnicity, language preference, health literacy, transportation needs, and social isolation.

No changes are proposed to the HH QRP measure selection criteria nor to the measures previously adopted for the CY 2022 program year (shown in Table 28 of the rule and in the summary table of previously adopted and finalized measures at IV.C.5 below). For CY 2023, CMS proposes the removal of one measure, the replacement of two measures by a single measure, and future public reporting of two measures. Finally, CMS proposes to update previously finalized start dates for data submission for two measures and six SDOH SPADE categories. More information on the HH QRP can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.

CMS estimates that the net impact of the HH QRP changes if finalized as proposed would be 3.1 hours of burden reduction and decreased costs per HHA of $242 annually. The aggregated cost reductions for all HHAs would be $233,092,681.

1. Measure Removal for CY 2023

CMS proposes to remove the Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care (Drug Education) measure beginning with CY 2023, citing measure removal factor 1: measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made (i.e., the measure is "topped out"). This OASIS-based process measure was adopted into the CY 2010 HH QRP.

CMS discusses data illustrating the Drug Education measure's topped out characteristics and identifies another current HH QRP measure that better addresses the area of medication management: Improvement in Management of Oral Medications (Oral Medications, NQF #0176) and notes that the latter measure is NQF-endorsed. CMS states that if removal of the Drug Education measure is finalized, HHAs would no longer be required to submit OASIS Item M2016 beginning January 1, 2023, and the measure would no longer be reported on *Care Compare* after October 1, 2023.

2. Measure Replacement for CY 2023

Also for CY 2023, CMS proposes to replace the two measures – Acute Care Hospital During the First 60 Days of Home Health (ACH, NQF #0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (ED, NQF #0173) – with the single measure Home Health Within Stay Potentially Preventable Hospitalization (PPH). CMS cites measure removal factor 6: a measure that is more strongly associated with desired patient outcomes for the particular topic is available. The two extant measures are claims-based and NQF-endorsed; the ACH measure was adopted into the HH QRP for CY 2013 and the ED measure for CY 2012. The proposed PPH replacement measure reports an HHA-level rate of risk-adjusted potentially preventable hospitalizations or observation stays for Medicare fee-for-service (FFS) beneficiaries that occur within a home health (HH) stay for all eligible stays for each HHA.[21] The PPH measure is claims-based and is not yet NQF-endorsed.

CMS discusses at length evidence to support that measuring preventable ED visits with subsequent hospitalizations continues to fill an important role in evaluating the quality of services delivered by HHAs. CMS notes that trends in health care delivery patterns have been associated with increases in hospital observation stays after ED visits in the HHA patient population and states its belief that the PPH measure better addresses observation stays than the current two measures. CMS further states that the PPH measure focuses more precisely on performance elements related to observation stays and hospitalizations that are within the control of HHAs.

CMS reviews the development of the PPH measure. The agency convened a Technical Expert Panel (TEP) that met several times in 2018 to provide recommendations on the measure's technical specifications. The work of the TEP was heavily targeted to defining "potentially preventable" and the associated list of primary conditions used to characterize observations and admissions deemed preventable by HHAs. As part of the usual pre-rulemaking process, the PPH measure was placed on the 2019 Measures Under Consideration (MUC) list and the NQF-convened Measures Application Partnership (MAP) undertook review of the measure.

The MAP's review ended with a decision of conditional support for rulemaking pending NQF review and endorsement.[22] However, the MAP made multiple recommendations for improving the measure including further consideration of the definition for preventable hospitalization, the look-back period for risk adjustment, and extending the measure to include Medicare Advantage (MA) patients. CMS describes in detail its subsequent efforts to address the MAP's recommendations including: analyzing the admission diagnoses most often association with HHA patient admissions in comparison to those on the PPH measure's potentially preventable list; defining planned admissions; and confirming prior testing results that showed the measure's risk adjustment to be valid and reliable. CMS supports adding MA patients to the measure's cohort when the MA data needed for this measure become readily available nationally. CMS also

[21] A *home health stay* is defined as a sequence of HH payment episodes that are within 2 days or fewer from an adjacent payment episode. Episodes separated from other home health payment episodes by more than 2 days are considered separate stays.

[22] See the report at https://www.qualityforum.org/Projects/i-m/MAP/PAC-LTC_Workgroup/2020_Considerations_for_Implementing_Measures_Draft_Report.aspx.

solicited stakeholder feedback through a public comment period, responses to which focused on the intersection of this measure with the HHA PDGM. CMS has subsequently determined that claims-based measures such as the PPH are not adversely impacted by the PDGM.

3. Publicly Reported Measures Beginning with the CY 2022 HH QRP

CMS proposes to begin public reporting of two OASIS-based measures beginning in April 2022: Percent of Residents Experiencing One or More Major Falls with Injury (Application of Falls, NQF #0674) and Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (Application of Functional Assessment, NQF #2631). Section 1899B of the Act requires that 1) PAC provider performances, including HHAs, be publicly reported; 2) a review and corrections period be provided to PAC providers prior to public data display; and 3) information be made public beginning not later than 2 years after the specified measure application date for a measure and PAC provider combination. CMS notes that these two measures were adopted into the HH QRP beginning with CY 2020 and with a specified application date of January 1, 2019. Measure performances have been available to HHAs in confidential reports effective January 1, 2020 and will be available for review on the January 2022 HH Provider Preview Report.

4. Revised Compliance Date for Certain HH QRP Reporting Requirements for CY 2023

CMS proposes to require HHAs to begin reporting two measures – Transfer of Health (TOH) Information to PAC and TOH Information to Patient-PAC – and the elements in the six SDOH SPADE data categories beginning January 1, 2023. These measures and SPADEs were initially adopted as HH QRP requirements for CY 2022 but their adoption was subsequently delayed as part of the CMS response to the COVID-19 PHE to decrease provider burden.

In the May 8, 2020 COVID-19 IFC (85 FR 27550), the compliance date was changed to January 1st of the year that is at least one full CY after the end of the PHE. Reporting the TOH measures and the SDOH SPADEs requires the availability of an updated OASIS assessment instrument version (OASIS-E). CMS believed at the time of IFC-2 publication that the delayed compliance date would minimally impact the HH QRP but now believes that PHE has reinforced the need for rapid health information transfer as well as highlighting health care disparities that could be identified through the SPADEs.

CMS reviews evidence suggesting that HHAs are now much better able to report the TOH measures and SDOH SPADEs and to undergo training to use the OASIS-E version. than when the May 8, 2020 COVID IFC was published. CMS, therefore, proposes to modify the compliance date for reporting to begin January 1, 2023. CMS notes its plan to release a draft of OASIS-E in early 2022 and thereafter to make available education and training to HHAs to prepare for OASIS-E usage.

5. Summary Table of HH QRP Measures

Summary Table: Measures for the 2022 and 2023 HH QRP

Short Name	Measure Name & Data Source
OASIS-based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167)
Application of Falls	*Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) -- Public reporting proposed to begin April 2022*
Application of Functional Assessment	*Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631) Public reporting proposed to begin April 2022*
Bathing	Improvement in Bathing (NQF #0174)
Bed Transferring	Improvement in Bed Transferring (NQF #0175)
DRR	Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care (PAC) Home Health Quality Reporting Program
Drug Education	*Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care – Proposed for Removal beginning CY 2023*
Dyspnea	Improvement in Dyspnea
Influenza	Influenza Immunization Received for Current Flu Season (NQF #0522)
Oral Medications	Improvement in Management of Oral Medication (NQF #0176)
Pain	Improvement in Pain Interfering with Activity (NQF #0177) *Removed in 2022*
Pressure Ulcers	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury\
Timely Care	Timely Initiation of Care (NQF #0526)
Transfer of Health Information **	*Transfer of Health Information to the Patient-PAC Measure - Added in 2022* *Transfer of Health Information to the Provider-PAC Measure - Added in 2022*
Claims-based	
ACH	*Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) -- Proposed for Replacement beginning CY 2023 by PPH measure*
ED Use	*Emergency Department Use without Hospitalization During the First 60 Days of Home Health (NQF #0173) – Proposed for Replacement beginning CY 2023 by PPH measure*
DTC	Discharge to Community-Post Acute Care (PAC) HH QRP*
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB) –PAC HH QRP
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health Quality Reporting Program
PPH	*Home Health Within Stay Potentially Preventable Hospitalization* *Proposed as replacement for ACH and ED Use measures beginning CY 2023*
HHCAHPs-based	
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

*Baseline NF residents excluded from this measure beginning with the 2021 HH QRP.
** Compliance date delayed due to COVID-19 PHE, now proposed for reporting to begin January 1, 2023.

D. Proposed Changes to the Home Health Conditions of Participation

1. Home Health Aide Supervision

CMS proposes to make permanent selected regulatory blanket waivers related to the requirements for the supervision of HH aides that were issued to Medicare participating HHAs during the PHE. At §484.80(b)(1) and (2), CMS differentiates aide supervision requirements based on the level of care required by the patient:

- On-site supervisory visits every 14 days are required for aides caring for a patient receiving skilled care from nurses or therapists.
- On-site supervisory visits every 60 days are required for aides caring for a patient who is not receiving skilled care.

CMS believes the current requirement for the 14-day on-site supervisory visit of an aide when a patient is receiving skilled services is an important component to assess the quality of care and services provided by the aide, and to ensure that aide services are meeting the patient's needs. CMS thinks it is important to permit HHA's to complete this assessment virtually, in the rare circumstances that an onsite visit cannot be coordinated within the 14-day period.

CMS proposes to allow HHAs telecommunication flexibility for the supervisory assessment of the aide service and allow two-way audio-video telecommunications technology that provides interaction between the RN (or other appropriate skilled professional) and the patient. CMS proposes the telecommunications technology cannot exceed 2 virtual supervisory assessments per HHA in a 60-day period. The home health aide does not need to be present during the supervisory assessment.

CMS proposes to define interactive telecommunications systems as multimedia communications equipment that includes at a minimum, audio and video permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

CMS proposes when the supervising individual notes an area of concern during the 14-day supervisory assessment, the supervising individual must make an on-site visit to the location where the patient is receiving care while the aide is performing care, in order to observe and assess the aide.

CMS expects, however, that in most instances, the HHAs would plan to conduct the 14-day supervisory telecommunications options only for unplanned occurrences that would otherwise interrupt scheduled in-per visits. CMS provides examples of unplanned occurrences such as a severe weather event or a patient request to change the date of the scheduled visit.

For home health aide services to a patient who is not receiving skilled care, CMS proposes to maintain the requirement that the RN must make an onsite, in person visit every 60 days but CMS proposes it would remove requiring that the RN must directly observe the aide in person during those visits. CMS proposes that the aide does not need to be present during this visit. However, CMS proposes that semi-annually, the RN must make an on-site visit to the location where a patient is receiving care to observe and assess each aide while they are performing non-

skilled services. If a deficiency in aide services is verified during an on-site visit, CMS proposes that the agency must conduct and the aide must complete, retraining and a competency evaluation for the deficient and all related skills.

CMS requests **comments** on these proposals, including comments from patients and caregivers who have experienced virtual supervisory assessments of HH aides during the PHE.

2. Permitting Occupational Therapists to Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment

CMS proposes to update the HH CoPs to implement Division CC, section 115 of the CAA 2021 which requires CMS to permit an occupational therapist to conduct the initial assessment visit and complete the comprehensive assessment under the Medicare program, but only when occupational therapy (OT) is on the plan of care with either physical therapy (PT) or speech therapy and skilled nursing services are not initially on the plan of care. CMS notes that OT alone would not initially establish program eligibility under the Medicate HH benefit. OT can maintain eligibility for Medicare HH care after the need for skilled nursing, PT, and speech language pathology (SLP) services have ceased.[23]

CMS proposes to add additional language at §484.55(a)(2) that allows the occupational therapist to complete the initial assessment for Medicare patients when skilled nursing is not initially on the plan of care, but occupational therapy (OT) is ordered with another rehabilitation therapy service (PT or SLP) that establishes program eligibility as a need for HH.

CMS proposes to modify §484.55(b)(3) to allow an occupational therapist to complete the comprehensive assessment for Medicare patients when ordered with another qualifying rehabilitation therapy service (SLP or PT) that establishes program eligibility when skilled nursing is not initially part of the plan of care.

3. Adequacy of Aide Staffing

CMS believes that ensuring aide services are meeting the patient's needs is important for maintaining safe, quality care. In the March 2019 Report to Congress, MedPAC reported that between 1998 and 2017 home health visits declined by 88 percent.[24] Based on this finding, CMS requests **comments** on the following:

- Whether HH agencies employ or arrange for (under contract) HH aides to provide aide services;
- The number of HH aides per HHA (both directly employed and under contract) and whether the number has increased or decreased over the past 5-10 years;
- The average number of aide hours per beneficiary with aide service ordered on the plan of care; and
- The effect of the public health emergency on the ability of HHAs to employ HH aides or arrange for (under contract) the provision of HH aide services.

[23] See sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act.
[24] http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec_rev.pdf?sfvrsn=0.

IV. Home Infusion Therapy

A. Home Infusion Therapy Payment Categories

1. Background

The 21st Century Cures Act established a new Medicare home infusion therapy benefit effective January 1, 2021. At the same time, the 21st Century Cures Act changed payment for home infusion drugs from 95 percent of the October 2003 average wholesale price (AWP) to the latest quarter's average sales price plus 6 percent effective January 1, 2017. This statutory change resulted in a large reduction in payment for home infusion drugs. Specialty pharmacies have indicated that they used the margins from 95 percent of AWP to furnish home infusion therapy services. The Balanced Budget Act of 2018 later established a home infusion therapy services benefit transitional payment beginning January 1, 2019, effective two years earlier than the permanent home infusion therapy benefit.

Under the home infusion therapy benefit, Medicare Part B will cover professional services, including nursing services, training and education (not otherwise paid for as durable medical equipment (DME))[25], remote monitoring, other monitoring services and home infusion drugs furnished by a qualified home infusion therapy supplier in the individual's home. The patient must be under a plan of care established by a physician and under the care of a physician, nurse practitioner, or physician assistant. A home infusion drug is a parenteral drug or biological administered for 15 minutes or more through an item of durable medical equipment (DME). Local Coverage Determination on External Infusion Pumps (LCD L33794) is the source for drugs that may be covered under home infusion therapy benefit. A "qualified home infusion therapy supplier" is a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished.

2. Payment Categories

Beginning January 1, 2021, a single payment will be made to a qualified home infusion therapy supplier. The single payment amount must be adjusted to reflect wages and other costs that may vary by region, patient acuity, and the complexity of drug administration. The single payment may be adjusted to reflect outlier situations. All payment adjustments are budget neutral. CMS is required to apply an annual update based on the Consumer Price Index for all urban consumers (CPI-U) beginning January 1, 2022. Total payment for a calendar day cannot exceed the amount that would be paid under the Medicare physician fee schedule (PFS) in a physician's office for 5 hours of infusion therapy.

[25] CMS distinguishes home infusion therapy from DME. Home infusion therapy services are professional services (such as nursing services) furnished in the patient's home associated with home infusion therapy as well as the home infusion drugs themselves. Medicare Part B will cover a limited number of home infusion drugs as DME if: (1) the drug is necessary for the effective use of an external infusion pump classified as DME and (2) the pump is reasonable and necessary for administration of the drug and the drug is reasonable and necessary for the treatment of an illness or injury. The infusion pump must be appropriate for use in the home.

CMS has established the following payment categories:

Category 1: Intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs (both initial and subsequent injection/hour). G0088 for the initial visit and G0068 for subsequent visits.

Category 2: Subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions (both initial and subsequent injection/hour). G0089 for the initial visit and G0069 for the subsequent visits.

Category 3: Intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals (both initial and subsequent injection/hour). G0090 for the initial visit and G0070 for subsequent visits.

For the mapping of J codes to categories, see MLN 11880: MM11880 (cms.gov). The home infusion therapy payment category for additions to LCD L33794 and compounded infusion drugs not otherwise classified will be determined by the DME Medicare Administrative Contractors (MACs).

Each payment category is paid at amounts consistent with how the HCPCS codes for the drug administration are paid using the Physician Fee Schedule (PFS) for 2021 only. After 2021, the initial amounts are updated using the CPI-U reduced for multifactor productivity (MFP).

If drugs and biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category is made. CMS does not provide proposed payment rates for each of the three categories as the proposed 2022 physician fee schedule rates are not yet available.

Self-administered drugs (SADs) were paid under the transitional home infusion therapy benefit through December 31, 2020. Hizentra® is a self-administered drug (SAD) that was covered under the transitional home infusion payment system. As SADs do not meet the statutory definition of "home infusion drug," CMS excluded Hizentra® from coverage under the home infusion therapy benefit effective January 1, 2021. However, Division CC, section 117 of Consolidated Appropriations Act (CAA) of 2021 amended the law to allow the definition of home infusion therapy drug to include a drug or biological that was a transitional home infusion drug identified by a HCPCS code effective January 1, 2021. As Hizentra® meets this requirement, CMS will pay for this drug under the home infusion therapy benefit retroactive to January 1, 2021.

The proposed rule indicates that changes to the list of SAD drug exclusions does not require notice and comment rulemaking and can be made by the DME MACs changing LCD L33794. CMS will implement changes to the SAD exclusion list through the change request process.

B. Required Payment Adjustments for 2022 Home Infusion Therapy Services

1. Home Infusion Therapy Geographic Wage Index Adjustment

CMS adopted a policy in the 2020 HH PPS to adjust the single payment amount by the PFS geographic adjustment factor (GAF)—a weighted composite of each PFS locality's physician work, practice expense (PE), and malpractice (MP) geographic practice cost index (GPCI). The GAF is updated at least every 3 years per statute and is implemented over a 2-year phase in. The GPCIs were lasted updated in 2020 and are scheduled to be updated in the 2023 PFS proposed rule.

Application of the GAF is budget neutral so there is no overall cost impact. Proposed 2022 GAFs are not yet available so CMS is not providing the proposed budget neutrality adjustment. CMS will include this information in a forthcoming change request to implement the 2022 home infusion therapy payment amounts. The 2022 GAF will be posted as an addendum to the 2022 PFS rule at: Physician Fee Schedule | CMS

2. Payment Update

CMS proposes to increase the single payment amount annually beginning in 2022 by the percentage increase in the CPI-U, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business MFP. The CPI-U for the 12-month period ending in June of 2021 and the corresponding productivity adjustment is not yet available and will be provided in the final rule.

3. Initial and Subsequent Visit Adjustments

In the 2020 HH PPS final rule, CMS adopted a policy to increase the payment amounts for each of the three payment categories for the first visit by the relative difference in payment for a new patient versus an established patient evaluation and management (E/M) service for a given year under the PFS. Overall, this adjustment would be budget-neutral.

For 2021, CMS initially estimated a 19 percent increase in the first visit payment amount and a 1.18 percent decrease in the subsequent visit payment amounts based on the average difference between the original 2021 PFS E/M codes amounts for new and existing patients. However, subsequent changes made by Division N, section 101 of the CAA 2021 to PFS E/M payments changed these percentages to a 20 percent increase for the first visit payment amount and a 1.3310 decrease for all subsequent visits. CMS proposes to maintain these percentages for 2022.

C. 2022 Payment Amounts for Home Infusion Therapy Services

Division N, section 101 of CAA 2021 provided a 3.75 percent increase in PFS payment amounts for 2021 only. For 2022, CMS will remove the 3.75 percent increase from the PFS amounts used to establish the 2021 home infusion therapy payment rates. The resulting rates will be updated for 2022 by the CPI-U for the 12-month period ending in June of 2021 reduced by the 10-year moving average of changes in annual economy-wide private nonfarm MFP. The final home

infusion therapy 5-hour payment amounts will be released in a forthcoming change request posted at: Billing and Rates | CMS.

V. Medicare Provider and Supplier Enrollment Changes

CMS is proposing regulatory changes to its enrollment provisions that will affect all providers and suppliers, not just home infusion therapy suppliers.

A. Background – Provider and Supplier Enrollment Process

The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare meet federal and state requirements to do so. The process helps prevent unqualified and potentially fraudulent individuals and entities from being able to enroll and inappropriately bill Medicare. To enroll in Medicare, a provider or supplier must file form CMS-855 with its MAC. The MAC then reviews the information on the CMS-855 to determine whether a provider or supplier is qualified to enroll in Medicare. There are different versions of the CMS-855 depending on whether the provider or supplier is enrolling in Medicare for the first time, changing a Medicare enrollment or for other reasons (such as change of ownership).

CMS is proposing a number of changes to its enrollment regulations. Generally, these proposed regulations are adopting current long-standing policies that have only been documented in the Program Integrity Manual (PIM).

B. Proposed Provisions

1. Effective Dates

a. Effective Date of Billing Privileges.

Current policy allows billing privileges to be effective on the date that is the later of: (1) the date of filing of a Medicare enrollment application that a Medicare contractor subsequently approved; or (2) the date that the provider or supplier first began furnishing services at a new practice location. Providers and suppliers can retrospectively bill for services when they have met all program requirements (including state licensure), and services were provided at the enrolled practice location for up to—

- Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act precluded enrollment in advance of providing services to Medicare beneficiaries.

Under 42 CFR §§ 424.520(d) and 424.521(a), CMS applied these policies to physicians, non-physician practitioners, ambulance suppliers, opioid treatment programs and home infusion therapy suppliers. Under PIM guidance, CMS applied these policies to: (1) Part B hospital

departments; (2) Clinical Laboratory Improvement Amendment laboratories; (3) intensive cardiac rehabilitation facilities; (4) mammography centers; (5) mass immunizers/pharmacies; (6) radiation therapy centers; (7) physical therapists; (8) occupational therapists; and (9) speech language pathologists.

CMS proposes to add these latter nine provider and supplier categories to 42 CFR §§ 424.520(d) and 424.521(a).

b. Effective Dates of Reassignments

Reassignments. Employee physicians typically reassign Part B benefits to an employer. To do so, the physician files a form CMS-855R application. If the physician is not enrolled in Medicare, they physician must also complete form CMS-855I. Under the applicable PIM guidance, the effective date of reassignments is applied as described above. CMS proposes to add a new 42 CFR § 424.522 to codify these policies in regulation.

Practitioner Enrolling Solely to Order or Certify. There are some physicians that enroll in Medicare solely to order: (1) imaging services; (2) clinical laboratory services; (3) durable medical equipment, prosthetics, orthotics, and supplies; and/or (4) home health services. These physicians do not seek payments from Medicare. Form CMS-855O is the enrollment application to enroll in Medicare solely to order/certify items and services without receiving payment from Medicare. Under PIM guidance, the effective of date of enrolling only to order/certify items and services is the date the MAC received the application. CMS proposes to codify this requirement in new 42 CFR § 424.522(b).

2. Rejections and Returns

The proposed rule distinguishes between a "rejected" and "returned" CMS-855 enrollment application. A rejected application is one in which the MAC has reviewed the information and rejected the provider or supplier as being unqualified to enroll. However, CMS indicates that an applicant can usually remedy the problem prior to rejection either within 30 days of submitting the enrollment application or the MAC's request for additional or corrected information. A "returned" application is one that cannot be remedied without an entirely new application because the initial submission was invalid or otherwise could not be accepted and processed.

42 CFR § 424.525(a) currently provides the following three reasons for an application being rejected.

- The prospective provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the MAC's request for the missing information.
- The prospective provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.
- The prospective institutional provider does not submit the application fee in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.

The PIM provides nine other reasons for rejecting an enrollment application. CMS proposes to modify 42 CFR § 424.525(a) to include the following ten rejection scenarios (nine of which were previously included in the PIM):

- The application is missing required data needed to process the application (such as, but not limited to, names, social security number, contact information, and practice location information).
- The application is unsigned or undated.
- The application contains a copied or stamped signature.
- The application is signed more than 120 days prior to the date on which the Medicare contractor received the application.
- The application is signed by a person unauthorized to do so under 42 CFR Part 424, subpart P.
- For paper applications, the required certification statement is missing.
- The paper application is completed in pencil.
- The application is submitted via fax or e-mail when the provider or supplier was not otherwise permitted to do so.
- The provider or supplier failed to submit all of the forms needed to process a form CMS-855 reassignment package within 30 days of receipt.
- The provider or supplier submitted the incorrect form CMS-855 application.

CMS further proposes new 42 CFR § 424.526(a) providing the following grounds for returning a provider or supplier enrollment application (although the MAC may return the application, it is not required to):

- The provider or supplier sent its paper form application CMS-855, form CMS-588, or form CMS-20134 application to the incorrect Medicare contractor for processing.
- The Medicare contractor received the application more than 60 days prior to the effective date listed on the application. For providers and suppliers submitting a form CMS-855A application, ambulatory surgical centers, or portable x-ray suppliers, the timeframe is 180 days.
- The seller or buyer in a change of ownership submitted its form CMS-855A or form CMS-855B application more than 90 days prior to the anticipated date of the sale.
- The MAC confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.
- The provider or supplier submitted an initial enrollment application prior to the expiration of their existing reenrollment bar under 42 CFR § 424.535 or reapplication bar under 42 CFR § 424.530(f).
- The application is not needed for (or is inapplicable to) the transaction in question.
- The provider or supplier submitted a revalidation application more than 7 months prior to the provider's or supplier's revalidation due date.
- A Medicare Diabetes Prevention Program supplier submitted an application with a coach start date more than 30 days in the future.
- The provider or supplier requests that their application be withdrawn prior to or

during the MAC's processing.

- The provider or supplier submits an application that is an exact duplicate of an application that (1) has already been processed or (2) is currently being processed or is pending processing.
- The provider or supplier submits a paper form CMS-855 or form CMS-20134 application that is outdated and/or has been superseded by a revised version.
- In situations where the provider or supplier submits a form CMS-855A or form CMS-855B initial enrollment application followed by a form CMS-855A or form CMS-855B change of ownership application and the MAC:

    - Has not yet made a recommendation for approval concerning the initial application, both applications may be returned.
    - Has made a recommendation for approval concerning the initial application, the Medicare contractor may return the change of ownership application.

  If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial form CMS-855A or form CMS-855B application containing the new owner's information within 30 days of the date of the letter, the MAC may return the originally submitted initial form CMS-855A or form CMS-855B.

Several of these return grounds involve situations where the application is submitted prematurely requiring contractors to hold and track the submitted application for many months until the application could be processed at a time closer to the supplier's commencement date. To alleviate contractors of this burden, the PIM identified various dates before which the provider or supplier could not submit an application. CMS proposes to add these dates to the 42 CFR § 424.526.

CMS further proposes to modify the regulations to state that a provider or supplier may not appeal a return of their enrollment application and clarify that all of the provisions apply for both rejections and returns of all CMS provider enrollment forms.

3. Deactivation

Deactivation means that the provider's or supplier's billing privileges are stopped but can be reactivated without reenrolling. Revocation that means the provider or supplier no longer has billing privileges and must reenroll to obtain them. 42 CFR § 424.540(a) lists the following grounds for deactivation:

- The provider or supplier does not submit any Medicare claims for 12 consecutive calendar months.
- The provider or supplier does not report a change in its enrollment information within 90 calendar days of the change. (Changes in ownership or control must be reported within 30 calendar days.)

- The provider or supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification to submit a revalidation.
- For changes of ownership:

    - A prospective new owner fails to submit a new enrollment application containing information within 30 days of the change of ownership;
    - A change of ownership application is submitted containing material omissions; or
    - CMS has information that makes it question whether the provider agreement will be transferred to the new owner.

To reactivate billing privileges, the provider or supplier must: (1) recertify that their enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate; or (2) submit a complete Form CMS-855 application if required.

CMS proposes to include the following additional grounds for deactivation 42 CFR § 424.540(a):

- The provider or supplier is not in compliance with all enrollment requirements in Title 42 CFR.
- The provider's or supplier's practice location is non-operational or otherwise invalid.
- The provider or supplier is deceased.
- The provider or supplier is voluntarily withdrawing from Medicare.
- The provider is the seller in an HHA change of ownership under 42 CFR § 424.550(b)(1).

No new policy is being made with this proposal. The first two bases above are already included in sub-regulatory guidance while the latter three are technical and non-substantive.

CMS further proposes to revise 42 CFR § 424.540(b)(1) to state: "In order for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title."

Consistent with current policy, CMS further proposes to modify the regulation to state that the deactivation date is the date that the provider's or supplier's action or non-compliance occurred or commenced and it may be a retroactive date. For the last three reasons listed above, the deactivation date would be the date of provider's or supplier's death, withdrawal from Medicare or change of ownership, respectively.

Under current policy, the PIM has permitted retroactive payment to bill for services or items furnished up to 30 days prior to the effective date of the reactivation. However, CMS proposes to change this policy to prohibit such payments altogether for program integrity purposes and to avoid rewarding non-compliance with enrollment requirements.

CMS is further proposing to:

- Eliminate the opening sentence of 42 CFR § 424.540(c) that states deactivation "is considered an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments" on the basis that this language is overly restrictive and does not fully describe all of the reasons why a provider or supplier enrollment may be deactivated.
- Clarify that existing deactivation authority under 42 CFR § 424.540(a)(2) applies to both the changes of ownership that must be reported within 90 days and those within 30 days by deleting the existing language and stating that deactivation is permitted if the provider or supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under this title.
- Incorporate the applicable PIM guidance into 42 CFR § 424.540(d)(2) with a modification to state that reactivation is generally the date on which the Medicare contractor approved a reactivation application (as opposed to "processing it to completion.").

4. HHA Capitalization

HHAs are required to have sufficient initial reserve operating funds during the 3-month period following the conveyance of Medicare billing privileges. To enable CMS or the MAC to verify compliance with these requirements, the HHA must submit adequate proof of the availability of initial reserve operating funds. 42 CFR § 489.28(d) states that bank statements must "accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA." As several national bank chains are no longer providing these attestation statements, CMS proposes to insert "(if the financial institution offers such attestations)" after the term "financial institution" in 42 CFR § 489.28(d) and (e).

5. HHA Changes of Ownership

If there is a change in majority ownership of an HHA by sale within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the HHA's provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must: (1) enroll in Medicare as a new (initial) HHA; and (2) obtain a state survey or accreditation.

These rules are intended to prevent HHA ownership from transferring to an unqualified party. However, CMS recognizes there are instances where qualified HHAs change their ownership without any intent to circumvent a state survey or initial enrollment. There are several exceptions in which the 36-month rule does not apply including one for HHAs that have submitted 2 consecutive years of full cost reports. To address provider questions, CMS is clarifying that this rule applies to initial enrollments and a change in majority ownership.

VI. Survey and Enforcement Requirements for Hospice Programs

A. Background

CMS reviews the statutory and regulatory history of the hospice program. Section 1864(a) of the Act authorizes the State survey agencies (SAs) or other appropriate local agencies, under an agreement with CMS, to perform surveys of health care providers and suppliers to assess their compliance with applicable Medicare requirements. Section 1865(a) of the Act allows most health care facilities to demonstrate their compliance through accreditation by a CMS-approved Accrediting Organization (AO) instead of a SA survey. AOs accreditation standards must meet or exceed the applicable Medicare program requirements. Providers and suppliers have the choice to seek accreditation from an approved AO or seek Medicare certification through the SA.

CMS is responsible for providing oversight of the AOs' accreditation programs, ensure AOs have formalized procedures to ensure health care facilities meet the AOs accreditation standards, and ensure that the AOs accreditation standards meet or exceed the Medicare program requirements. Current regulations at §488.4 establish the general provisions for CMS-approved accreditation programs for providers and suppliers. The requirements at §488.5 establish the application procedures for national AOs seeking to obtain CMS approval of their accreditation programs (referred to as "deeming authority").

As of March 2021, three AOs have CMS-approved hospice accreditation programs: Accreditation Commission for Health Care, Inc. (ACHC), Community Health Accreditation Partner (CHAP), and The Joint Commission (TJC). Approximately half of the over 5,000 Medicare-certified hospice programs are surveyed by these three AOs.

B. Provisions of the Proposed Rule

1. Overview

The CAA 2021[26] added a new section 1822 and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements. CMS proposes to add new subparts M and N to 42 CFR part 488. Subpart M would provide survey and certification processes and subpart N would provide enforcement remedies for hospice programs with deficiencies that are not in compliance with Medicare requirements. CMS proposes to amend terminations and appeals requirements in 42 CFR parts 489 and 498 based on the proposed enforcement remedies.

CMS summarizes the effective date for these provisions. Unless noted below, provisions in the legislation were effective upon enactment of the CAA 2021, December 27, 2021.

[26]Division CC, section 407 of the CAA 2021

2. Subpart A: General Provisions

a. Statutory Basis (§§ 488.2 and 498.1)

The CAA 2021 added section 1822 of the Act for hospice program survey and enforcement procedures. CMS proposes to amend the requirements at §488.2 and at §498.1 to include this statutory reference to hospice program services.

b. Application and Re-Application Procedures for National Accrediting Organizations (§488.5)

As part of the hospice program AO's application and reapplication process, CMS proposes at §488.5(a)(4)(x) to require AOs to submit a statement acknowledging that the AO will include a statement of deficiencies (the Form CMS-2567 or a successor form) to document findings of the hospice Medicare CoPs in a manner specified by CMS. This provision of the CAA 2021 is effective on October 1, 2021.

Currently, AOs are required to submit documentation of survey findings, but they not required to utilize the same form as SA surveyors when documenting survey findings of noncompliance. Each of the three AOs with CMS-approved hospice program deeming authority have a unique proprietary software with a unique survey report for their organizations. The AO's survey reports include the deficiencies related to CMS requirements and any additional AO standards combined into one report.

Form CMS-2567 (Statement of Deficiencies and Plan of Correction)[27] is the legal form used by SAs and CMS Federal surveyors to report findings of compliance and noncompliance (deficiencies) from an inspection of Medicare-participating providers and suppliers. SAs are required to document all deficiency findings on Form CMS-2567 (§488.18). CMS regulations delineate how findings must be recorded, including the evidence to support each finding. The provider/supplier uses the form to document their plan for correcting deficiencies. CMS' Automated Survey Processing Environment (ASPEN) survey software is the national database used by SAs to collect and manage healthcare provider data. The ASPEN system is being transitioned to a new, web-based Internet Quality Improvement and Evaluation System (iQIES). CMS will begin starting transition of HHAs to this system in mid-2021.

CMS discusses the challenges related to AOs using and submitting the Form CMS-2567 to CMS. Although AOs can access the online PDF version of the Form CMS-2567 they do not have access to the ASPEN system. AOs use the database, Accrediting Organization System for Storing User Recorded Experiences (ASSURE), to submit their AO survey findings to CMS. CMS notes the ASSURE system does not and cannot develop a statement of deficiency of findings on Form CMS-2567. CMS states it is unable to tell the AOs exactly how to incorporate the Form CMS-2567 into their proprietary systems but will work with the AOs to determine how this form can be submitted to CMS via electronic data exchange. CMS also needs to update the format of the Form CMS-2567 to include a place for the name of the AO performing the survey

[27] Form CMS-2567 is available at https://www.cms.gov/Medicare/CMS-Forms/CMS/Downloads/CMS2567.pdf

and is in the process of seeking approval of this revised form in accordance with provisions of the Paperwork Reduction Act (PRA).

CMS seeks **comment** on how AOs can customize their proprietary systems to incorporate a version of the Form CMS-2567 and then submit it to CMS via electronic data exchange.

c. Release and Use of Accreditation Surveys (§ 488.7)

CMS proposes the Form CMS-2567 must be posted in a manner that is prominent, easily accessible, readily understandable, and searchable by the public and is timely updated.

Prior to the CAA 2021, CMS did not have the authority to publish AO surveys for deemed hospice programs except for information related to an enforcement action taken by CMS against the provider. CMS reports SA complaints or validation survey results on the Quality, Oversight, and Certification Reports (QCOR) public website.[28]

CMS acknowledges the various system challenges to integrate AO survey results on the Form CMS-2567. Based on the CAA 2021, CMS is removing the prohibition that allowed AO hospice program survey reports to be considered confidential and proprietary. CMS also proposes to require that AOs release deficiency reports for hospice program surveys conducted under their deeming authority to increase transparency for the hospice beneficiary community.

CMS acknowledges that releasing national survey data will require collaboration with stakeholders to assure the development of the data is fair and equitable across all hospice programs and is useable by the public. CMS seeks **comments** on the following:

- How data elements from the Form CMS-2567 may be utilized and displayed.
- Other recommendations for relevant provider information that will assist the public in obtaining a more comprehensive understanding of a hospice's overall performance.

The CAA 2021 provision requiring public disclosure of survey information is effective no later than October 1, 2022.

d. Providers or Suppliers, Other than SNFs, NFs, HHAs, and Hospice Programs with Deficiencies (§ 488.28)

Providers or suppliers deficient in one or more of the standards in the CoPs, must submit an acceptable plan of correction (POC) for achieving compliance. An acceptable POC must be received within a reasonable time to continue Medicare participation. A provider/supplier is expected to achieve compliance within 60 days of being notified of the deficiencies; the SA may recommend additional time as needed. SNFs, NFs, and HHAs are exempt from this requirement; similar provisions are established in the regulations specific to these provider types.

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[28] The QCOR website can be accessed at https://qcor.cms.gov.

Section 1822(c) of the Act authorizes the Secretary to take actions to ensure the removal and correction of condition-level deficiencies in a hospice program through an enforcement remedy or termination or both. A non-compliant hospice program must submit a POC for approval by the SA or CMS. CMS proposes revising the heading for §488.28 to indicate that hospice programs would also be exempt from these enforcement requirements. Proposed new subpart N (discussed below) outlines the enforcement remedy requirements for hospices.

3. Proposed New Subpart M: Survey and Certification of Hospice Programs

a. Basis and Scope (§488.1100)

The proposed regulations at §488.1100 is based on the rulemaking authority in section 1822 of the Act and additional specific statutory provisions discussed in the proposed rule.

b. Definitions (§488.1105)

CMS proposes the following definitions for the hospice program:

- *Abbreviated standard survey* would mean a focused survey other than a standard survey that gathers information on hospice program's compliance with specific standards or CoPs. An abbreviated survey may be based on complaints received or other indicators such as media reports or OIG investigations.
- *Complaint survey* would mean a survey that is conducted to investigate substantial allegations of noncompliance as defined in § 488.1.
- *Conditional-level deficiency* would mean noncompliance as described in §488.24 of Subpart M.
- *Deficiency* would mean a violation of the Act and regulations in 42 CFR part 418, subparts C and D, determined as part of a survey, and can be either standard or condition-level.
- *Noncompliance* would mean any deficiency found at the condition-level or standard-level.
- *Standard-level deficiency* would mean noncompliance with one or more of the standards that make up each CoP for the hospice program.
- *Standard survey* would mean a survey conducted in which the surveyor reviews the hospice program's compliance with a selected number of standards and/or CoPs to determine the quality of care and services furnished by a hospice program,
- *Substantial compliance* would mean compliance with all condition-level requirements as determined by CMS or the State.

c. Hospice Program Surveys and Hospice Program Hotline (§488.1100*)*

CMS proposes the following requirements for hospice program surveys:

- A standard survey would be conducted not later than 36 months after the date of the previous standard survey.
- A survey could be conducted more frequently than 36 months to assure that hospice services comply with CoPs and confirm that the hospice program corrected previously

cited deficiencies.
- A standard or abbreviated standard survey would be conducted when complaint allegations against the hospice were reported to CMS, the state, or local agency.

CMS acknowledges that for AOs with hospice deeming programs, the proposed 36-month survey requirement would mirror the current requirements for AOs to describe the frequency of surveys as part of the AO application process (§488.5(a)(4)(i)).

Section 1864(a) of the Act requires that agreements between the Secretary and the State, under which SAs carry out the certification process, shall provide for the State or local agency to establish a toll-free hotline for HHAs and to maintain a unit for investigating HHAs complaints. The CAA 2021 amended these requirements to include a new hospice program hotline that is effective 1 year after the enactment of the CAA, December 27, 2021. CMS proposes that the State or local agency is responsible for establishing and maintaining a toll-free hotline to receive complaints (and answer questions) about hospice programs in the State or locality and for maintaining a unit to investigate these complaints.

CMS intends to describe the requirements for the hotline in the annual CMS Quality, Safety and Oversight Group's Mission and Priority Document (MPD). The MPD serves as the scope of work which State Agencies are contractually required to follow.

To help develop the hospice toll-free hotline, CMS requests **comments** about current experiences with the HHA toll-free hotline. Specifically, CMS requests information about what data elements and processes should be included to assure confidentiality and immediate communication with SAs to facilitate prompt responses.

d. Surveyor Qualifications and Prohibition of Conflicts of Interest (§488.1115)

Section 1822(a)(4)(C) of the Act requires the Secretary to provide training for State and Federal surveyors, and any surveyor employed by the AO, including a training and testing program approved by the Secretary, no later than October 1, 2021. No surveyor can conduct hospice program surveys until they complete training and testing.

CMS describes the current AO requirements for training surveyors (§488.5(a)(8)). As part of the AO application and reapplication process, the AO is required to submit a description of the content and frequency of the training provided to survey personnel. CMS proposes the following:
- All SA and AO hospice program surveyors would be required to take CMS-provided surveyor basic training currently available, and additional training as specified by CMS.
- Until this rule is finalized, CMS will accept the current training that was previously reviewed and approved by CMS during the AO application process.

CMS believes that SA surveyors are already in compliance with the new training requirement.

CMS notes that AOs have voluntary access to the Quality, Safety & Education Portal (QSEP)[29] which contains the CMS training. CMS is updating the hospice program basic training to include enhanced guidance for surveyors that will emphasize assessment of quality of care. The revised training will emphasize the requirements for establishing individualized written plan of care and regular update of these plans. CMS invites commenters to review the trainings by obtaining a free account on the QSEP website.[30] CMS invites **comments** on the requirement for continued SA and AO surveyor training as CMS releases additional basic course updates.

In accordance with section 1822(a)(4)(B) of the Act, CMS proposes to establish requirements that will disqualify a surveyor from surveying a particular hospice. CMS notes that the statute specifically addresses SA surveyors, but given the importance of this issue, it is proposing to also include hospice AO surveyors in the proposed requirements.

CMS describes the current requirements to mitigate conflicts of interest in the HHA survey process. In addition, CMS' longstanding policy noted in section 4008 of CMS' State Operations Manual (SOM) describes examples of scenarios that would be conflicts of interest for SA surveyors of any provider or supplier type, including surveyors with an outside relationship with a facility surveyed by the SA. CMS notes the SOM generally applies only to SA surveyors.

CMS proposes the following for both SA and AO surveyors to ensure there is no conflict of interest between the organization and the surveyor:

- A surveyor would be prohibited from surveying a hospice program if the surveyor currently serves, or within the previous two years has served, on the staff of or as a consultant to the hospice program undergoing the survey.
    - The surveyor could not have been a direct employee, employment agency staff at the hospice program, or an officer, consultant, or agent for the surveyed hospice program regarding compliance with CoPs.
- A surveyor would be prohibited from surveying a hospice program if they have a financial interest or an ownership interest in that hospice.
- The surveyor would be disqualified if they have an immediate family member who has a financial interest or ownership interest with the hospice program to be surveyed or has an immediate family member who is a patient of the hospice program to be surveyed.
    - Immediate family member includes husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.[31]

[29] The QSEP website can be accessed at https://qsep.cms.gov.
[30] The trainings can also be accessed by choosing the "Public Access" button on the upper right-hand corner of the QSEP website homepage.
[31] §411.351

e. Survey Teams (§ 488.1120)

Section 1822(a)(4)(A) of the Act requires the use of multidisciplinary survey teams when the survey team consists of more than one surveyor, with at least one person being a RN. This provision is effective on October 1, 2021.

CMS discusses the current requirements for SA surveyors in the SOM, Appendix M. CMS proposes under a new subpart M to require that SAs and AOs include diverse professional backgrounds among their surveyors to reflect the professional disciplines responsible for providing care to hospice patients. Multidisciplinary teams should include professionals included in hospice core services and may include physicians, nurses, medical social workers, pastoral, or other counselors.

CMS discusses the challenges that SAs and AOs might have to fulfill this CAA requirements, including time to reconstruct the survey workforce, additional costs for potentially higher rates of average pay for some disciplines, and training requirements. To help track compliance with this provision, CMS proposes to collect the following: (1) the extent to which surveys are conducted by one professional, who by regulation must be a registered nurse; (2) the professional makeup of their current workforce; and (3) a timeframe estimate in which they could effectuate multidisciplinary teams if not already in place.

Hospice programs must use interdisciplinary teams or groups to determine a plan of care for the hospice program patient and family that includes a physician, a RN, a medical social worker, and pastoral or other counselor (§481.56). CMS proposes that when the survey teams has more than one surveyor, the additional positions would be filled by professionals from among these disciplines. To implement this new requirement for hospice multidisciplinary survey teams, CMS is considering using its current guidance for long-term care facilities, which uses specialty surveyors with expertise not typically included in a survey team (e.g., a pharmacist, physician, or registered dietitian) who may not be needed for the entire survey, but must be onsite at some time during the survey.

f. Consistency of Survey Results (§ 488.1125)

Section 1822(a)(3) of the Act requires that each State and the Secretary implement programs to measure and reduce inconsistency in the application of hospice program survey results among surveyors. To ensure consistency of survey results across SAs, CMS believes this requirement also applies to reducing discrepancies between SA and AO surveys of hospice providers.

CMS proposes to enhance the requirements of the State Performance Standards System (SPSS) to direct States to implement processes to measure the degree or extent to which surveyors' findings are aligned with federal regulatory compliance and with an SA supervisor's determination. CMS states it expects to promulgate objective measures of survey accuracy; accuracy could be whether a survey finding aligns with the selected regulatory deficiency as well as failing to cite a deficiency. CMS seeks **comments** on what measures are feasible for States and measures that utilize currently collected data. CMS wants measures that would allow it to determine the need for corrective action or education for individual surveyors or for groups of surveyors.

CMS discusses the current processes used to monitor consistency of hospice surveys. Consistency among SAs includes review of an SA's Form CMS-2567s by the assigned CMS Survey Operations Group (SOG) Location. Consistency among AOs is determined through validation surveys conducted by SAs. Validation surveys report disparate findings as the percentage of validation surveys that have conditions identified by the SA but missed by the AO survey team; this percentage is known as the disparity rate. CMS reports the AO's disparity rate annually to Congress.[32]

CMS discusses the processes it uses for validation surveys for other provider types, including nursing homes. CMS believes that a similar methodology could be applied to all hospice surveying entities.

CMS proposes to require agencies that review other entities' survey findings for missed condition-level deficiency citations[33] notify each survey entity of its disparity rate annually and to require a formal corrective action plan as part of the survey entity's (SA or AO) Quality Assurance program. CMS notes this includes SAs review for AOs and CMS SOG Locations for SAs. A disparity rate above 10 percent in 2 consecutive cycles would trigger remedial activity such as implementing corrective action through education or mentoring and determinations of deficiencies with regulatory requirements.

g. Special Focus Program (SFP) (§ 488.1130)

Section 1822(b) of the Act requires the Secretary to conduct a SFP for hospice programs that the Secretary identified as substantially failing to meet applicable requirements of the Act.

CMS proposes a hospice program may be required to participate in a SFP if any one of the following criteria exists:

- The hospice program is found to be deficient with condition-level findings during two consecutive standard surveys.
- The hospice program is found to be deficient with condition-level findings during two consecutive complaint surveys.
- The hospice program is found to be deficient with two or more condition-level findings during a validation survey.

CMS proposes that it would provide the State SA's with a list of hospice programs identified as meeting the proposed criteria for inclusion in the SFP. A program that meets the criteria will be placed on the SFP candidate list. The SA and CMS SOG Location would select a subset of

[32] The most recent report can be found at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Administrative-Information-Memos-to-the-States-and-Regions-Items/AdminInfo-20-02-ALL.

[33] A condition-level deficiency requires remediation and could lead to termination of the hospice program.

hospice programs for the SFP. CMS notes it uses a similar program with long-term care facilities.

CMS proposes that SAs would conduct an onsite survey of each hospice in the SFP not less than once every 6 months to examine all of the Medicare CoPs and recommend enforcement remedies. Once an SFP hospice program has complemented two consecutive 6-month SFP surveys with no condition-level deficiencies cited, the facility would graduate from the SFP. If the hospice program did not meet the requirements to graduate, it would be placed on a termination track.

CMS invites **comments** on the following issues:

- Should CMS utilize a similar criteria/process/framework for the SFP as used in the Long-Term Care Program. What if any differences should CMS consider to enhance the overall impact of the hospice SFP?
- Additional selection criteria that CMS should consider for the identification and participation in the SFP, including the use of current or future data elements that could be incorporated into a more comprehensive algorithm.
- Utilization of a Technical Expert Panel (TEP) to enhance the SFP with selection, enforcement, and technical assistance criteria. CMS states that a TEP may identify data and relevant information to assist the public in understanding the Form CMS-2567 survey data and the overall performance of a hospice provider.

4. Proposed New Subpart N – Enforcement Remedies for Hospice Programs with Deficiencies

a. Statutory Basis (§ 488.1200)

Section 1822(c) of the Act authorizes the Secretary to take actions to remove and correct deficiencies in a hospice program through additional enforcement remedies. This requirement to develop and implement a range of enforcement remedies is effective no later than October 1, 2022. Prior to the enactment of this section, the only enforcement action available to CMS was the termination of a hospice's Medicare provider agreement.

b. Definitions (§ 488.1205)

CMS proposes the following definitions for the hospice program:

- *Directed plan of correction* means CMS or the temporary manager (with CMS/SA approval) may direct the hospice program to take specific corrective action to achieve specific outcomes within specific timeframes.
- *Immediate jeopardy (IJ)* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient(s).
- *New admission* means an individual who becomes a patient or is readmitted to the hospice program on or after the effective date of a suspension of a payment remedy.
- *Per instance* means a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a remedy.

- *Plan of correction (POC)* means a plan developed by the hospice program and approved by CMS. The plan is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.
- *Repeat deficiency* means a condition-level deficiency that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency cited on the most recent previous standard survey or any intervening survey since the most recent standard survey. Repeated non-compliance is not on the basis that the exact regulation for the deficiency was repeated.
- *Temporary management* means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator. The hospice program's governing body must ensure that the temporary manager has the authority to hire, terminate or reassign staff, obligate fund, alter procedures and manage the hospice program to correct deficiencies.

c. General Provisions (§ 488.1210)

CMS proposes general rules pertaining to enforcement actions against a hospice program that is not in substantial compliance with CoPs. If CMS determines that a hospice program is not in compliance with CoPs and the deficiencies may pose IJ to the health and safety of individuals under the care of the hospice program, CMS may terminate the hospice program's provider agreement, impose one or more enforcement remedies, or both. CMS' decision will be based on the degree of noncompliance with the hospice program Federal requirements.

CMS proposes the following additional general provisions:

- Regardless of which remedy is applied, a non-compliant hospice program must submit a POC for approval by CMS or the State Survey Agency. The POC must be submitted within 10 calendar days from receipt of the statement of deficiencies. CMS would determine if the POC was acceptable.
- The notification requirements for enforcement activities would be issued by CMS. CMS would provide a note of intent to the hospice program that would include the intent to impose a remedy, the statutory basis, the nature of the noncompliance, the proposed effective date of the sanction, and the appeal rights. For payment suspensions, the notice would also identify which payments are being suspended, and for civil monetary penalties (CMPs), the amount being imposed.
- For all remedies imposed, except for CMPs, when there is IJ, the notice period is at least 2 calendar days before the effective date of the enforcement action. When there is no IJ, then the notice period is at least 15 calendar days before the effective date of the enforcement action.
- For CMPs, once the administrative determination to impose the CMP is final, CMS would send a final notice to the hospice program with the amount of the penalty assessed, the total number of days of noncompliance, the total amount due, the due date of the penalty, and the rate of interest on unpaid balances.
- The hospice program could appeal the determination of noncompliance leading to the imposition of a remedy under the provisions of 42 CFR 498. A pending hearing would

not delay the effective date of the remedy against the hospice program and remedies will be in effect regardless of any pending appeals proceedings. CMPs would accrue during the pendency of an appeal, but would not be collected until the administrative determination is final.

CMS notes that an AO cannot recommend or implement enforcement remedies; AOs communicate any condition-level findings to the applicable CMS SOG Location. CMS makes any determination regarding the imposition of enforcement remedies. CMS notes that in accordance with SOM Chapter 2, section 205B, it may temporarily remove deemed status of an accredited hospice program due to condition-level findings and if deficiencies remain uncorrected oversight of the hospice program is transferred to CMS. When an enforcement remedy is imposed on a formerly accredited hospice program and deemed status is removed, oversight of the hospice program is performed by the SA.

d. Factors to be Considered in Selecting Remedies (§ 488.1215)

CMS discusses its discretion to impose enforcement remedies and termination of a hospice program's participation in the Medicare program. CMS states the choice of any enforcement remedy or termination would reflect the impact on patient care and the seriousness of the hospice's patterns of noncompliance.

CMS proposes the following factors, that are consistent with the factors used for HHAs, when determining which remedy to apply:

- The extent to which the deficiencies pose IJ to patient health and safety.
- The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.
- The presence of repeat deficiencies (defined as condition-level), the hospice program's compliance history in general, and specifically concerning the cited deficiencies, and any history of repeat deficiencies at any of the hospice program's additional locations.
- The extent to which deficiencies are directly related to a failure to provide quality patient care.
- The extent to which the hospice program is part of a larger organization with documented performance problems.
- Whether the deficiencies indicate a system-wide failure of providing quality care.

e. Available Remedies (§ 488.1220)

Section 1822(c)(5)(B) of the Act explicitly provides the following enforcement remedies to be included in the available remedies:

- CMPs in an amount not to exceed $10,000 for each day of noncompliance.
- Suspension of all or part of the payments.
- Appointment of temporary management of the hospice program.

In addition to those remedies specified in statute, CMS propose to add the following remedies:

- Directed POC.

- Directed in-service training.

f. Action when Deficiencies Pose Immediate Jeopardy (§ 488.1225) and Termination (§ 489.53)

If there is IJ to the hospice program's patient health or safety, CMS proposes it would take immediate action to ensure the removal of the IJ and to correct deficiencies or terminate the provider agreement. If the IJ is not resolved within 23 days from the last day of the survey, because the hospice program is unwilling or unable to correct the deficiencies, CMS would terminate the hospice's provider agreement. CMS may also impose one or more enforcement remedies. CMS proposes that for deficiencies that pose IJ, CMS would provide the hospice program with at least 2 days advance notice of any proposed remedies, except CMPs. CMS notes that under its existing survey process, providers are informed of any IJ finding during the survey or as part of the exit conference.

For terminations, CMS proposes it would provide the hospice program notice within 2 days before the effective date of the termination (this is consistent with the requirements for HHAs). CMS proposes it would require a hospice program whose provider agreement is terminated to appropriately and safely transfer patients to another local hospice program within 30 days of termination. The hospice would be responsible for providing information, assistance, and any arrangements necessary for the transfer of its patients.

g. Action when Deficiencies are at the Condition-level but do not Pose Immediate Jeopardy (§ 488.1230)

In section 1822(c)(2) of the Act, if the Secretary determines that a hospice program is no longer in compliance with the CoPs, either because the condition-level deficiencies substantially limit the provider's ability to furnish adequate care but do not pose IJ, or the hospice program has repeat condition-level deficiencies, CMS may impose remedies instead of terminating the hospice's. Enforcement remedies would be imposed before the termination becomes effective, but cannot continue for a period that exceeded 6 months. Enforcement remedies would continue until the hospice program achieves compliance or has its Medicare participation terminated.

Consistent with the general rule for providers and supplies, CMS proposes that CMS would provide the hospice program at least 15 days advance notice of any proposed remedies, except for CMPs.

h. Temporary Management (§ 488.1235)

CMS proposes that temporary management would be imposed when a hospice program is determined to have condition-level deficiencies and that the deficiencies or the management limitations of the hospice program are likely to impair the hospice's ability to correct the deficiencies and return the hospice program to compliance with all of the CoPs within the required timeframe. CMS proposes to impose temporary management within 6 months of the date of the survey identifying noncompliance.

If the hospice program refuses to relinquish authority and control to the temporary manager,

CMS will terminate the hospice's provider agreement. If the temporary manager was appointed, but the hospice failed to correct the condition-level deficiencies within 6 months from the last day of the survey, the hospice's Medicare participation would be terminated. The appointment of a temporary manager would not relieve the hospice program of its responsibility to achieve and maintain compliance with the participation requirements.

CMS proposes the temporary management would end when one of the following occur:

- CMS determines that the hospice program has achieved substantial compliance and has the management capability to remain in compliance.
- CMS terminates the provider agreement.
- The hospice program resumes management control without CMS approval. In this case, CMS may impose additional enforcement remedies.
- Temporary management will not exceed a period of 6 months from the date of the survey identifying noncompliance.

CMS proposes the hospice program has to agree to pay the temporary manager's salary for the duration of the appointment. The salary would not be less than the amount equivalent to the prevailing salary paid by providers in the geographic area for positions of this type based on the BLS, National Occupational Employment and Wage Estimates. In addition, the hospice would have to pay for any additional costs that the hospice program may have incurred if the person has been in an employment relationship, and any other costs incurred by such a person in furnishing services under such an agreement or as otherwise set by the State. Failure to pay the salary would be considered a failure to relinquish authority and control to temporary management.

i. Suspension of Payment for All or Part of the Payments (§ 488.1240)

CMS proposes if a hospice has a condition-level deficiency (regardless of whether or not an IJ exists, it may suspend all or part of the payments to which a hospice would otherwise be entitled to on or after the effective date of the enforcement remedy. CMS will determine whether to impose a suspension of payment based on the factors outlined in proposed § 488.1215 (discussed above) that are considered when selecting remedies. CMS proposes that payment suspension would be for a period not to exceed 6 months and would end when the hospice program either achieved substantial compliance or was terminated.

The hospice program may not charge a newly admitted hospice patient who is a Medicare beneficiary for services for which Medicare payment is suspended unless the hospice can show that before initiating care it provided oral and written notice of the suspension of Medicare payment to the beneficiary or their representative.

j. CMPs (§ 488.1245)

Section 1822(c)(5)(C) of the Act outlines the requirements for CMP procedures. CMS proposes to impose a CMP against a hospice for either the number of days the program is not in compliance with one or more CoPs or for each instance that a program is not in compliance, regardless of whether the hospice's deficiencies pose IJ. CMS could also impose a CMP for the

number of days of IJ. The statute limits the CMP amount to $10,000 for each day of noncompliance. CMS notes these proposals align with the impositions of CMPs for HHAs.

CMS proposes both per-day and per-instance CMP; a per-day and a per-instance CMP may both be imposed simultaneously for the same deficiency in conjunction with a survey. CMS proposes to define "per instance" as a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a remedy. CMS may impose a CMP for the number of days of noncompliance since the last standard survey, including the number of days of IJ.

In addition to the factors described at §488.1215 (discussed above), CMS proposes that it would consider the following factors when determining a CMP amount:

- The size of the hospice program and its resources.
- Evidence that a hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the CoPs.

The statute allows CMS to adjust penalties based on revisit survey findings. CMS may increase a CMP in increments based on a hospice's inability or failure to correct deficiencies, the presence of a system-wide failure in providing quality care, or a determination of IJ with actual harm. Conversely, CMS may decrease a CMP in increments when substantial and sustainable improvements have been implemented even through the hospice is not yet in compliance with the CoPs.

CMPs are limited to $10,000 for each day of noncompliance. CMS proposes to establish a three-tier system with subcategories that would establish the amount of a CMP:

- Upper range – For a deficiency that poses IJ to public health and safety, CMS would assess a penalty within the range of $8.500 to $10,000 per day of condition-level noncompliance.
- Middle range – For repeat and/or a condition-level deficiency that did not pose IJ, but is directly related to poor quality patient care outcomes, CMS would assess a penalty within the range of $1,500 to $8,500 per day of noncompliance with the CoPs.
- Lower range – For repeated and/or condition-level deficiencies that did not constitute IJ and were deficiencies in structures or processes that did not directly relate to poor quality patient care, CMS would assess a penalty within the range of $500 to $4,000 per day of noncompliance.

The proposed CMP amounts would be subject to annual adjustments for inflation[34]; annually adjusted amounts are published at 45 CFR part 102.

CMS proposes it would send the hospice program written notification of the intent to impose the CMP, including the amount and the proposed effective date. Once the administration

[34] Annual adjustments for inflation are in determined in accordance with the Federal CMP Inflation Adjustment Act of 1990 (Pub. L. 101-130), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015 (section 701 of Pub. L. 114-74).

determination is final, CMS would send a final notice to the hospice with the amount of the penalty assessed; the total number of days for noncompliance (for per day CMPs); the total amount due; the due date of the penalty; and the rate of interest to be charged on unpaid balances. Once the hospice program has received the notice of intent to impose the CMP, it would have 60 calendar days from the receipt of the written notice to either request an administrative hearing (in accordance with §498.40) or to provide notice to CMS of its intent to waive its right to an administrative hearing (in accordance with §488.1245(c)(2)), to receive a 35 percent reduction in the CMP amount. The CMP would be due within 15 calendar days of the hospice's written request for waiver. If the hospice did not respond within 60 days of receipt, it would waive its right to a hearing and the CMP would not be reduced by 35 percent.

A per-day CMP would begin to accrue as early as the beginning of the last day of the survey that determines that the hospice was out of compliance and would end on the date of correction of all deficiencies, or the date of termination. In IJ situations, if the IJ is not removed, CMS proposes the CMP would continue to accrue until CMS terminated the provider agreement (within 23 calendar days after the last day of the survey, which first identified the IJ). For a hospice program being involuntarily terminated and for which a CMP had been imposed and was still due, CMS proposes it would include the final due and payment notice as part of the termination notice.

CMS proposes a CMP would become due and payable 15 calendar days from:

- The time to appeal had expired without the hospice appealing its initial determination;
- CMS received a request from the hospice program waiving its right to appeal the initial determination;
- A final decision of an Administrative Law Judge or Appellate Board of the Departmental Appeals Board which upheld CMS's determination; or
- The hospice program was terminated from the program and no appeal request was received.

A request for a hearing would not delay the imposition of the CMP; a request would only affect the collection of any final amounts due to CMS.

k. Directed Plan of Correction (§ 488.1250)

CMS proposes to include a directed POC as an immediate remedy on a hospice program that is out of compliance with the CoPs. A directed POC remedy would require the hospice program to take specific actions to bring the hospice program back into compliance and correct the deficient practice(s).

CMS proposes that the directed POC would be developed by CMS or by the temporary manager, with approval by CMS. The directed POC would establish the outcomes to be achieved, the corrective actions necessary to achieve these outcomes and the specific date the hospice program would be expected to achieve these outcomes. The hospice program would be responsible for achieving compliance. If the hospice program failed to achieve compliance within the timeframes specified in the directed POC, CMS could impose enforcement remedies until the hospice achieved compliance or was terminated from the Medicare program. Before imposing remedies, CMS would provide appropriate notice to the hospice program.

l. Directed In-Service Training (§ 488.1255)

CMS outlines the requirements for conducting directed-in service training for hospice programs with condition-level deficiencies. CMS proposes it may require the staff of a hospice program to attend in-service training program(s) if CMS determines the hospice has condition level deficiencies and education is likely to correct the deficiencies. CMS proposes that hospice programs use in-service programs conducted by established centers of health education and training, or consultants with backgrounds in education and training with Medicare hospice providers, or as deemed acceptable by CMS or the State. CMS will only recommend possible training locations to a hospice program. CMS notes that when the hospice is subject to the SFP, additional technical assistance and/or resources could be made available. The hospice program would be responsible for payment for the directed in-service training.

CMS proposes if the hospice program did not achieve substantial compliance after training, CMS could impose one or more additional remedies. Before imposing additional remedies, CMS would provide appropriate notice to the hospice program.

m. Continuation of Payments to a Hospice program with Deficiencies (§ 488.1260)

CMS proposes the continuation of Medicare payments to hospice programs with condition-level deficiencies that do not constitute IJ for up to 6 months from the last date of the survey if all of the following criteria are met:

- An enforcement remedy or remedies (with the exception of suspension of all payments) has been imposed on the hospice program and termination has not been imposed;
- The hospice program has submitted a POC approved by CMS; and
- The hospice program agrees to repay the Federal government the payments received under this arrangement should the hospice program fail to take the corrective action outlined in its approved POC in accordance with the approved plan and timetable.

If any of these three requirements outlined in section 1822(c)(4)(A) of the Act were not met, a hospice program would not receive any Federal payments from the time that deficiencies were initially identified. CMS would also terminate the agreement at any time before the end of the 6-month correction period.

If a hospice program provided an acceptable POC but could not achieve compliance with the CoPs upon resurvey within 6 months of the last day of the survey, CMS proposes it would terminate the provider agreement.

n. Termination of Provider Agreement (§ 488.1265)

CMS proposes that termination of the provider agreement would end all payments to the hospice program and any enforcement remedy. CMS proposes it would terminate a hospice program's provider agreement under any one of the following conditions:

- The hospice program failed to correct condition-level deficiencies within 6 months unless the deficiencies constitute IJ.

- The hospice program fails to submit an acceptable POC.
- The hospice program fails to relinquish control to the temporary manager when that remedy is imposed by CMS.
- The hospice program fails to meet the eligibility criteria for continuation of payment.

CMS proposes using the procedures for terminating a hospice program at §489.53 and providing appeal rights in accordance with 42 CFR part 489. CMS proposes using the procedures for payments 30 days post termination for hospice programs at §489.55. Payment is available for up to 30 days after the effective date of termination for hospice care furnished under a plan established before the effective date of termination.

VII. Requests for Information (RFIs)

A. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Post-Acute Care Quality Reporting Programs – RFI

CMS requests comments from HHA stakeholders on a series of questions in support of the agency's stated plan for transformation of the agency's quality enterprise, including the HH QRP, to fully digital by 2025. CMS focuses particular attention on the role that Fast Healthcare Interoperability Resources (FHIR, © Health Level 7 International may play as a universal standards language for information exchange using interoperable health information technology (HIT). CMS specifically asks about the following:

- EHR/IT systems currently used by commenters and if they participate in a health information exchange;
- How commenters share information currently with other providers;
- Approaches by which CMS could incent or reward commenters who use health information technology (HIT) in innovative ways to reduce burden for HHAs (and other post-acute care) providers;
- Resources and tools for use by HHAs (and other post-acute care providers) and HIT vendors to facilitate interoperable, fully electronic health information sharing that incorporates FHIR standards and secure application programming interfaces (APIs); and
- Willingness of HIT vendors who work with HHAs (and other post-acute care providers) to participate in pilots or models that align measure collection standards across care settings (e.g., sharing patient data via secure FHIR-based APIs for calculating and reporting digital measures).

CMS indicates that it will not respond to comments received through the HH PPS final rule, but the input from commenters will be considered in future policy making.

In providing background for this RFI, CMS offers a definition for digital quality measures (dQMs): quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. CMS notes that a dQM's score includes a calculation that processes digital data; the agency also lists multiple examples of dQM data sources (e.g., electronic health records - EHRs, wearable medical devices).

CMS discusses the potential role of FHIR-based standards for efficient exchange of clinical

information across clinical settings by clinicians through APIs. Exploration is underway at the agency regarding the use of FHIR-based APIs to access quality data already being collected through its Quality Improvement and Evaluation System (QIES) and the Internet QIES (iQIES), with consideration also being given to using FHIR interfaces to access standardized assessment data from EHRs used by HHAs.

CMS concludes the discussion of this RFI with a commitment to using policy levers and collaborating with stakeholders to transition to fully digital quality measurement across the agency, with staged implementation of a cohesive portfolio of dQMs and incorporation of principles from the HHS National Health Quality Roadmap.

B. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs – RFI

CMS requests information on potential revisions to the HH QRP to facilitate comprehensive and actionable reporting of health disparities, specifically:

- Recommendations for measures or measurement domains addressing health equity;
- Guidance on social determinants of health to be added to those already included in the HH QRP as standardized patient assessment data elements (SPADEs);
- Recommendations that promote equity in outcomes, such as providing facility-level performance data to each HHA stratified by social risk factors (similar to reports being given to hospitals about their readmissions for dual-eligible versus other beneficiaries);
- Data sources and methods already in use by commenters for reducing disparities and improving outcomes; and
- Changes to address current challenges in capturing and exchanging patient information on social determinants of health for use in care delivery and decision making.

CMS states that it will not respond in the HH PPS final rule to comments received but will consider the responses in future policy making.

As background for this RFI, CMS provides multiple examples of poor health outcomes that could stem from disparate care across patient populations (e.g., higher COVID-19 complication rates for black, Latino, and Indigenous and Native Americans relative to whites).

CMS uses for this RFI a definition of equity from Executive Order 13985 issued on January 21, 2021: "the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality".

Finally, examples are provided of ongoing efforts by CMS to enhance the transparency of information about healthcare disparities, such as the addition of SPADEs for required reporting of selected social determinants of health in HH QRP beginning with FY 2020.

VIII. Revised Compliance Date for Certain Reporting Requirements Adopted for Inpatient Rehabilitation Facility (IRF) QRP and Long-Term Care Hospital (LTCH) QRP

A. IRF QRP

CMS proposes to require IRFs to begin reporting two measures – TOH Information to PAC and TOH Information to Patient-PAC – and the elements in the six SDOH SPADE data categories beginning October 1, 2022. These measures and SPADEs were initially adopted as IRF QRP requirements for the FY 2022 program but their adoption was subsequently delayed as part of the CMS response to the COVID-19 PHE to decrease provider burden.

In the May 8, 2020 COVID-19 IFC (85 FR 27550), the compliance date was changed to January 1st of the year that is at least one full CY after the end of the PHE. Reporting the TOH measures and the SDOH SPADEs requires the availability of an updated IRF Patient Assessment Instrument (PAI) assessment tool version (IRF-PAI V4.0). CMS believed at the time of IFC-2 publication, the delayed compliance date would minimally impact the IRF QRP but now believes that the PHE has reinforced the need for rapid health information transfer as well as highlighting health care disparities that could be identified through the SPADEs.

CMS reviews evidence suggesting that IRFs are now much better able to report the TOH measures and SDOH SPADEs and to undergo training to use the IRF-PAI V4.0 than when the May 8, 2020 COVID IFC was published. CMS, therefore, proposes to modify the compliance date for reporting to begin October 1, 2022. CMS notes its plan to release a draft of IRF-PAI V4.0 in early 2022 and thereafter to make available education and training to IRFs to prepare for IRF-PAI V4.0 usage.

B. LTCH QRP

CMS proposes to require LTCHs to begin reporting two measures – TOH Information to PAC and TOH Information to Patient-PAC – and the elements in the six SDOH SPADE data categories beginning October 1, 2022. These measures and SPADEs were initially adopted as LTCH Continuity Assessment Record and Evaluation Data Set (LCDS) requirements for the FY 2022 program but their adoption was subsequently delayed as part of the CMS response to the COVID-19 PHE to decrease provider burden.

In the May 8, 2020 COVID-19 IFC (85 FR 27550), the compliance date was changed to January 1st of the year that is at least one full CY after the end of the PHE. Reporting the TOH measures and the SDOH SPADEs requires the availability of an updated LCDS – LCDS V5.0. CMS believed at the time of IFC-2 publication, the delayed compliance date would minimally impact the LTCH QRP but now believes that the PHE has reinforced the need for rapid health information transfer as well as highlighting health care disparities that could be identified through the SPADEs.

CMS reviews evidence suggesting that LTCHs are now much better able to report the TOH measures and SDOH SPADEs and to undergo training to use the LCDS V5.0. than when the May 8, 2020 COVID IFC was published. CMS, therefore, proposes to modify the compliance

date for reporting to begin October 1, 2022. CMS notes its plan to release a draft of LCDS V5.0 in early 2022 and thereafter to make available education and training to prepare LTCHs for LCDS V5.0 usage.

IX. Regulatory Impact Analysis

CMS estimates that the net impact of the HH PPS policies in this final rule is an increase of 1.7 percent, or $310 million, in Medicare payments to HHAs for 2022. The overall impact of the changes in the HH PPS system on payments to HHAs in 2022 is summarized in the following table.

Summary of Overall Impact of Proposed HH PPS Changes		
Policy	**2022 impact**	
	Percentage	**Dollars**
HH PPS update	+ 1.8%	+$330 million
Statutory rural add-on provision	-0.1%	- $20 million
Net impact	**+1.7%**	**+$310 million**

Table 38, 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. It breaks out the payment effects of the case-mix weights recalibration budget neutrality factor, the 2022 wage index update, the rural add-on payment, and the 2022 update percentage. Proprietary free-standing urban HH facilities (about 72 percent of all facilities) would experience an average increase of payments of 1.7 percent. Voluntary/Non-profit HHAs would experience a 1.9% increase. Government-based facilities would experience a 2.4 percent increase.

Table 38: Estimated HHA Impacts by Facility Type and Area of Country, 2022

	Number of Agencies	**Case-Mix Weights Recalibration Neutrality Factor**	**2022 Updated Wage Index**	**2022 Rural Add-On**	**2022 Proposed HH Payment Update Percentages**	**Total**
All Agencies	**9,401**	**0.0%**	**0.0%**	**-0.1%**	**1.8%**	**1.7%**
Facility Type and Control						
Free-Standing/Other Vol/NP	939	0.4%	-0.3%	-0.1%	1.8%	1.8%
Free-Standing/Other Proprietary	7,588	-0.2%	0.1%	-0.1%	1.8%	1.6%
Free-Standing/Other Government	183	0.8%	0.1%	-0.4%	1.8%	2.3%
Facility-Based Vol/NP	487	0.6%	-0.1%	-0.2%	1.8%	2.1%
Facility-Based Proprietary	50	0.3%	0.0%	-0.2%	1.8%	1.9%
Facility-Based Government	154	0.5%	0.4%	-0.3%	1.8%	2.4%

	Number of Agencies	**Case-Mix Weights Recalibration Neutrality Factor**	**2022 Updated Wage Index**	**2022 Rural Add-On**	**2022 Proposed HH Payment Update Percentages**	**Total**
Subtotal: Freestanding	8,710	0.0%	0.0%	-0.1%	1.8%	1.7%

Subtotal: Facility-based	691	0.5%	-0.1%	-0.2%	1.8%	2.0%
Subtotal: Vol/NP	1,426	0.5%	-0.3%	-0.1%	1.8%	1.9%
Subtotal: Proprietary	7,638	-0.2%	0.1%	-0.1%	1.8%	1.6%
Subtotal: Government	337	0.6%	0.3%	-0.3%	1.8%	2.4%
Facility Type/Control: Rural						
Free-Standing/Other Vol/NP	224	0.3%	-0.1%	-0.7%	1.8%	1.3%
Free-Standing/Other Proprietary	798	-0.2%	0.0%	-0.3%	1.8%	1.3%
Free-Standing/Other Government	122	0.8%	0.2%	-0.8%	1.8%	2.0%
Facility-Based Vol/NP	216	0.6%	-0.1%	-0.7%	1.8%	1.6%
Facility-Based Proprietary	19	0.3%	-0.3%	-0.6%	1.8%	1.2%
Facility-Based Government	114	0.5%	0.5%	-0.6%	1.8%	2.2%
Facility Type/Control: Urban						
Free-Standing/Other Vol/NP	715	0.4%	-0.3%	0.0%	1.8%	1.9%
Free-Standing/Other Proprietary	6,790	-0.2%	0.1%	0.0%	1.8%	1.7%
Free-Standing/Other Government	61	0.7%	0.1%	-0.1%	1.8%	2.5%
Facility-Based Vol/NP	271	0.6%	-0.1%	-0.1%	1.8%	2.2%
Facility-Based Proprietary	31	0.3%	0.2%	0.0%	1.8%	2.3%
Facility-Based Government	40	0.4%	0.3%	0.0%	1.8%	2.5%
Facility Location: Urban or Rural						
Rural	1,493	0.0%	0.0%	-0.4%	1.8%	1.4%
Urban	7,908	0.0%	0.0%	0.0%	1.8%	1.8%
Facility Location: Region of the Country						
New England	323	0.3%	-0.7%	-0.1%	1.8%	1.3%
Mid Atlantic	428	0.8%	-0.6%	-0.1%	1.8%	1.9%
East North Central	1,588	0.0%	-0.2%	-0.2%	1.8%	1.4%
West North Central	618	0.3%	0.2%	-0.3%	1.8%	2.0%
South Atlantic	1,530	0.3%	0.5%	-0.1%	1.8%	2.5%
East South Central	370	-0.1%	-0.6%	-0.1%	1.8%	1.0%
West South Central	2,219	-0.3%	-0.3%	0.0%	1.8%	1.2%
Mountain	674	-0.1%	0.0%	-0.1%	1.8%	1.6%
Pacific	1,609	-0.6%	0.5%	0.0%	1.8%	1.7%
Outlying	42	0.7%	-1.4%	-0.4%	1.8%	0.7%
Facility Size (Number of 30-dayPeriods)						
< 100 periods	1,998	0.2%	0.0%	-0.1%	1.8%	1.9%
100 to 249	1,512	-0.2%	0.0%	-0.1%	1.8%	1.5%
250 to 499	1,711	-0.3%	0.1%	-0.1%	1.8%	1.5%