Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements

(CMS-1711-FC)

Summary of Final Rule with Comment Period

On October 31, 2019, the Centers for Medicare & Medicaid Services (CMS) released a final rule addressing the 2020 Home Health Prospective Payment System (HH PPS) rate update;[1] implementation of the Patient-Driven Groupings Model (PDGM); the Home Health Value-Based Purchasing (HHVBP) model; changes to the home health quality reporting requirements; and updates to home infusion therapy. The changes are generally effective January 1, 2020.

In this rule, CMS also solicits comments on the criteria that can be considered to allow coverage of additional drugs under DME local coverage determination (LCD) L33794. If a DME drug is covered under LCD 33794, it triggers beneficiary eligibility for home infusion therapy. **The deadline for public comment is December 30, 2019.**

Table of Contents

I. Highlights

Home Health Prospective Payment System (HH PPS)
This final rule updates the payment rates for home health agencies (HHAs) for 2020 and implements the PDGM, a revised case-mix adjustment methodology that was finalized in the 2019 HH PPS final rule. The PDGM removes therapy thresholds for payment and changes the

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

unit of home health payment from 60-day episodes of care to 30-day periods of care. As required by the BBA of 2018, the home health payment update for 2020 is 1.5 percent.

CMS finalizes reducing the split-percentage payment amounts for existing HHAs in 2020 and proposes eliminating split percentage payments in 2021. The final rule would also allow therapist assistants to furnish maintenance therapy; CMS clarifies that all therapist assistants, not just physical therapist assistants, can perform maintenance therapy.

Home Health Value-Based Purchasing (HHVBP) Model
CMS finalizes public reporting of the total performance score and percentile ranking from the final model performance year (2020) for each HHA that qualifies for a payment adjustment under the nine-state HHVBP Model for 2020.

Home Health Quality Reporting Program (HH QRP)
Changes to the HH QRP requirements include the removal of one quality measure, the adoption of two new quality measures, the modification of an existing measure, and the reporting of a new set of standardized patient assessment data elements.

Medicare Coverage of Home Infusion Therapy Services
The 2020 payment rates for the temporary transitional payment for home infusion therapy services are updated as required by the BBA of 2018. CMS also finalizes payment provisions for home infusion therapy services for 2021 and subsequent years as required by the 21st Century Cures Act.

Impact
CMS estimates that the net impact of the proposed HH PPS policies in this rule will be an increase of 1.3 percent, or $250 million, in Medicare payments to HHAs for 2020. This estimate does not take into account the approximately $1.2 million decrease in Medicare payments to home infusion suppliers in 2020 which will shift from the temporary transitional payments to eligible home infusion suppliers for items and services associated with the furnishing of transitional home infusion drugs.[2]

II. Overview

Current System for Payment of Home Health Services
CMS reviews the statutory and regulatory provisions for the HH PPS and updates to that system. It also reviews and highlights key aspects of the current system for payment of home health services. To adjust for case-mix in the current system, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). Patients are grouped into these payment categories based on clinical severity level, functional severity level, and service utilization. This information is obtained from the Outcome and Assessment Information Set (OASIS) assessment instrument. Therapy service use is measured by the number of therapy visits provided during the 60-day episode based on nine visit level categories ranging from 0-5 to 20 or more visits. The national, standardized 60-day episode payment rate includes

[2] These payments are contingent on the final 2020 Physician Fee Schedule which was not available for this analysis.

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) is made separately and is not part of the national, standardized 60-day rate.

For episodes with four or fewer visits, 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 60-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.

New HH PPS for 2020 and Subsequent Years
The PDGM, finalized in the 2019 HH PPS final rule (83 FR 56446), is a new patient case-mix adjustment methodology that shifts the focus from volume of services to a model that relies more on patient characteristics. For home health periods of care beginning on or after January 1, 2020, the PDGM uses timing, admission source, principal and other diagnoses, and functional impairment to case-mix adjust payments resulting in 432 unique case-mix groups. CMS also finalized a change in the unit of home health payment from 60-day episodes of care to 30-day periods of care and eliminated the use of therapy thresholds to adjust payment. NRS are included in the base payment rate for the PDGM.

The LUPA threshold varies for a 30-day period and uses the 10^{th} percentile value of visits to create a payment group specific LUPA threshold of at least 2 visits for each payment group. Thirty-day periods of care may also be adjusted for outliers and partial episodes.

For 2020 through 2022, 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 others (section 50208 of the BBA of 2018)).

Analysis of Fiscal Year 2017 HHA Cost Report Data for 60-Day Episodes and 30-Day Periods
In the proposed rule, CMS provided a summary of its analysis of fiscal year (FY) 2017 HHA cost report data. This analysis included how the data would impact CMS' estimate of the percentage difference between Medicare payments and HHA costs. CMS includes this analysis again in this final rule.

Estimated Costs for 60-Day Episodes. Table 2 (in this final rule) provides the estimated costs for 60-day episodes by discipline and the total estimated cost for a 60-day episode for 2017. CMS estimates the total 60-day episode costs as $2,524.64 and the total 60-day episode costs with NRS as $2,589.76.

To estimate the costs for 2020, in the proposed rule, CMS updated the 2017 60-day episode costs by using the home health market basket update of 1.5 percent as required by the BBA of 2018. For this final rule, CMS estimates the costs for 2020 using the same approach for estimating costs for 2018 and 2019. Specifically, the estimated 2020 60-day episode costs and 30-day period costs were calculated by applying each year's market basket update minus the multifactor

productivity factor (MPF) for that year. For 2020, based on IHS Global Inc. 2019 third quarter forecast, the forecasted MFP-adjusted home health market basket update is 2.6 percent.[3] Using this methodology, for 2020, CMS estimates the total 60-day episode costs to be $3,220.79, approximately 16 percent more than the estimated 60-day episode cost of $2,767.15 in the proposed rule (Table 3 replicates the information from the proposed rule).

Estimated Costs for 30-Day Periods. CMS also looked at the estimated costs for 30-day periods of care in 2017 using FY 2017 cost reports and 2017 claims. Thirty-day periods were simulated from 60-day episodes, excluding LUPA and PEP adjustments. The 30-day periods were linked to OASIS assessments and covered the 60-day episodes ending in 2017. Table 4 provides the estimated costs for 30-day episodes by discipline and the total estimated cost for a 30-day period for 2017. CMS estimates the total 30-day period costs as $1,468.07 and the total 30-day period costs with NRS as $1,505.69.

To estimate the costs for 2020, using the same approach as the updated estimated 2020 60-day episode costs, CMS updated the estimated 30-day period costs with NRS by the home health market basket update, minus the MFP adjustments for 2018, 2019, and 2020. For 2020, CMS estimates the total 30-day period costs as $1,608.82 (additional updated details by discipline are provided in Table 5).

The estimated budget-neutral 30-day payment for 2020 is $1,824.99 (discussed below in section III.E.). Updating this amount by the 2020 home health market basket of 1.5 percent and the wage index budget neutrality factor results in an estimated 2020 30-day payment amount of $1,864.03. This episode payment amount is approximately 16 percent more than the estimated 2020 30-day period costs of $1,608.82.

CMS intends to continue to analyze the costs by discipline and the overall costs for a 30-day period of care to determine the effects, if any, of the PDGM.

III. Provisions for Payment Under the Home Health Prospective Payment System (HH PPS)

A. Implementation of the Patient-Driven Groupings Model (PDGM) for 2020

1. Background and Legislative History

In the 2019 HH PPS final rule (83 FR 56406), CMS finalized provisions implementing changes mandated by Section 51001 of the BBA of 2018 for 2020:

- A change in the unit of payment from a 60-day episode of care to a 30-day period of care.
- The elimination of therapy thresholds for adjusting home health payment.

CMS also finalized the Patient-Driven Groupings Model (PDGM), an alternative case-mix adjustment methodology to adjust payments for home health periods of care beginning on and after January 1, 2020.

[3] For 2020, the home health market basket update is forecasted to be 2.9 percent and the MFP adjustment is forecasted to be 0.3 percent.

The BBA of 2018 also required the Secretary to implement the transition from the 60-day to 30-day unit of service in a budget neutral manner. The Secretary is required to calculate the standard prospective payment amount so that estimated expenditures for 2020 under a 30-day unit of service are equal to estimated expenditures for 2020 if the law had not changed the unit of service from 60 to 30 days. This calculation is done before the application of the update to the standard prospective payment amounts.

Additionally, the Secretary is directed to make certain assumptions about changes in behavior of home health agencies (e.g., patterns of service delivery) that might occur due to the shorter unit of service as well as changes in case-mix adjustment factors. These behavior assumptions were discussed in the 2019 HH PPS proposed rule (83 FR 32389) and further described in this rule (section III.B)

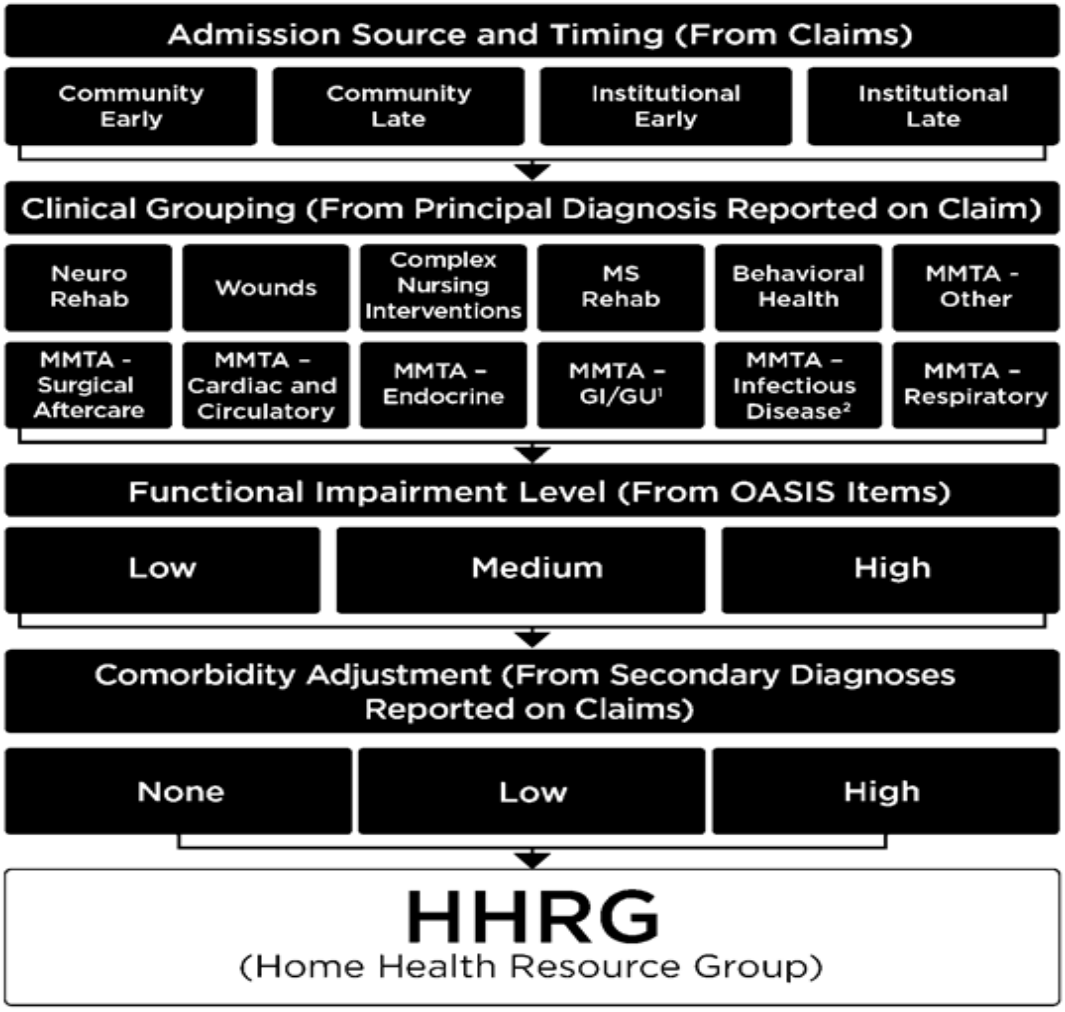
For each year beginning in 2020 and ending in 2026, the Secretary must determine the difference between the estimated impact of the behavior changes it assumed for 2020 (and included in the calculation of the standard prospective payment amount) and the actual impact of those behavior changes for that year. The Secretary is required to make one or more permanent prospective adjustments (increases or decreases) to the standard prospective payment amount to offset the difference between actual and estimated behavior changes for purposes of future payment. The Secretary must also make one or more temporary prospective adjustments (increases or decreases) to the payment amount for a unit of home health services to offset any difference between actual and estimated behavior changes for a previous year. Any temporary adjustments are not taken into account in computing the payment amount for future years.

2. Overview and 2020 Implementation of the PDGM

In this section, CMS reviews the PDGM. The PDGM uses a 30-day period of care as the unit of payment, eliminates the use of the number of therapy visits provided to determine payment, and relies on clinical characteristics and other patient information – diagnosis, functional level, comorbid conditions, and admission source – for patient placement into clinically meaningful payment categories. A national, standardized 30-day period payment amount is adjusted by the case-mix weights as determined by the PDGM variables. The national, standardized payment amount includes payment for NRS.

Figure 1, reproduced below, from the final rule, provides an overview of the structure of the PDGM. Each 30-day period of care will be placed into one of the 432 Home Health Resource Groups (HHRGs). The different payment groups are based on five main case-mix variables: timing, admission source, clinical grouping, functional impairment level, and comorbidity adjustment. Case-mix weights are generated for each of the different PDGM payment groups by regressing resource use for each of these five variables using a fixed effects model. Through the annual rulemaking cycle, CMS will recalibrate the PDGM case-mix weights to ensure that the case-mix weights reflect the most recent utilization. The final 2020 PDGM case-mix weights are listed in section III.D. of this rule.

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



a. Timing: Early or Late Episode. The 30-day periods of care will be classified as "early" or "late" depending on when they occur within a sequence of 30-day periods. The first 30-day period of care will be classified as early and all subsequent 30-day periods of care in the sequence will be classified as late. A 30-day period will not be considered early unless there is a gap of more than 60 days between the end of one period and the start of another.

Information about the timing of a 30-day period will come from the Medicare home health claims data and not the OASIS assessment. CMS notes that certification and recertification requirements will continue on a 60-day basis and there are no changes in §488.55, "Condition of Participation: Comprehensive assessment of patients."

b. Admission Source: Community or Institutional. Each 30-day period will be classified depending on the healthcare setting utilized by the beneficiary in the 14 days prior to home health. The 30-day period is categorized as institutional if an acute or post-acute stay occurred in the 14 days prior to the start of the period of care. The institutional category includes beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility (IPF)

stays, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long-term care hospital (LTCH) stays within 14 days prior to home health admission.

- The institutional category will also include patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care for which the patient was not discharged from home health and readmitted to an acute care hospital. CMS states this is based on the fact that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital discharge.
- The institutional category will not include PAC stays (SNF, IRF, or LTCH) or IPF stays that occur during a previous 30-day period and within 14 days of a subsequent, contiguous 30-day period of care. CMS expects the HHA to discharge the patient if the patient requires PAC or IPF care in a different setting and then readmit the patient, if necessary, after discharge from the PAC or IPF.

All other 30-day periods will be considered community admissions.

Medicare claims processing systems will automatically determine whether a beneficiary has been discharged from an institutional setting with an associated Medicare claim to systematically identify admission source. If an institutional claim is found, and the stay occurred within 14 days of the home health admission, the systems with trigger an automatic adjustment of the corresponding HH claim to the appropriate institutional category. Similarly, when the Medicare claims processing systems receive a Medicare acute or PAC claim for an institutional stay, the systems will check for the presence of a subsequent HH claim with a community payment group. If a claim is found, and the institutional stay occurred within 14 days of the home health admission, the systems will trigger an automatic adjustment of the HH claim to the appropriate institutional category. This process may occur any time within the 12-month timely filing period for the acute or PAC claim. The OASIS assessment will not be utilized in evaluating admission source information.

HHAs can manually indicate on home health claims that an institutional admission source occurred prior to the beginning of the home health admission. If an occurrence code is submitted on the home health claim, the claim will be categorized as an institutional admission. HHAs can report one of two admission source occurrence codes on home health claims:

- Occurrence Code 61: indicates an acute care hospital discharge within 14 days prior to the "From Date" of any home health claim, or
- Occurrence Code 62: indicates a SNF, IRF, LTCH, or IPF discharge within 14 days prior to the "Admission Date" of the first home health claim.

If the HHA does not include an occurrence code on the HH claim to indicate that the home health patient had a previous acute or post-acute stay, the period of care will be categorized as a community admission source. The Medicare systems will adjust community-admitted home health claims on a claim-by-claim basis if an acute/PAC Medicare claim for an institutional stay occurring within 14 days of the home health admission is received. The HHA will also be able to resubmit a claim that included an occurrence code, subject to the timely filing deadline, and payment adjustments would be made accordingly. For purposes of a Request for Anticipated

Payment (RAP), only the final claim will be adjusted to reflect the admission source.[4] CMS notes the Medicare Claims Processing Manual, Chapter 10[5], has been updated to reflect all changes associated with implementation of the PDGM.

c. Clinical Groupings. Based on the principal diagnosis reported on home health claims, each 30-day period of care will be grouped into one of 12 clinical groups which describe the primary reason patients are receiving home health services (final rule Table 6, reproduced below).

Table 6: PDGM Clinical Groups	
Clinical Group	**Primary Reason for the HH Encounter is to Provide:**
Musculoskeletal Rehabilitation	Therapy (physical, occupational or speech) for a musculoskeletal condition
Neuro/Stroke Rehabilitation	Therapy (physical, occupational or speech) for a neurological condition or stroke
Wound-Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care	Assessment, treatment & evaluation of a surgical wound(s); assessment, treatment & evaluation of non-surgical wounds, ulcers, burns, and other lesions
Behavioral Health Care	Assessment, treatment & evaluation of psychiatric and substance abuse conditions
Complex Nursing Interventions	Assessment, treatment & evaluation of complex medical & surgical conditions, including IV, TPN, enteral nutrition, ventilator, and ostomies
Medication Management, Teaching and Assessment (MMTA)	Assessment, evaluation, teaching, and medication management for:
MMTA – Surgical Aftercare	Surgical care
MMTA – Cardiac/Circulatory	Cardiac or other circulatory related conditions
MMTA – Endocrine	Endocrine related conditions
MMTA – GI/GU	Gastrointestinal or genitourinary related conditions
MMTA – Infectious Disease/Neoplasms/Blood-forming Diseases	Infectious diseases, neoplasms, and blood-forming diseases
MMTA – Respiratory	Respiratory related conditions
MMTA – Other	A variety of medical and surgical conditions not classified in one of the previously listed groups

CMS notes that if the principal diagnosis changes between the first and second 30-day period of care, the claim for the second 30-day period of care will reflect the new principal diagnosis; HHAs should not change the claim for the first 30-day period. A change in the principal diagnosis does not necessarily mean that an "other follow-up" OASIS assessment would need to be completed just to make the diagnosis match. If a patient experienced a significant change in condition before the start of a subsequent, contiguous 30-day period of care, the HHA is required to update the comprehensive assessment (§484.55(d)). More detailed guidance for the

[4] Information about admission source reporting requirements for RAP and claims submissions can be found in Change Request 11081, "Home Health (HH) Patient-Drive Groupings Model (PDGM)-split Implementation" at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4228CP.pdf

[5] Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c10.pdf

completion of an "other follow-up assessment" is provided in the "Outcome and Assessment Information Set OASIS-D Guidance Manual," effective January 1, 2019.[6]

CMS updated current billing instructions to clarify that there will not be a need for the HHA to complete an "other follow-up" assessment to make the OASIS diagnosis match the claim diagnosis. For claims with "From Dates" on or after January 1, 2020, the ICD-10-CM code and principal diagnosis code used for payment grouping will be from the claim and not OASIS. As a result, the claim and OASIS diagnosis will no longer be expected to match in all cases.

Although the clinical groups represent the primary reason for home health services during a 30-day period of care, CMS states that home health is a multidisciplinary benefit and payment is bundled to cover all necessary home health services identified in the individualized home health plan of care. The Conditions of Participation (CoPs) at §484.60(a)(2) require HHAs to ensure that the individualized home health plan of care addresses all care needs and the disciplines needed to provide care.

The Interactive Grouper Tool has been updated to include all of the ICD-10 diagnosis codes used in the PDGM, and HHAs can use this tool to generate informational case-mix weights for their patient census.[7] To assist HHAs in evaluating the effects of the PDGM, a Home Health Claims-OASIS Limited Data Set (LDS) for the 2020 HH PPS final rule can be requested from CMS by following the instructions on the CMS website: https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/index.html.

d. Functional Impairment Level. Each 30-day period will be placed into one of three functional impairment levels (low, medium, or high) based on responses to certain OASIS functional items (Table 7, reproduced below). Responses to these OASIS items are grouped together into response categories with similar resource use, and each response category has associated points.

Table 7: OASIS Items Used for Functional Impairment Level in the PDGM

OASIS Item	Description
M1033	Risk for Hospitalization (excluding responses 8, 9, and 10)
M1800	Grooming
M1810	Current ability to dress upper body safely
M1820	Current ability to dress lower body safely
M1830	Bathing
M1840	Toilet transferring
M1850	Transferring
M1860	Ambulation and locomotion

The sum of these points results in a functional impairment level score used to group 30-day periods of care into a functional impairment level with similar resource use. Table 8 in the final rule (reproduced below) demonstrates how the OASIS items used for the functional level are

[6] The guidance manual is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/draft-OASIS-D-Guidance-Manual-7-2-2018.pdf

[7] The Interactive Grouper Tool is available on both the HHA Center webpage (https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html) and the PDGM webpage https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html

assigned points. Table 9 in the final rule lists the 2020 threshold for the level of functional impairment by clinical group.

TABLE 8: 2020 OASIS Points Table for Those Items Associated with Increased Resource Use Using a Reduced Set of OASIS Items*			
Variable	**Responses**	**Points (2018)**	**Percent of Periods in 2018 with this Response Category**
M1800: Grooming	0 or 1	0	39.6%
	2 or 3	5	60.4%
M1810: Current Ability to Dress Upper Body	0 or 1	0	37.5%
	2 or 3	6	62.5%
M1820: Current Ability to Dress Lower Body	0 or 1	0	18.0%
	2	5	60.5%
	3	12	21.5%
M1830: Bathing	0 or 1	0	4.6%
	2	3	16.5%
	3 or 4	13	54.0%
	5 or 6	20	24.9%
M1840: Toilet Transferring	0 or 1	0	66.2%
	2, 3, or 4	5	33.8%
M1850: Transferring	0	0	2.5%
	1	3	32.3%
	2, 3, 4, or 5	7	65.3%
M1860: Ambulation/Locomotion	0 or 1	0	6.2%
	2	9	22.5%
	3	11	55.8%
	4, 5, or 6	23	15.4%
M1032: Risk of Hospitalization	3 or fewer items marked (excluding responses 8, 9, or 10)	0	81.2%
	4 or more items checked (excluding responses 8, 9, or 10)	11	18.8%
*Source: 2018 home health claims and OASIS data (as of July 31, 2019)			

The functional level will remain the same for the first and second 30-day periods of care unless there has been a significant change in condition which resulted in an "other follow-up" OASIS assessment prior to the second 30-day period of care. For each 30-day period, the Medicare claims processing system will look for the most recent OASIS assessment based on the "From Date" on the claim. The finalized 2020 functional points table and the functional impairment thresholds are posted both on the HHA Center webpage and the PDGM webpage.

e. Comorbidity Adjustment. Home health 30-day periods of care can receive a comorbidity adjustment based on certain secondary diagnoses reported on home health claims. These diagnoses are based on a home-health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use. Specifically, these diagnoses have resource use at least as high as the median and represent more than 0.1 percent of 30-day periods of care. A comorbidity payment adjustment can be received under the following circumstances:

- Low comorbidity adjustment: There is a reported secondary diagnosis that falls within one of the home-health specific individual comorbidity subgroups associated with higher resource use. (Table 10 lists the 13 subgroups.)
- High comorbidity adjustment: There are two or more secondary diagnoses reported within the same comorbidity subgroup interaction that are associated with higher resource use. (Table 11 lists the 31 subgroups.)
- No comorbidity adjustment: There is no secondary diagnosis or the diagnosis does not meet the criteria for a low or high comorbidity adjustment.

A 30-day period of care can receive either a payment for a low or high comorbidity adjustment but not both. Only one low comorbidity adjustment or one high comorbidity adjustment can occur during a 30-day period regardless of the number of secondary diagnoses reported that fall into one of the individual comorbidity subgroups or comorbidity group interactions. The low comorbidity adjustment amount will be the same across the subgroups; the high comorbidity adjustment amount will be the same across the comorbidity subgroup interactions. The finalized 2020 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups (including those diagnoses within each) are posted on the HHA Center webpage and the PDGM webpage.

CMS notes that the PDGM was finalized in the 2019 HH PPS final rule and no structural changes in this case-mix adjustment methodology were made in the 2020 final rule. As such, CMS did not solicit comments on the PDGM. CMS did, however, receive 179 comments on various components of the finalized PDGM; the comments and responses are summarized in the final rule. Highlights of the comments and responses are below; the interested reader is referred to the final rule for more details.

General PDGM Comments. CMS acknowledges stakeholder concerns about possible perverse financial incentives that could arise from the new case-mix adjustment methodology and a change in the unit of payment. CMS reiterates that it expects services to be provided to best meet the patient's needs and in accordance with the home health CoPs at §484.60. CMS also notes that HHAs are already tasked with informing beneficiaries of their rights and coverage under the Medicare home health benefit (CoP §484.50(c)). In addition, CMS will update the necessary public information to ensure full transparency and to provide resources for beneficiaries and their families, as well as for HHAs. In response to a specific request about the education budget connected with the PDGM implementation, CMS notes that each individual policy change does not have a corresponding specific budget associated with its implementation.

Admission Source. CMS acknowledges concerns that the admission source variable may create incentives to favor institutional admission sources, and it intends to monitor provider behavior under the PDGM. It plans to reassess the appropriateness of the payment levels for all of the case-mix variables to determine if HHAs are inappropriately changing their behavior, including both increased and decreased provision of care. If warranted, any concerns will be shared with the Medicare Administrative Contractors (MACs) and other program integrity contractors.

Therapy Thresholds. CMS does not agree with a suggestion for eliminating the 30-day therapy reassessment requirement, but as part of its initiative to reduce unnecessary burden it will continue to monitor home health utilization, including the provision of therapy visits, to re-evaluate any existing policies in future rulemaking. In response to concerns about potential utilization of therapy services, CMS reiterates its plans to monitor the provision of services.

Non-routine Supplies (NRS). In response to a recommendation that the cost of NRS should be included in outlier payments, CMS notes that significant modifications in the claims payment systems would be required to incorporate supply costs into the outlier calculation. It will monitor this issue and if appropriate will consider this recommendation in future rulemaking.

Clinical Groups. CMS received coding comments that included recommendations to change or add a specific ICD-10-CM diagnosis code to a clinical group variable. Table 12 in the final rule lists the 55 coding recommendations and CMS' responses. As part of reviewing these comments, CMS evaluated the consistency in the clinical group assignments and reassigned ten ICD-10-CM diagnosis codes (listed in Table 13).

Comorbidities. In response to comments about specific codes, CMS discusses how it developed the home health specific comorbidity diagnosis list by focusing on chronic conditions that its literature review and data analysis showed to be clinically and statistically significant on their overall impact on home health resource use (discussed in detail in the 2018 proposed rule, 82 FR 35322). CMS notes that the comorbidity subgroups that can receive an adjustment in a given year fluctuate, depending on the frequency of the reported codes and their impact on resource use. CMS stresses the importance of reporting secondary diagnosis on the home health claim, regardless of whether or not there is a comorbidity payment adjustment associated with the diagnosis, and notes that coding instructions indicate that all conditions should be reported.

B. Implementation of a 30-Day Unit of Payment for 2020

In calculating a 30-day payment amount in a budget-neutral manner, CMS must take into account behavior changes that could occur as a result of the case-mix adjustment factors implemented in 2020. In the 2019 HH PFS final rule (83 FR 56456), CMS finalized three assumptions about 2020 behavior change that it will use in calculating the budget-neutral 30-day payment amount:

- Clinical Group Coding: The principal diagnosis code for the patient reported on the home health claim is a key component of determining payment under the PDGM. CMS assumes that HHAs will change their documentation and coding practices and put the highest paying diagnosis as the principal diagnosis code. This will result in a 30-day period to be placed into a higher-paying clinical group. (Although CMS does not support or condone coding practices to maximize payment, it often takes into account expected behavioral effects of policy changes.)

- Comorbidity Coding: The PDGM further adjusts payments based on patients' secondary diagnoses reported on the home health claim, which allows HHAs to designate one

primary diagnosis and 24 secondary diagnoses. The OASIS only allows one primary diagnosis and five secondary diagnoses. CMS assumes that by taking into account the additional diagnoses codes listed on the claim, more 30-day periods of care will receive a comorbidity adjustment than periods otherwise would have received if only the OASIS diagnosis codes were used for payment. Under the PDGM, the comorbidity adjustment can increase payments by up to 20 percent.

- LUPA Threshold: CMS notes that current data suggests that about 1/3 of the LUPA episodes with visits near the LUPA threshold move up to become non-LUPA episodes. CMS assumes this experience will continue under the PDGM and that HHAs will provide 1 to 2 extra visits for about 1/3 of those episodes slightly below the LUPA thresholds in order to receive a full 30-day payment.

CMS estimates what the 30-day payment amount would be for 2020 (using 2018 home health utilization data) to achieve budget neutrality with and without the behavioral assumptions (Table 14, reproduced below). These payment amounts do not include the 2020 home health payment update of 1.5 percent. A detailed explanation of how CMS calculated the 30-day budget-neutral payment amount is provided in the 2020 proposed rule (84 FR 34615).

Table 14: Estimated 30-Day Budget-Neutral Payment Amounts

Behavioral Assumption	30-day Budget-Neutral Standard Amount	Percent Change from No Behavioral Assumption[1]
No Behavioral Assumption	$1,908.18	
LUPA Threshold (1/3 of LUPAs 1-2 visits away from threshold get extra visits and become case-mix adjusted)	$1,872.33	-1.88%
Clinical Group Coding[2] (among available diagnoses, one leading to highest payment clinical grouping classification designated as principal)	$1,7986.33	-6.40%
Comorbidity Coding (assigns comorbidity level based on comorbidities appearing on HHA claims and not just OASIS)	$1,903.46	-0.25%
Clinical Group Coding + Comorbidity Coding + LUPA Threshold	$1,748.11	-8.39%

[1]Adding all the percent decreases for each behavior assumption results in a total percent decrease of -8.53 percent. There is overlap and interaction between the behavior assumptions and when combined, the budge-neutral payment amount results in a -8.389 percent decrease from the payment amount without these assumptions applied.
[2]The clinical group coding assumption has a higher percent decrease (-6.40%) in this year's final rule compared to the percent decrease in the 2019 HH PPS proposed rule (-4.28%). This is because the 2019 clinical coding assumption was based on six clinical groups and the 2020 clinical coding assumptions is based on the finalized 12 clinical groups.

In response to comments about the behavior assumptions, CMS reiterates the evidence supporting these assumptions and continues to believe they are valid and supported by evidence. CMS agree with comments that given the scope of the payment system changes, it might take HHAs more than the initial year to fully implement the behavior assumed by CMS. CMS notes that the implementation of the MS-DRG system resulted in a 2.5 percent change in documentation and coding (about half of the estimated 4.8 percent change expected) in the first

year of the IPPS MS-DRGs and a 5.4 percent change in documentation and coding in the second year. Based on the MS-DRG implementation experience and the magnitude of changes in the home health requirements, CMS believes it is reasonable to apply the three behavior change assumptions to only half of the 30-day periods in its analytic file (randomly selected).

After consideration of comments and reconsideration of the frequency of assumed behaviors during the first year of the transition to a new payment system and case-mix adjustment methodology, **CMS finalizes a -4.36 percent behavior change assumption adjustment in order to calculate the 30-day payment rate in a budget-neutral manner for 2020**. The finalized 2020 30-day budget-neutral payment amount with the -4.36 percent behavioral assumption adjustment will be $1,824.99, and the 2020 30-day payment rate, with the wage-index budget neutrality factor and the home health payment update of 1.5 percent, will be $1,864.03, with a fixed dollar loss ratio of 0.56.

CMS reiterates that the Secretary is required to annually analyze data for 2020 through 2026, after implementation of the 30-day unit of payment and new case-mix adjustment methodology, to determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. The data will be used to determine whether a prospective adjustment (increase or decrease) is needed. Such an adjustment may apply only to payments occurring in 2022 through 2028. Temporary adjustments allow CMS to recover excess spending or give back the difference between actual and estimated spending not addressed by permanent adjustments.

The 30-day payment amount will apply to 30-day periods of care beginning on and after January 1, 2020. Because 2020 is the first year of the PDGM, there will be a transition period to account for home health episodes of care that span the implementation date. For 60-day episodes (not LUPA episodes) that begin on or before December 31, 2019 and end on or after January 1, 2020, payment will be the 2020 national, standardized 60-day episode payment (discussed in Section III.E.4.b. of this final rule). For home health periods of care that begin on or after January 1, 2020, the unit of service will be a 30-day period and payment will be the 2020 national, standardized prospective 30-day payment amount (Section III.E.4.d. of this final rule). For home health services that begin on or after December 3, 2020 through December 31, 2020 and end on or after January 1, 2021, the payment will be the 2021 national, standardized prospective 30-day payment amount.

CMS agrees with MedPAC's comment that the proposed behavior adjustments may not reflect all of the behavior changes that could occur, such as providing additional visits after an initial 30-day period to trigger an additional 30-day payment. CMS is not adding additional behavior adjustments because it believes the finalized behavior changes are the ones best supported by prior experience with changes to payment systems. As required by the statute, it will analyze data for 2020 through 2026 and plans to examine all behavior changes and not just those currently finalized.

In response to comments requesting that CMS provide expected total aggregate budget neutral HH PPS expenditures for future years, CMS believes it would be difficult to accurately predict these expenditures because it cannot anticipate future year home health updates, which vary

yearly. In addition, it cannot anticipate future legislation that would require a specific home health rate update for a given year. CMS also notes that it provided a detailed explanation of how it calculated the behavior adjustments in the 2020 proposed rule (84 FR 34615) and included additional information in this current rule. It does not agree with comments that excluded claims[8] would be useful for inclusion of the behavior assumption adjustment. CMS does not see any relationship between standard data cleaning procedures and the *Jimmo vs. Sebelius* settlement agreement, which addresses Medicare coverage of certain types of maintenance therapy for certain Medicare providers.

CMS appreciates commenter concerns regarding the impact of the behavior assumptions on smaller and rural HHAs but notes that the regulatory impact analysis in the proposed rule (84 FR 34706) showed that the impact of the PDGM and the 30-day unit of payment (with behavior assumptions) on rural providers would be 3.7 percent and the impact on smaller providers (less than 100 episodes) would be 2.1 percent. CMS also notes that even with the behavior assumption adjustment of 8.389 percent, the 2020 30-day payment rate would be approximately 11 percent higher than the estimated 2020 30-day period cost. In addition, MedPAC stated that the analysis of payments and costs in the proposed rule suggests that payments will be more than adequate in 2020.

C. 2020 HH PPS Case-Mix Weights for 60-Day Episodes of Care that Span the Implementation Date of the PDGM

In the 2015 HH PPS final rule (79 FR 66072), CMS finalized that it would annually recalibrate the HH PPS case-mix weights – adjusting the weights relative to one another – using the most current, complete data available. As discussed below in section III.D, CMS is recalibrating the 2020 case-mix weights for 30-day periods of care. These recalibrated case-mix weights are not applicable for 60-day episodes of care that begin on or before December 31, 2019 and end on or after January 1, 2020.

Instead of separately recalibrating the case-mix weights for 60-day episodes that span the January 1, 2020 change to 30-day episodes, CMS proposed that these 60-day episodes would be paid the national standardized 60-day episode payment amount (discussed below in section III.D) and case-mix adjusted using the 2019 case-mix weights as listed in Table 6 of the 2019 HH PPS final rule (83 FR 56422) and posted on the HHA Center webpage. CMS believed this proposal would be less burdensome for HHAs because it would not require HHAs to download a new, separate 153-group case-mix weight data file in addition to the 432 case-mix weight data file for 2020. For 60-day episodes that end after January 1, 2020 with a continued need for home health services, CMS proposed that any subsequent periods of care would be paid the 30-day national, standardized payment amount with the appropriate 2020 PDGM case-mix weight applied.

[8] For the final 2020 calculations, CMS used a 2018 analytic file that included 6,388,974 60-day episodes ($18 billion in total expenditures); 9.5 percent of claims were excluded because they could not be linked to an OASIS assessment, or were RAPs without a final claim, or were claims with zero payments. The resulting 2018 analytic file represented 5,471,454 60-day episodes and $16.6 billion in total expenditures.

CMS disagrees with a commenter that all variables that affect payment in 2020 should be updated for 2020.

CMS finalizes its proposal that 60-day episodes spanning the January 1, 2020 implementation date of the PDGM and the change to a 30-day unit of payment will be paid the 2020 national, standardized 60-day episode payment amount of $3,220.79 (Table 17 in the final rule) and will be case-mix adjusted using the 2019 case-mix weights listed in the 2019 HH PPS final rule. For 60-day episodes that end after January 1, 2020 with a continued need for home health services, CMS finalizes that any subsequent periods of care would be paid the 30-day national, standardized payment amount with the appropriate 2020 PDGM case-mix weight applied.

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

1. 2020 PDGM LUPA Thresholds.

Under the current payment system, if an HHA provides four visits or less in a 60-day episode, the provider is paid a standardized per visit payment instead of an episode payment for a 60-day episode of care. These payment adjustments are called LUPAs. Currently, approximately 7 to 8 percent of episodes are LUPAs.

For the PDGM, CMS changed its approach for calculating the LUPA thresholds due to the change in the unit of payment to 30-day periods of care. CMS believes the LUPA thresholds for 30-day periods of care should be correspondingly adjusted to target approximately the same percentage of LUPA episodes as under the current case-mix system. As finalized in the 2019 HH PPS final rule (83 FR 56492), LUPA thresholds are set at the 10^{th} percentile value of visits or 2 visits, whichever is higher for each payment group. Consequently, the LUPA threshold for each 30-day period of care varies based on the PDGM payment group to which it is assigned.

CMS will update the LUPA thresholds every year based on the most current utilization data available. For this final rule, CMS used 2018 Medicare home health claims (as of July 31, 2019) linked to OASIS assessment data. The LUPA thresholds for the 2020 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in Table 16.

Under the PDGM, if the LUPA threshold is met, the 30-day period of care will be paid the full 30-day period payment. If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment will be made using the 2020 per-visit payment amount.

CMS agrees with a comment that there are some institutional admission source LUPA thresholds that are less than their community counterparts and notes that the LUPA threshold does not necessarily relate to the case-mix weight of the 30-day period. CMS states that the finalized policy for the PDGM LUPA thresholds targets approximately the same percentage of LUPAs as under the 153 case-mix weight system. The LUPA thresholds for each PDGM payment group will be reevaluated every year based on the most current utilization data available.

2. 2020 PDGM Case-Mix Weights.

CMS discusses the methodology it used to determine the 2020 PDGM case-mix weights. CMS utilized a data file based on home health 30-day periods of care, as reported in the Medicare home health claims (as of July 31, 2019) linked to OASIS assessment data to obtain patient characteristics. The claims data provide visit-level data and data on whether NRS were provided during the period and the total NRS charges. CMS determined the case-mix weight for each of the 432 different PDGM payment groups by regressing resource use on a series of indicator variables for each of the categories using a fixed effects model, as discussed in detail in the proposed rule. The case-mix weight is then used to adjust the base payment to determine each 30-day period's payment. Table 15 in the final rule shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use for PDGM payment groups. The final 2020 case-mix weight for each HHRG payment group is provided in Table 16.

CMS will annually recalibrate the case-mix weights using the most current data available.

E. 2020 Home Health Payment Rate Updates

1. CY 2020 Home Health Market Basket Update for HHAs

The 2020 update of 1.5 percent is reduced by 2.0 percentage points for HHAs that do not submit quality data required by the Secretary. Thus, the 2020 update will be:

- For HHAs reporting the required quality data: 1.5 percent
- For HHAs not reporting the required quality data: -0.5 percent

As amended by the Bipartisan Budget Act (BBA) of 2018, the statute requires a 1.5 percent home health payment update for 2020.[9] The MFP adjustment does not apply to this mandated 2020 update.

2. CY 2020 Home Health Wage Index

CMS finalizes its proposal to continue to use the pre-floor, pre-reclassified hospital wage index as the wage index to adjust the labor portion of HH PPS rates. For 2020, CMS will use FY 2016 hospital cost report data as its source for the updated wage data and will continue to use the Office of Management and Budget's (OMB's) February 28, 2013 revisions to the delineations of Metropolitan Statistical Areas (MSAs) and the creation of Micropolitan Statistical Areas, and Core-based Statistical Areas (CBSAs).[10]

[9] Prior to the enactment of the BBA of 2018, the home health payment update percentage for 2020 would have been a 2.6 percent.

[10] OMB issued Bulletin No. 17-01 which announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area. The CY 2020 HH PPS wage index value for CBSA 46300 (Twin Falls, Idaho) will be 0.8252. OMB's most recent bulletin (No. 18-04) published on September 14, 2018 has no impact on the geographic delineation used to wage adjust HH PPS payments.

The wage index file for 2020 is available on the CMS Home Health PPS webpage.[11]

3. Comment Solicitation

CMS solicited comments on concerns stakeholders may have regarding the wage index used to adjust home health payments and suggestions for possible updates and improvements to the geographic adjustment of home health payments.

In response to a recommendation that the wage index account for areas with higher minimum wage standards, CMS notes that such increase would be reflected in future data used to create the hospital wage index to the extent those changes are reflected in increased wages to staff. CMS received several recommendations for developing a home health specific wage index and for improving the wage index applied to home health. CMS will consider these recommendations for future rulemaking.

After considering comments, CMS will continue using the pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the HH PPS rates. For 2020, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2015 and before October 1, 2016 (FY 2016 cost report data).

4. CY 2020 Annual Payment Update

a. Background. Effective for 30-day periods of care beginning on or after January 1, 2020, the unit of home health payment changes from a 60-day episode to a 30-day episode. The standardized 60-day payment rate will apply to case-mix adjusted episodes (not LUPAs) beginning on or before December 31, 2019 and ending on or before February 28, 2020. Those 60-day episodes that begin on or before December 31, 2019 and are LUPA episodes will be paid the national, per-visit payment rates shown in Table 23 of the proposed rule.

CMS discusses the methodology it uses to compute the case-mix and wage-adjusted 60-day episodes (for those episodes that span the PDGM implementation date of January 1, 2020) and the 30-day period rates for 2020. CMS may adjust the 60-day or 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect:

- A LUPA is 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).

b. CY 2020 National, Standardized 60-Day Episode Payment Rate. To determine the 2020 national, standardized 60-day episode payment rate for those 60-day episodes than span the implementation date of the PDGM and the change to a 30-day unit of payment, CMS applied a wage index budget neutrality factor and the home health payment update. CMS finalizes its decision not to update the case-mix weights for the 153-group case-mix methodology in 2020.

[11] The wage index file is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Noticesl.html.

Because it will continue to use the 2019 case-mix weights, CMS states it does not have to apply a case-mix weight budget neutrality factor to the 2020 60-day episode payment rate.

The methodology and payment amount for the national standardized 60-day episode payment for HHAs submitting and not submitting quality data are reviewed. Below is a summary of the proposed calculations.

2020 National, Standardized 60-Day Episode Payment Amount, for HHAs Submitting and Not Submitting Quality Data (Tables 17 and 18)		
	HHAs submitting quality data	HHAs not submitting quality data
CY National standardized amount		
2019 amount	$3,154.27	
Wage index budget neutrality factor	x 1.0060	
HH payment update percentage	x 1.5	x 0.995
CY 2020 payment amount	**$3,220.79**	**$3,157.33**

c. *CY 2020 Non-routine Medical Supply (NRS) Payment Rates for 2020 60-day Episodes of Care*. CMS finalizes its proposal to update the NRS conversion factors for particular severity levels.

2020 NRS Conversion Factor for HHSs that Do and Do Not Submit the Required Quality Data (Tables 19 and 21)		
	HHAs that submit quality data	HHAs that do not submit quality data
2019 NRS Conversion Factor	$54.20	
2020 HH Payment Update	1.015	0.995
2020 NRS Conversion Factor	$55.01	$53.93

The 2020 NRS payment amounts for each of the six severity levels based on that conversion factor for HHAs that do and do not submit the required quality data are shown in Tables 19 and 21, respectively. For those that submit quality data, NRS payment amounts range from $14.84 at severity level 1 (the lowest) to $579.00 at severity level 6 (the highest).

CMS notes that under the PDGM, NRS payments are included in the 30-day base payment rate.

d. CY 2020 National, Standardized 30-Day Period Payment Amount. To determine the 2020 national, standardized 30-day period payment rate, CMS applied a wage index budget neutrality factor and the home health payment update percentage. CMS reviews the methodology and payment amount for the national standardized 30-day period for HHAs submitting and not submitting quality data.

2020 National, Standardized 30-Day Episode Payment Amount, for HHAs Submitting and Not Submitting Quality Data (Tables 23 and 24)		
	HHAs submitting quality data	HHAs not submitting quality data
CY National standardized amount		
2020 30-day budget neutral standardized amount (Table 12)	$1,824.99	
Wage index budget neutrality factor	x 1.0063	
HH payment update percentage	x 1.5	x 0.995
CY 2020 30-day payment amount	**$1,864.03**	**$1.827.30**

e. *CY 2020 National Per-Visit Rates for both 60-Day Episodes of Care and 30-Day Periods of Care*. Computations are presented for the 2020 per-visit amounts for each type of service. CMS reminds the reader that the LUPA per-visit amounts are not calculated using case-mix rates. The 2020 per-visit amounts for those HHAs submitting the required quality data (Table 25 in the final rule) are as follows:

2020 National, Per-Visit Payment Amounts for HHAs that Submit Quality Data						
	Home health aide	Medical social services	Occupational therapy	Physical therapy	Skilled nursing	Speech-language pathology
2019 per-visit rates	$66.34	$234.82	$161.24	$160.14	$146.50	$174.06
Wage index budget neutrality factor	1.0066					
2020 Payment update	1.015					
2020 per-visit rates	**$67.78**	**$239.92**	**$164.74**	**$163.61**	**$149.68**	**$177.84**

HHAs that do not submit required quality data would have the payment update for per-visit services reduced from 1.5 percent to -0.5 percent (Table 26 in the final rule), resulting in the following payment rates:

2020 National, Per-Visit Amounts for HHAs that Do Not Submit Quality Data						
	Home health aide	Medical social services	Occupational therapy	Physical therapy	Skilled nursing	Speech-language pathology
2020 per-visit rates	**$66.44**	**$235.19**	**$161.49**	**$160.39**	**$146.73**	**$174.33**

f. Rural Add-On Payments for 2020 Through 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 new 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.

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 website.[12]

The HH PRICER module within the CMS' claims processing system will apply the rural add-on amounts prior to applying any case-mix and wage index adjustments. Table 27 (reproduced below) lists the 2020 through 2022 rural add-on payments outlined in law.

Table 27: HH PPS Rural Add-On Percentages, 2020-2022			
Category	**2020**	**2021**	**2022**
High utilization	0.5%	None	None
Low population density	3.0%	2.0%	1.0%
All other	2.0%	1.0%	None

Several commenters recognized that the phase-out of the rural add-on is based on the BBA of 2018 but expressed concerns that this reduction coupled with other payment system changes would make it financially difficult for rural HHAs. Some commenters suggested that CMS should consider providing coverage for telehealth services related to therapy in rural areas. CMS notes that virtual home health visits would not qualify for payment under the home health benefit. It will consider ways to broadly support such technology as a part of the home health benefit when used to augment the plan of care, but not replace in-person visits.

g. LUPA Add-On Factors and Partial Payment Adjustments. In the 2019 HH PPS final rule (83 FR 56440), CMS finalized its policy to continue multiplying the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor to determine the LUPA add-on payment amount for 30-day periods of care. For 2020 CMS finalizes its proposal not to make any changes in the LUPA add-on factors, which apply for the first or only visit in an episode. The per-visit adjusters for the initial visit are 1.8451 for skilled nursing, 1.6700 for physical therapy, and 1.6266 for speech-language pathology.

The current PEP adjustment is a proportion of the episode payment and is based on the span of days including the start-of-care date or first billable service date through and including the last billable service date under the original plan of care before the intervening event in a home health beneficiary's care. The intervening event is defined as a beneficiary elected transfer or a discharge and return to home health that would warrant, for payment, a new OASIS assessment, physician certification of eligibility, and a new plan of care.

In the 2019 HH PPS final rule (83 FR 56515), CMS finalized its policy to maintain the current process for PEP adjustments for 30-day periods of care. When a new 30-day period begins due to

[12]This information is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html

an intervening event of the beneficiary elected transfer or discharge and return to home during the 30-day episode, the original 30-day period will be proportionally adjusted to reflect the length of time the beneficiary remained under the HHA care prior to the intervening event. The proportional payment is the partial payment adjustment. The PEP is calculated by using the span of days under the original plan as a proportion of 30. To obtain the 30-day payment, the proportion is multiplied by the original case-mix and wage index.

F. Payments for High-Cost Outliers Under the HH PPS

1. Background

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 2020 in the rate update change request to be issued after the publication of the 2020 HH PPS final rule.

In the 2019 HH PPS final rule (83 FR 56521), CMS finalized a policy to maintain the current methodology for payment of high-cost outliers and that beginning in 2020, with the implementation of the PDGM, it will calculate payment for high-cost outliers based upon 30-day periods of care.

2. Fixed Dollar Loss (FDL) 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 2.5 percent aggregate level (as required by statute (section 1895(b)(5)(A) of the Act). 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. In 2017, CMS raised the FDL ratio to 0.55 (from 0.45 in 2016). The FDL ratio is used in the calculation to determine the outlier threshold amount.[13]

For 2019 CMS finalized an FDL ratio of 0.51 to pay up to, but no more than, 2.5 percent of total payments as outlier payments. For 2020, CMS finalizes its proposal not to update the FDL ratio for those 60-day episodes than span the implementation date of the PDGM. For 2020, the FDL ratio is 0.51 for 60-day episodes.

Given the statutory requirements that total outlier payments not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, CMS proposed to set the 2020 FDL ratio for 30-day periods of care at 0.63. Using updated claims data (2018 claims data as of July 31, 2019), CMS finalizes an FDL ratio of 0.56 for 30-day periods of care for 2020.

[13] The national, standardized 60-day episode payment is multiplied by the FDL ratio, and then wage adjusted. This amount is then added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold.

G. Changes to the Split-Percentage Payment Approach for HHAs in 2020 and Subsequent Years

Under the current HH PPS, there is a split-percentage payment approach to the 60-day episode. The first bill, a Request for Anticipated Payment (RAP), is submitted at the beginning of the initial episode for 60 percent of the anticipated final claim payment amount. The second, final bill is submitted at the end of the 60-day episode of care for the remaining 40 percent. For all subsequent episodes, the episodes are paid at a 50/50 percentage payment split. HHAs submit a notice of admission (NOA) within 5 days of the start of care to assure being established as the primary HHA for a beneficiary. The NOA alerts the claims processing system that a beneficiary is under a HH period of care, and it enforces the consolidated billing edits required by law.

In the 2018 HH PPS proposed rule (82 FR 35270), CMS discussed the possibility of phasing out the split percentage payment approach. It continues to believe that as a result of the 30-day period of care, that a split-percentage approach may not be needed to maintain HHAs' cash flow. CMS notes that about 5 percent of requests for anticipated payment are not submitted until the end of a 60-day episode of care and the median length of days for RAP submission is 12 days from the start of the 60-day episode. CMS believes eliminating RAP payments would address existing program integrity vulnerabilities and provides examples.

To address program integrity concerns and the reduced timeframe for the unit of payment, in the 2019 HH PPS final rule (83 FR 56628) CMS finalized the following policies:

- Not to allow newly enrolled HHAs (HHAs certified for participation in Medicare effective on or after January 1, 2019) to receive RAP payments beginning in 2020. CMS stated this allows newly enrolled HHAs to structure their operations without becoming dependent on a partial, advanced payment.
    - These HHAs will still be required to submit a "no pay" RAP at the beginning of care in order to establish the home health episode, as well as 30-days thereafter.
- Allow existing HHAs (HHAs certified for participation in Medicare with effective dates prior to January 1, 2019) to continue to receive RAP payments in 2020.

In the 2019 HH PPS final rule, CMS discussed the possibility of phase-out of the split percentage approach by reducing the percentage of the upfront payment over a period of time and requiring an NOA to be submitted upon full elimination of the split-percentage payment. CMS did not propose this alternative, but it stated it discussed this possibility to clearly signal its intent to potentially eliminate the split percentage payment approach over time.

To address program integrity vulnerabilities, CMS proposed a phase-out approach to split-percentage payments in 2020 and elimination of these payments in 2021. CMS proposed:

- To lower the split-percentage payment from the current 60/50 percent (dependent on whether the RAP is for the initial or subsequent period of care) to 20 percent in 2020 for all 30-day HH periods of care (both initial and subsequent periods of care);
- Full elimination of the split-percentage payments for all providers in 2021;
- Starting in 2021, all HHAs would submit a one-time submission of a NOA, within 5 calendar days of the start of care date, to establish that the beneficiary is under a

Medicare home health period of care and failure to submit a timely NOA would result in a reduction to the 30-day payment amount;
- For periods of care in which an HHA fails to submit a timely NOA, no LUPA payments would be made for days that fall within the period of care prior to the submission of the NOA; and
- CMS may waive the consequences of failure to submit a timely-filled NOA.

Most commenters did not support the phase-out of the split percentage payment. Other commenters stated that CMS was implementing too many policy changes at once and requested additional time for implementation; some commenters requested a multi-year phase-out. CMS continues to believe that with the change in the unit of payment from a 60-day episode of care to a 30-day period of care that a split percentage approach to payment may not be needed for HHAs. CMS believes that the RAP payment of 20 percent in 2020 should help transition existing providers to the new payment system. CMS also believes the phase-out of RAPs will significantly streamline claims processing as HHAs would only need to submit a one-time NOA instead of a RAP for each 30-day period of care. CMS does not think a multi-year phase-out approach would help providers and would continue to subject the program to fraud schemes related to the submission of RAPS. CMS will continue to monitor this issue and may make additional adjustments in future rulemaking if an access to care issue develops.

In response to a commenter's request for CMS to clarify the responsible party in a change of ownership (CHOW) when the RAP is eliminated, CMS notes that a CHOW of an HHA does not change the RAP requirements. CMS also believes that the new RAP policy does nothing to change any corporate protections or the rules regarding civil prosecutions that currently exist. CMS provides examples of HHAs that were identified for billing large amounts of RAPS after a CHOW or the acquisition of an existing agency.

A few commenters supported the NOA proposal; others stated that the NOA requirements were excessive and burdensome. CMS agrees with commenters that since the NOA does not have a payment tied to its submission, the requirements to fulfill the NOA should not be the same requirements associated with the submission of a RAP. For the NOA, starting in 2022, CMS will require the following:
- A written or verbal order from the physician (containing the services required for the initial visit) signed and dated by the physician and if verbal, signed and dated by the registered nurse or qualified therapist (as defined in §484.115) responsible for furnishing or supervising the ordered service in the plan of care signed by the physician; and
- The HHA to conduct the initial start of care visit.

In response to comments requesting that CMS adopt a simple mechanism for timely notification, such as requiring notations in the common working file (CWF) or through the electronic data interchange (EDI), CMS notes there is currently no mechanism that would allow providers to make notations in the CWF. In addition, CMS would be concerned about program integrity risks associated with providers making notations in the CWF. CMS believes the home health NOA process will be operationalized through an EDI submission, similar to the submission of the hospice Notice of Election (NOE). CMS did consider different time frames for the submission of the one-time NOA, including a 7 calendar day timeframe, but it decided to be consistent with

similar requirements in other settings and believes the 5 calendar day requirement would ensure that the claims processing system is alerted as soon as possible to mitigate any potential claims denials of other providers for services covered under the home health benefit. CMS disagrees with commenters opposed to the financial penalty for failing to submit a timely NOA. CMS believes that having a penalty or a reduction in the payment amount is appropriate to aid in expediting the submission of the NOA. In addition, the reduction in payment amount for the late NOA submission is in alignment with the hospice policy for timely submission of the hospice NOE.

CMS appreciates commenters concerns about instituting an NOA process in 2021 after having to make other system changes in 2020. CMS also acknowledges that operational issues with the Medicare claims processing system may make a 2021 implementation date overly ambitious. Therefore, CMS will delay the implementation of an NOA process until 2022. CMS plans to provide education and develop additional guidance on the NOA policy.

CMS final policies for RAPs and submission of NOAs are summarized below. CMS finalizes the corresponding regulation text changes at §484.205.

For CY 2020:

- CMS finalizes for existing HHAs (HHAs certified for participation in Medicare with effective dates prior to January 1, 2019) the upfront split-percentage payment will be reduced from the current 60/50 percent (dependent on whether the RAP is for a new or subsequent period of care) to 20 percent in 2020 for all 30-day HH periods of care (both initial and subsequent periods of care).

In the 2019 HH PPS final rule, CMS finalized that newly enrolled HHAs (HHAs enrolled in Medicare on or after January 1, 2019) are not eligible to receive split-percentage payments in 2020. CMS finalizes its proposal that newly enrolled HHAs will continue to submit "no-pay" RAPS at the beginning of every 30-day period in 2020.

For CY 2021:

- CMS finalizes full elimination of the split-percentage payments for all providers for all 30-day periods of care beginning on or after January 1, 2021.

For 2021, all HHAs (both existing and newly-enrolled HHAs) will submit a "no-pay" RAP at the beginning of each 30-day period to allow the beneficiary to be claimed in the CWF and also to trigger the consolidated billing edits.

The "no-pay" RAP for all HHAs in 2021 will require less information. Starting in 2021, CMS finalizes that the information needed to submit a "no-pay' RAP will be the same as the information also finalized in the NOA. Specifically, the submission of "no-pay" RAPs can be made when the following criteria are met:

1. The appropriate physician's written or verbal order that sets out the services required for the initial visit has been received and documented as required at §§484.60(b) and 409.43(d); and

2. The initial visit within the 60-day certification period must have been made and the individual admitted to home health care.

CMS will allow the HHA to submit both the RAP for the first 30-day period of care and the RAP for the second 30-day period of care (for a 60-day certification) at the same time. In addition, CMS also finalizes a reduction in the payment amount when the HHA does not submit the RAP within 5 calendar days from the start of care date for the first 30-day period of care in a 60-day certification period and within 5 calendar days of day 31 for the second 30-day period of care in the 60-day certification period. This reduction in payment amount would be the same as the NOA non-timely payment reduction: the reduction in payment amount would be equal to a 1/30th reduction to the wage-adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submits the "no-pay" RAP.

CMS also finalizes exceptions to the timely filing consequences of the RAP requirements that are in alignment with the finalized timely-filing NOA provisions.

For CY 2022:

- CMS finalizes that submission of RAPs will be eliminated and the one-time NOA submission policy for all HHAs will be implemented.

All HHAs will be required to submit an NOA to their Medicare contractor within 5 calendar days from the start of care date. The NOA establishes the home health period of care and covers contiguous 30-day periods of care until the individual is discharged from home health services. CMS also finalizes that NOA submission criteria will require HHAs to have a verbal or written order from the physician for the services required for the initial visit and to conduct an initial visit at the start of care.

CMS finalizes that failure to submit a timely NOA would result in a reduction to the 30-day Medicare payment amount, from the start of care date to the NOA filing date. The penalty for not submitting a timely home health NOA would result in Medicare not paying for those days of home health services from the start of care date to the NOA filing date. Specifically, if an HHA failed to submit a timely NOA, the reduction in payment amount would be equal to a 1/30th reduction to the wage-adjusted 30-day period payment amount for each day from the home health start of care until the date the HHA submitted the NOA.

CMS also finalizes its proposal for exceptions to the timely filing consequences of the NOA requirements. An HHA would request a waiver through their MAC. CMS will use the same exceptional circumstances already in place for the hospice NOE. Specifically, exceptional circumstances for a waiver would include, but not be limited to, the following:

- Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the HHA's ability to operate.
- A CMS or MAC systems issue that is beyond the control of the HHA.
- A newly-certified Medicare-certified HHA that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.
- Other situations determined by CMS to not be under the control of the HHA.

CMS also finalizes its proposal that no LUPA payments would be made for days that fall within the period of care prior to the submission of the NOA. These days would be a provider liability, the payment reduction could not exceed the total payment of the claim, and the provider may not bill the beneficiary for these days.

H. Regulatory Change to Allow Therapist Assistants to Perform Maintenance Therapy

CMS discusses the regulations at §409.44(c)(2)(iii) for coverage of therapy visits in the home health setting. CMS notes that a therapist assistant is able to perform restorative therapy (the goals of care are geared towards patient improvement), but the regulations at §409.44(c)(2)(iii)(C) state that only a qualified therapist, and not an assistant, can perform maintenance therapy (therapy is provided when improvement is not feasible in order to prevent or slow decline or deterioration of the patient's condition).

CMS believes it would be appropriate to allow therapist assistants to perform maintenance therapy services under a maintenance program established by a qualified therapist under the home health benefit, if acting within the therapy scope of practice defined by state licensure laws. The qualified therapist would still be responsible for the initial assessment; plan of care; maintenance program development and modifications; and reassessment every 30 days. In addition, the qualified therapist would be responsible for supervising the services provided by the therapist assistant. This policy would be consistent with other post-acute care settings, including SNFs. CMS believes this policy would allow home health agencies more flexibility in resource utilization.

All commenters were supportive of this proposal. Several commenters noted that the proposal and regulations text referenced "physical therapist assistants" and requested the proposal allow all therapist assistants (physical, occupational, and speech-language pathology) to perform maintenance therapy. CMS clarifies that the proposal would allow therapists from all therapy disciplines to perform maintenance therapy within their scope of practice. Additional comments provided mixed recommendations about the need to track whether a visit is for maintenance or restorative therapy or would be appropriate to only identify if the service is furnished by a qualified therapist or an assistant. CMS will take these comments under consideration for future rulemaking and analysis.

CMS finalizes its proposal to allow therapist assistants to perform maintenance therapy under the home health benefit. CMS finalizes the proposed regulations text at §409.44(c)(2)(iii)(C)(1) and (2) with a modification to reflect that all therapist assistants, rather than only physical therapist assistants, can perform maintenance therapy.

I. Changes to the Home Health Plan of Care Regulations at §409.43

As a condition for payment, the regulations at §409.43(a) state that the plan of care must contain those items listed in §484.60(a) that specify the standards relating to a plan of care that an HHA must meet in order to participate in the Medicare program. In the 2017 "Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies" final rule (82 FR 4504), CMS finalized changes to the plan of care requirements under the home health CoPs by reorganizing

the existing plan of care content requirements at §484.18(a), adding two additional plan of care content requirements, and moving the plan of care content requirements to §484.60(a). CMS added that a home health plan of care must also include a description of the patient's risk for emergency department visits and hospital admission, and all necessary interventions to address the underlying risk factors; and information related to any advanced directives.

Since implementation of the new content requirements, CMS clarified in subregulatory guidance in the Medicare Benefit Policy Manual, chapter 7,[14] that the plan of care must include the identification of the responsible discipline(s) providing home health services, and the frequency and duration of all visits, as well as those items required by the CoPs that establish the need for such services (§484.60(a)(2)(iii) and (iv)).

CMS is concerned that the current requirements at §409.43 may be too prescriptive and interfere with timely payments for otherwise eligible episodes of care and proposed to change the regulations. It believes that violations for missing required items should be addressed through the survey process instead of through claims denials for otherwise eligible periods of care. Specifically, CMS proposed to change the regulations text to state that for HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient-specific needs identified in the comprehensive assessment.

All commenters supported the proposal. CMS finalizes its proposal to change the regulations text at 409.43(a) to state that for HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient-specific needs identified in the comprehensive assessment. The plan of care must include the identification of the responsible discipline(s) and the frequency and duration of all visits, as well as those items list in §484.60(a) that establish the need for such services. All care provided must be in accordance with the plan of care.

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

A. Background

The HHVBP Model was established in the 2016 HH PPS final rule (80 FR 68624) as a five-year test in nine states through the Center for Medicare and Medicaid Innovation (CMMI). The first payment adjustments under the HHVBP were applied to 2018 payments based on data for 2016 (performance year (PY) 1). The nine states (AZ, FL, IA, MD, MA, NE, NC, TN, and WA) were selected using a randomized selection methodology set forth in that rule; participation of all Medicare-certified HHAs providing services in those states and meeting data minimums[15] is mandatory. Several changes to the model were subsequently made in the HH PPS final rules for 2017 (81 FR 76741-76752), 2018 (82 FR 51700-51711) and 2019 (83 FR 56527-56547).

[14] The Benefit Manual is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.

[15] HHAs must have a minimum of 20 episodes of care during a performance year to generate a performance score on at least five measures in order to have a payment adjustment percentage calculated.

B. Public Reporting of HHVBP Total Performance Score and Rankings

CMS finalizes its proposal to publicly report HHVBP performance data for HHAs in the nine model states that qualified for a payment adjustment in 2020. Specifically, data on each HHA's HHVBP Total Performance Score (TPS) and TPS percentile ranking from the final 2020 PY 5 Annual Report for HHAs will be displayed on the HHVBP page of the CMS Innovation website.[16] Performance will be reported by HHA name, city, state, and CMS Certification Number. Definitions and descriptions of the scoring methodology will be provided to assist public understanding of the data. CMS expects the data will be made public after December 1, 2021, when the appeals process will be completed and each HHA will have received its final annual report. A reference to the star ratings available on the CMS website will also be included.

Acknowledging that HHVBP performance data will only be provided for the final year of the model, CMS believes public reporting will encourage HHAs to continue to improve the quality of care they provide. It notes that evaluation reports are available on the CMS website and will be updated with forthcoming reports: https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model.

C. HHVBP Measures, Weighting and Performance Scoring

The 2016 HH PPS final rule established a "starter set" of 24 quality measures already reported via the OASIS patient assessment instrument.[17] Four of these measures were subsequently removed in the 2017 HH PPS final rule effective beginning with PY 1. In subsequent rulemaking additional measures were removed or replaced. The final measure set for PY 4 (2019 data for 2021 payment) includes 16 measures, shown in a table below.

No changes were proposed to the HHVBP measure set, the weighting of HHVBP measures or other factors used in calculating the TPS. In the 2019 HH PPS final rule, the weighting was modified beginning with PY 4, and other changes were adopted to the performance scoring methodology.

CMS notes that elsewhere in the final rule the measure Pain Interfering with Activity (NQF #0177) is removed from the HH QRP. (See section V.B below.) HHAs will no longer be required to submit data for this measure effective January 1, 2021. This date falls after the end of the final HHVBP Model reporting year (2020), and therefore the removal of this measure will have no effect on the model measure set.

Measure Set for the HHVBP Model Beginning PY 4			
NQS Domains	**Measure Title**	**Measure Type**	**Data Source**
Clinical Quality of Care	Improvement in Dyspnea	Outcome	OASIS

[16] https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model

[17] OASIS-C2 is the current version of OASIS. It was developed from OASIS-C1/ICD-10 to accommodate new data being collected for HH QRP in support of the IMPACT Act. The OASIS-C2 data item set was implemented on January 1, 2017.

Measure Set for the HHVBP Model Beginning PY 4			
NQS Domains	**Measure Title**	**Measure Type**	**Data Source**
Communication & Care Coordination	Discharged to Community	Outcome	OASIS
	Advance Care Plan	Process	Web Portal
Efficiency & Cost Reduction	Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health	Outcome	Claims
	Emergency Department Use without Hospitalization	Outcome	Claims
Patient Safety	Improvement in Pain Interfering with Activity	Outcome	OASIS
	Improvement in Management of Oral Medications	Outcome	OASIS
Population/Community Health	Influenza Vaccination Coverage for Home Health Care Personnel	Process	Web Portal
	Herpes Zoster (shingles) Vaccination: Has the Patient Ever Received the Shingles Vaccination?	Process	Web Portal
Patient & Caregiver Centered Experience (HHCAHPS)	Care of Patients	Outcome	HHCAHPS
	Communications between Providers and Patients	Outcome	HHCAHPS
	Specific Care Issues	Outcome	HHCAHPS
	Overall Rating of Home Health Care	Outcome	HHCAHPS
	Willingness to Recommend the Agency	Outcome	HHCAHPS
Patient and Family Engagement	Total Normalized Composite Change in Self-Care	Composite Outcome	OASIS
	Total Normalized Composite Change in Mobility	Composite Outcome	OASIS

D. Impact Analysis of HHVBP Model

Because the only change in the HHVBP Model in this final rule involves public reporting, CMS does not change its prior estimate of the five-year impact of the model. In the 2017 HH PPS final rule, CMS estimated that model would reduce payments for 2018 through 2022 by approximately $378 million, and this figure remains the estimate. The 2019 HH PPS final rule included detailed tables showing the distributional effects of the HHVBP model payment adjustments. Because the newly finalized policy on public reporting does not affect its analysis of the distribution of payment adjustments, no updated tables are included.

V. Home Health Care Quality Reporting Program (HH QRP)

A. Background

CMS provides background on the HH QRP, the pay-for-reporting program implemented in 2007 under which the market basket percentage increase is reduced by 2 percentage points for HHAs that do not report required quality data. The previously adopted and finalized measures are shown in a table at the end of this section.

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: HHAs, SNFs, IRFs and LTCHs.

B. Removal of Measure for 2022

The measure Improvement in Pain Interfering with Activity (NQF #0177) is removed from the HH QRP beginning with 2022. The measure reports the percentage of HH episodes during which the patient's frequency of pain with activity or movement is improved. HHA reporting of the associated OASIS item (M1242) for this measure is no longer required effective January 1, 2021 and public reporting of HHA performance on Home Health Compare will continue until April 2020.

The removal is based on the previously adopted removal factor 7: Collection or public reporting of the measure leads to negative unintended consequences other than patient harm. CMS is concerned that the measure could have unintended consequences with respect to the responsible use of opioids for pain management. Although it is unaware of any studies that link this measure to opioid prescribing practices, CMS removes the measure it out of an abundance of caution and to avoid any potential unintended consequences.

A majority of commenters opposed the removal of this measure because pain is an important concern of patients, information on pain is valuable to the care team, and because pain can be a root cause of declining health and quality of life. They also noted the lack of evidence that pain measurement is linked to increased opioid use, and that HHAs do not generally prescribe opioids. Commenters were concerned that removal could reduce the priority of pain management.

In response CMS states that it has a particular concern that measures assessing whether a patient's pain has improved may incentivize over-prescribing of opioids. It plans to further evaluate this issue across all quality programs. Further, regarding removal of OASIS M1242, CMS notes that three new OASIS items assessing the impact of pain on function are finalized in this rule (section V.E below).

C. New and Modified Measures for the 2022 HH QRP

CMS adopts two new process measures for the HH QRP beginning with 2022 under a new quality measure domain entitled "Transfer of Health Information." In addition, it updates the specifications for the Discharge to Community PAC HH QRP measure in order to exclude baseline nursing facility (NF) residents from the measure. Specifications for the measures are posted at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures.html. (At the time this summary was prepared the final rule materials were not yet posted.) Background on the development of the measures, including Technical Expert Panel (TEP) reports and pilot testing results are discussed in the final rule.

These changes to the HH QRP parallel those CMS made for the quality reporting programs applicable to other PAC settings (SNFs, IRFs, and LTCHs) in payment rules for fiscal year 2020 that were published earlier this year. Data submission requirements for the two new measures are discussed in V.H below.

- *Transfer of Health Information to the Provider -- PAC Measure*. This measure assesses whether a current reconciled medication list is given to the subsequent provider when an individual transitions from a post-acute care setting to another setting. Specifically, the HH QRP measure will be calculated as the proportion of HH quality episodes with a discharge or transfer assessment indicating that a current reconciled medication list was provided to the admitting provider at the time of discharge or transfer. (A HH quality episode requires both a Start of Care (initial assessment) or Resumption of Care OASIS assessment and a Transfer or Discharge OASIS assessment.) The denominator is the total number of HH quality episodes ending in discharge or transfer to an admitting provider (short-term general hospital, intermediate care, home care of another home health service organization or hospice, institutional hospice, SNF, LTCH, IRF, inpatient psychiatric facility, or a critical access hospital). The numerator is the number of HH quality episodes indicating a current reconciled medication list was provided to the admitting provider at the time of discharge or transfer.
- *Transfer of Health Information to the Patient -- PAC Measure*. This related new measure assesses whether a current reconciled medication list was provided to the patient, family, or caregiver when a patient was discharged from a PAC setting to a private home/apartment, board and care home, assisted living, group home or transitional living. (CMS says that these locations were chosen because they are captured by items on OASIS.) The measure denominator is the total number of HH quality episodes ending in discharge to the locations listed above, and the numerator is the number of HH quality episodes with an OASIS discharge assessment indicating that a current reconciled medication list was provided to the patient, family, or caregiver at discharge.
- *Update to the Discharge to Community PAC Measure*. Specifications for this measure are modified to remove baseline nursing facility residents. The measure assesses successful discharge to the community from an HHA, including no unplanned re-hospitalizations and no death in the 31 days following discharge. Under the modification, CMS will exclude baseline NF residents from the measure beginning with the 2021 HH QRP, with baseline NF residents defined as HH patients who had a long-term NF stay in the 180 days preceding their hospitalization and HH episode, with no intervening community discharge between the NF stay and qualifying hospitalization. CMS is currently using quarterly Minimum Data Set (MDS) assessments to identify baseline NF residents.

CMS responds to a number of comments regarding the transfer of information measures. It states that it plans to submit them for NQF endorsement as soon as feasible, and notes that no current feasible non-NQF endorsed measures better address the topic. The measure timeline is intended to give providers sufficient time to become familiar with the new measures and engage in training on them. CMS states that although the measures are specified with respect to admitting providers, nothing precludes the sharing of information with therapists and other providers who may be involved in the patient's care once transferred or discharged. Based on TEP feedback and pilot testing, CMS believes these measures will not substantially increase burden on HHAs.

CMS acknowledges the importance of family caregivers and encourages HHAs to collaborate with the family or caregiver when authorized by the patient and to routinely provide opportunities for family and caregivers to identify questions. Finally, CMS encourages HHAs that are electronically capturing discharge information to exchange that information electronically with providers who have the capacity to accept it; electronic transmission of the medication list is not required.

Regarding exclusion of baseline nursing facility residents from the discharge to community measure, CMS reports that a majority of commenters supported this change but MedPAC does not. MedPAC suggests instead expanding the definition of "return to the community" to include baseline nursing home residents returning to the nursing home where they live. CMS disagrees with MedPAC and says that community is generally understood by policy makers, providers and other stakeholders to mean non-institutional settings, and that baseline nursing facility residents are an inherently different patient population.

D. Request for Information on HH QRP Quality Measures, Measure Concepts and Standardized Patient Assessment Data Elements under Consideration for Future Years

CMS describes comments it received in response to its request in the proposed rule regarding the importance, relevance, appropriateness and applicability of the following measures, Standardized Patient Assessment Data Elements (SPADEs) and concepts under consideration for future years. It does not respond to these comments in the final rule but will consider them in future policy making.

- *Quality Measures and Measure Concepts*
    - Potentially preventable hospitalizations
    - Functional improvement and maintenance outcomes
    - Opioid use and frequency
    - Exchange of electronic health information and interoperability
- *Standardized Patient Assessment Data Elements*
    - Cognitive complexity, such as executive function and memory
    - Dementia
    - Bladder and bowel continence including appliance use and episodes of incontinence
    - Care preferences, advance care directives, and goals of care
    - Caregiver Status
    - Veteran Status
    - Health disparities and risk factors, including education, sex and gender identity, and sexual orientation

Summary Table: Measures for the 2021 HH QRP and Changes Adopted for 2022
(2022 changes noted *in italics)*

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)
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)
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
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) ***Finalized for removal 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 – finalized for addition in 2022	*Transfer of Health Information to the Patient-PAC Measure* *Transfer of Health Information to the Provider-PAC Measure*
Claims-based	
ACH	Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171)
DTC	Discharge to Community-Post Acute Care (PAC) HH QRP**
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of Home Health (NQF #0173)
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
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

*Beginning in 2020 this measure replaces Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678)
**Baseline NF residents excluded from this measure beginning with the 2021 HH QRP.

E. Standardized Patient Assessment Data Reporting Beginning with 2022

The IMPACT Act requires that, beginning in 2019, HHAs must report SPADEs as required for at least the quality measures with respect to certain categories, summarized here as functional status; cognitive function; special services and interventions; medical conditions and comorbidities; impairments; and other categories deemed necessary and appropriate by the Secretary. The standardized patient assessment data must be reported under the HH QRP at least

with respect to admissions and discharges, but the Secretary may require the data to be reported more frequently.

SPADEs addressing two of the IMPACT Act categories were adopted in the 2018 HH PPS final rule: 1) Functional status: Data elements currently reported by HHAs to calculate the measure Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function and (2) Medical conditions and morbidities: data elements used to calculate the pressure ulcer measures.

In this rule, CMS finalizes requirements that HHAs report a new series of SPADEs. The list of newly adopted SPADEs, along with information on their current use in PAC patient assessment instruments and whether any changes apply to OASIS are summarized in a table at the end of this section. CMS anticipates publishing a draft of the revised OASIS instrument early in 2020.

Detailed specifications for the SPADEs, including a final change table and mockup of HH QRP data items, will be available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html. (Note that at the time this summary was prepared, only the proposed rule versions of these materials were available.) These change table and mockup documents also include the data elements associated with the new transfer of health information measures discussed above.

The required reporting will begin with the 2022 HH QRP. For 2022 the data will be reported with respect to both admissions and discharges between January 1, 2021 and June 30, 2021. For 2023 and later years, the data will be required for admissions and discharges that occur during a full calendar year – 2021 for the 2023 HH QRP, 2022 for the 2024 HH QRP, etc. The SPADEs must be submitted with respect to the start of care, resumption of care, and discharge, except that as noted below for certain SPADEs, information will only be collected at the start of care.

For each SPADE, the final rule discusses the rationale, whether the element is currently used in any PAC patient assessment instruments, past comments from stakeholders, the results of pilot testing, and responds to comments on the proposed rule. Most of the newly adopted SPADEs were proposed but not finalized as part of FY 2018 rulemaking. Those that were new in this year's rulemaking involve functional status (six mobility-related data elements already adopted for the other three PAC settings); high risk drug classes; pain interference; and social determinants of health, which is a newly added category of SPADEs. These address race, ethnicity, preferred language and interpreter services, health literacy, transportation, and social isolation.

With a change from the proposed rule, CMS finalizes that if certain SPADEs are submitted with respect to admission only, they will be deemed to have been submitted for both admission and discharge as generally required. This policy is finalized because assessment of certain elements is unlikely to change between admission and discharge. As proposed, this policy is finalized for the Hearing, Vision, and Race and Ethnicity SPADEs. In addition, based on comments received from stakeholders, CMS will also apply this policy to the new SPADEs regarding preferred language and interpreter services. CMS disagrees with comments suggesting the policy also

apply to other SPADEs, including transportation, social isolation and health literacy. Those elements will be collected at both admission and discharge because responses may change during the episode for some patients, such as those experiencing cognitive decline or loss of a loved one.

In responding to comments, CMS acknowledges that the introduction of SPADEs will impose additional burden on providers, but it believes that providers and patients will benefit from each of the SPADEs because they are clinically useful, support patient-centered care, and will promote interoperability and data exchange between providers. CMS will continue to evaluate and consider any burden that the IMPACT Act and the HH QRP place on providers. While not all SPADEs will be equally relevant to all patient or PAC providers, CMS believes that even relatively rare treatments or clinical situations are important to document for care planning and transfer of information to the next care setting. It notes that many of the less frequently occurring treatments and conditions are formatted to reduce burden by permitting assessors to check one row for "none of the above." Further, CMS notes that the SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessment in their settings that they believe to be needed and useful.

Most of the comments CMS received on the SPADEs involved the new social determinants of health category. CMS believes that collection of these data will help it identify potential disparities, conduct analyses, and assess whether risk adjustments are needed. Any future policy development will be made through notice and comment rulemaking. Further, it believes that providers will have a better understanding of individual patients' risk factors and preferences which will facilitate better care planning and coordination. With respect to data collection standards on race and ethnicity, readers are referred to the 2011 HHS Data Standards for more detailed information: https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status. CMS notes that while providers are required to ask patients for responses to every SPADE data element question, patients may choose not to respond, with their non-response documented by the provider.

In the collection of information requirements section of the final rule, CMS estimates that the burden of additional reporting of these SPADEs would increase costs by $15,082 on average per HHA annually.

Newly Adopted Standardized Patient Assessment Data Elements, by Category		
Data Elements	**Current Use/Test of Elements***	**Change to OASIS**
Cognitive Function and Mental Status		
Brief Interview for Mental Status (BIMS)	MDS IRF-PAI	New item
Confusion Assessment Method	LCDS (6 items) MDS (4 items)	New item
Patient Health Questionnaire-2 to 9 (depression screening)	MDS (PHQ-9) OASIS (PHQ-2)	Modify and add items

Newly Adopted Standardized Patient Assessment Data Elements, by Category		
Data Elements	**Current Use/Test of Elements***	**Change to OASIS**
Special Services, Treatments, and Interventions		
Cancer Treatment: Chemotherapy (IV, Oral, Other)	MDS (single)	New item
Cancer Treatment: Radiation	MDS	New item
Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-concentration Oxygen Delivery)	MDS OASIS (previous) PAC PRD	New item
Respiratory Treatment: Suctioning (Scheduled, As needed)	MDS PAC PRD	New item
Respiratory Treatment: Tracheostomy Care	MDS	New item
Respiratory Treatment: Non-invasive Mechanical Ventilator (BiPAP, CPAP)	LCDS MDS	New item
Respiratory Treatment: Invasive Mechanical Ventilator	LCDS MDS	New item
Intravenous (IV) Medications (Antibiotics, Anticoagulation, Vasoactive Medications, Other)	MDS OASIS	Replace item
Transfusions	MDS PAC PRD	New item
Dialysis (Hemodialysis, Peritoneal dialysis)	LCDS MDS	New item
Intravenous (IV) Access (Peripheral IV, Midline, Central line, Other)	OASIS	Replace item
Nutritional Approach: Parenteral/IV Feeding	LCDS MDS IRF-PAI OASIS	Modify and add items
Nutritional Approach: Feeding Tube	MDS OASIS IRF-PAI	
Nutritional Approach: Mechanically Altered Diet	MDS OASIS IRF-PAI	
Nutritional Approach: Therapeutic Diet	MDS	
High-Risk Drug Classes: Use and Indications		New item
Medical Condition and Comorbidity Data		
Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities)	OASIS MDS	Replace and add items
Impairment		
Hearing	MDS	New item**
Vision	MDS OASIS	Replace item**
Social Determinants of Health		
Race	MDS LCDS	Replace items**
Ethnicity		

Newly Adopted Standardized Patient Assessment Data Elements, by Category		
Data Elements	**Current Use/Test of Elements***	**Change to OASIS**
	IRF-PAI OASIS	
Preferred Language and Interpreter Services	MDS LCDS	New item**
Health Literacy		New item
Transportation	PREPARE/AHC screening tool	New item
Social Isolation	PROMISE/AHC screening tool	New item
*This column reflects whether CMS indicates that the specific elements proposed, or similar or related elements, are included in the current PAC assessment instruments or tested in the PAC PRD. The PAC instruments referenced are: OASIS; SNF Minimum Data Set (MDS); Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI); and Long-Term Care Hospital Continuity Assessment Record and Evaluation Data Set (LCDS). ** HHAs submitting these SPADEs with respect to admission only would be deemed to have submitted them for both admission and discharge. NOTE: Additional SPADEs are adopted in this rule for purposes of implementing the newly finalized transfer of information measures discussed in section V.C above.		

F. Codification of HH QRP Requirement

CMS codifies the requirements of the HH QRP in 42 CFR 484.285. This new section includes requirements for HH QRP participation; data submission; form, manner and timing of data submission; exceptions and extensions; reconsiderations; and appeals policy. Conforming changes are made to existing regulatory text.

G. Home Health Consumer Assessment of Providers and Systems (HHCAHPS) Survey

CMS does not finalize its proposal to remove Question 10 regarding communication about pain from the HHCAHPS surveys (both mail surveys and telephone surveys). The question asks "In the last 2 months of care, did you and a home health provider from this agency talk about pain?" and is part of the Special Care Issues composite measure which also asks about whether home health agency staff discuss with patients home safety, the purpose of the medications that are being taken, side effects of medications, and when to take medications. The HHCAHPS Survey is available on the official website for HHCAHPS, at https://homehealthcahps.org. The rationale offered for proposing removal of this question was to avoid potential unintended consequences that may arise from its inclusion in the HHCAHPS survey. The proposal was offered as consistent with removal of pain questions from the Hospital CAHPS survey as well as the removal of the measure on improvement in pain interfering with activity, as discussed above in section V.B of this summary.

Commenters objected to removal of this measure, and CMS took this into account as well as concerns raised within HHS that removal would affect the validity of the survey. Commenters

had a variety of concerns including pain assessment is a critical component of patient assessment; there is no evidence that discussion of pain is linked to opioid misuse; home health providers are not able to prescribe opioids; and pain may be the cause of limitations on patient activity.

H. Form, Manner, and Timing of Data Submission under the HH QRP

Data collection via OASIS on the two new transfer of health information quality measures (described in V.C above) will be required beginning with patients discharged or transferred on or after January 1, 2021. For the 2022 HH QRP, HHAs must report these data at discharge and transfer for January 1, 2021 through June 30, 2021. In subsequent years, calendar year reporting is required, beginning with 2021 reporting for the 2023 HH QRP.

The same six-month initial reporting period followed by calendar year reporting applies to data submission for the new SPADEs, as noted above. Specifically, for the initial 2022 payment year the data must be reported with respect to admissions and discharges occurring between January 1, 2021 and June 30, 2021. For 2023 and later years, the data are required for admissions and discharges that occur during a calendar year. (As discussed earlier, reporting of certain SPADEs will only be required at the start of care.)

I. All-Payer Data Reporting for the HH QRP

In the proposed rule, CMS sought comment on its intention to propose in future rulemaking expansion of HH QRP OASIS data reporting to include data on all patients regardless of payer. CMS acknowledged the issue of reporting burden, but notes that many HHAs already collect OASIS data on all patients to avoid clinical and workflow implications associated with maintaining different assessments by payer. CMS believes that collecting information on all patients would ensure that data is representative of HHA quality and allow it to determine whether Medicare beneficiaries receive the same quality of care as other patients. Further, CMS views the lack of all-payer data as limiting its ability to meet the IMPACT Act goal of comparing all patients receiving services in each PAC setting. Currently, all payer data are required for the LTCH and hospice quality reporting programs; CMS proposed but did not finalize collection of all-payer data for SNFs and IRFs in the respective FY 2020 payment rules.

Most commenters were opposed to all-payer OASIS data reporting. Concerns raised include administrative and training burdens, privacy of patient data, lack of difference by payer in care provided, differences in patient demographics, and differences in payer rules (e.g., Medicare's "homebound' requirement and commercial payer limits on visits).

J. Impact Analysis of HH QRP

Changes to the OASIS item collection beginning in 2021 under the HH QRP are estimated to result in a net additional cost of $168 - $172 million annually. (The impact analysis includes both figures in different places.)

Some 1,286 HHAs, about 11 percent of the 11,444 active Medicare-certified HHAs, did not receive the full annual percentage increase for the 2019 annual payment update determination because they failed to meet the requirements of the HH QRP. A 2.0 percentage point reduction to the annual home health market basket percentage applies to HHAs that fail to meet these requirements.

VI. Medicare Coverage of Home Infusion Therapy Services

A. Background and Overview

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 (ASP) 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))[18], 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 DME. 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.

Beginning January 1, 2021, a single payment is 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

[18] 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.

that would be paid under the Medicare physician fee schedule in a physician's office for 5 hours of infusion therapy.

Payment is not made for home infusion therapy for a self-administered drug or biological but this exclusion shall not apply during the transitional period to codes for the drugs and biologicals covered under the DME local coverage determination for External Infusion Pumps (L33794).

Under the transitional payment system in effect for 2019 and 2020, home infusion drugs are assigned to three payment categories based on the HCPCS code for the drug administration.

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).

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

Category 3: Intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals (both initial and subsequent injection/hour).

Transitional home infusion drug additions to LCD L33794 and compounded infusion drugs not otherwise classified will be determined by the DME Medicare Administrative Contractors (MAC).

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). If drug 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.

2. Summary of 2019 Home Infusion Therapy Provisions

CMS created a new HCPCS G-code for each of the three payment categories and finalized the billing procedure for the temporary transitional payment for eligible home infusion suppliers. The eligible home infusion supplier submits, in line-item detail on the claim, a G-code for each infusion drug administration calendar day on which professional services were furnished in person. The claim should include the length of time, in 15-minute increments, for which professional services were furnished.

CMS indicates that section 1834(u)(7)(E)(i) of the Act restricts payment to the date on which professional services were furnished. The 2019 final rule defined "infusion drug administration calendar day" as the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. This definition applies for both the transitional and the permanent home infusion therapy benefit.

CMS will monitor the effects of this definition on access to care and, if warranted and within the limits of its statutory authority, engage in additional rulemaking guidance regarding this definition. Comments on last year's final rule and this year's proposed rule and on this issue and others are being addressed in this year's final rule.

B. 2020 Temporary Transitional Payment Rates for Home Infusion Therapy Services

CMS will update the temporary transitional payments for 2020 based on the CPT code payment amounts in the 2020 PFS final rule not available at the time of publication of the 2020 home health final rule. Updated 2020 temporary transition payments will be provided in the January 2020 DME prosthetics and orthotics (POS) fee schedule.

One commenter complained about 2020 PFS rates being unavailable in the 2020 home health rule. CMS referred commenters to the following websites for the 2020 PFS and DMEPOS fee schedules:

PFS: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F.html

DMEPOS: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html. 2020 DMEPOS fee schedule rates are not yet posted.

Another commenter requested that CMS clarify that nurse practitioners are authorized to establish the home infusion plan of care during the temporary transitional period. CMS responded that it is maintaining its previously-stated requirement that only the physician can establish and review the plan. It is a statutory requirement under section 1861(iii)(1)(B) of the Act that the plan of care be established and periodically reviewed by a physician as defined in section 1861(r) of the Act. The section 1861(r) of the Act definition of a physician does not include nurse practitioners and physician assistants.

C. Home Infusion Therapy Services for 2021 and Subsequent Years

CMS proposed payment for home infusion therapy services for January 1, 2021. Section 1861(iii) of the Act establishes provisions related to home infusion therapy with respect to the requirements that must be met for Medicare payment to be made to qualified home infusion therapy suppliers, and that these provisions serve as the basis for determining the scope of the home infusion drugs eligible for coverage of home infusion therapy services; outline beneficiary qualifications and plan of care requirements; and establish who can bill for payment under the benefit. Additionally, CMS solicited comments on the definition of "infusion drug administration calendar day" and on its potential effects on access to care.

1. Infusion Drug Administration Calendar Day

Public commenters continued to disagree with CMS defining "infusion drug administration calendar day," to include only those days on which a professional is in the home furnishing

services. Commenters requested CMS allow payment of home infusion services "each day that an infusion drug physically enters the patient's body, irrespective of whether a skilled professional is in the individual's home." These commenters argue that CMS' definition fails to capture a broader cross-section of professional services furnished by pharmacists that do not occur in the patient's home.

A few commenters stated CMS' definition would force home infusion therapy suppliers to discontinue furnishing subcutaneous immunoglobulin as the administration of this biological requires virtually no professional services in the home. One commenter indicted that DME suppliers have begun to consolidate or no longer accept new patients and requested that CMS make utilization data from 2019 available for public review to allow for a full assessment of how the current policy has impacted access and/or contributed to provider consolidation. MedPAC continued to support CMS' definition of infusion drug administration calendar day.

CMS responds that its definition of "infusion drug administration calendar day" is consistent with section 1861(iii)(1) of the Act, which defines the term "home infusion therapy" as the items and services furnished by a qualified home infusion supplier, which are furnished in the individual's home. It also consistent with section 1834(u)(7)(E)(i) of the Act which refers to payment only for the date on which professional services were furnished to administer such drugs to such individual.

The final rule responds to concerns about professional services not provided in the home being uncompensated by indicating that the commenters described pharmacist services paid under the DME benefit. The DME supplier standards require the DME supplier to document that it or another qualified party has provided beneficiaries with the necessary information and instructions on how to use Medicare-covered items safely and effectively.[19] The rule distinguishes these services from limited amount of training and education on the appropriate and safe use of equipment associated with home infusion therapy that is not already covered under the DME benefit. The rule lists a number of professional services that would be covered under the home infusion therapy benefit but indicates the list is not exhaustive.

In response to concerns about access, CMS will continue to monitor home infusion therapy utilization to determine what, if any, effects on access to care occur after implementation of the temporary transitional payments for home infusion therapy. The drug pricing change from 95 percent of AWP in 2003 to the most recent quarterly ASP plus 6 percent took effect on January 1, 2017 before there was any payment for home infusion therapy services. CMS indicates there has been a steadily increasing utilization of home infusion therapy drugs across all three care settings (home, outpatient, and physician's office) in the 4th quarter of 2018 relative to the prior quarter. Although there has been fluctuation in the number of DME suppliers supplying transitional home infusion drugs from the 1st quarter of 2016 through the 3rd quarter of 2018, the number has increased between 3rd and 4th quarters indicating that access to services has not been negatively impacted since the change in payment for home infusion drugs even absent any payment at all for home infusion therapy.

[19] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/DMEPOSSupplierStandards.pdf

2. Home Infusion Drugs

For 2019 and 2020, the term "transitional home infusion drug" includes the HCPCS codes for the drugs and biologicals covered under LCD L33794. CMS proposed to carry forward the definition of "home infusion drugs" as defined for the temporary, transitional payment for home infusion therapy services (83 FR 56579).

Consistent with the definition of "home infusion therapy," the home infusion therapy payment explicitly and separately pays for the professional services related to the administration of the drugs identified on LCD L33794 for external infusion pumps. Services covered under the home infusion therapy benefit are intended to provide teaching and training on the provision of home infusion drugs besides the teaching and training covered under the DME benefit.

One commenter requested clarification regarding payment under the home infusion benefit for the administration of intravenous immunoglobulin (IVIG). Similarly, another commenter recommended including IV antibacterial drugs on the list of home infusion drugs eligible for services beginning in 2021. Other commenters requested coverage of home infusion therapy services for other drugs and biologicals under the LCD L33794. Many commenters expressed concern that relying on LCD L33794 limits the ability for new and/or innovative drugs to be added to the home infusion therapy benefit. Commenters recommended requiring the DME MACs further detail the criteria used to make coverage determinations.

CMS responded that IVIG does not require an external infusion pump for administration purposes and therefore, would not be covered under LCD L33794. Immune globulin for primary immunodeficiency currently is the only immune globulin which is administered subcutaneously, not intravenously, and is paid under payment category 2 of the temporary transitional home infusion therapy services payment. There are currently no antibacterial drugs covered under LCD L33794 and, therefore, services for these drugs would not be covered under the home infusion therapy benefit.

CMS declined to add drugs requested by commenters to the home infusion therapy benefit because the statute defines a "home infusion drug" as a parenteral drug or biological administered intravenously or subcutaneously. The drugs commenters requested that CMS add to the home infusion therapy benefit do not meet the statutory definition. CMS decline to add other drugs to the home infusion therapy benefit because 1861(iii)(3)(C) of the Act excludes insulin pump systems and any drugs or biologicals on self-administered drug exclusion lists from the definition of home infusion drug. CMS further added that there are drugs that meet the definition of "home infusion drug" for the transitional payment system but not the permanent home infusion therapy payment system because the exclusion of drugs on the self-administered drug list does not apply to the transitional payment system.

If the MACs determine that additional intravenous infusion drugs or biologicals meet the criteria to be added to LCD L33794, then home infusion therapy services for these newly added intravenous drugs would be covered and assigned to a home infusion therapy payment category.

While the criteria used to determine which items are included on the LCD L33794 is out of the scope of the final rule, **CMS is soliciting comments on the criteria CMS could consider to allow coverage of additional drugs under the DME benefit**. In addition, CMS encouraged commenters to use the reconsideration process to provide available evidence that was not considered in the initial review of a drug not included on LCD L33794 or to sensitize the MAC to emerging evidence that could be useful in an upcoming reconsideration.

3. Patient Eligibility and Plan of Care Requirements

The Medicare statute requires that the beneficiary must be under the care of a physician, nurse practitioner, or physician assistant to be eligible for home infusion therapy. The statute further requires the beneficiary must also be under a plan of care, established by a physician prescribing the type, amount, and duration of infusion therapy services that are to be furnished, and periodically reviewed, in coordination with the furnishing of home infusion drugs. CMS sets out these requirements in 42 CFR §486.520 as *conditions of coverage* for home infusion therapy suppliers to furnish services to Medicare beneficiaries. In the preamble to the rule, CMS further indicates the plan of care must include the specific medication, the prescribed dosage and frequency, as well as the professional services to be utilized for treatment.

CMS proposed to adopt these same requirements as *conditions of payment* for Medicare to pay for a specific instance of home infusion therapy. In addition to the type of home infusion therapy services to be furnished, CMS proposed that the physician's orders for services in the plan of care must also specify at what frequency the services will be furnished, as well as the healthcare professional that will furnish each of the ordered services.

In response to objections that only a physician may establish and periodically review the plan of care, CMS reiterated its earlier response that section 1861(iii)(1)(B) of the Act limits establishing and reviewing a plan of care to a physician as defined at section 1861(r)(1) of the Act that includes doctors of medicine and osteopathy but not nurse practitioners or physician assistants. CMS will consider whether a nurse practitioner or physician assistant can update the plan of care in future rulemaking.

Several commenters recommended that CMS require the physician to review the plan of care at least every 90 days. CMS declined to provide a specific timeframe for reviewing the plan of care because of comments concerned about conflicts with state law requirements. Consistent with the 2019 final rule, CMS is deferring to state law requirements on the timeframe for reviewing plan of care. As section 1861(iii)(1)(B) requires that review of the plan of care occur in coordination with the furnishing of home infusion drugs, CMS is requiring that the home infusion plan of care must be established and reviewed by the physician, in consultation with the DME supplier responsible for furnishing the home infusion drugs. CMS will consider establishing a timeframe for physician review of the plan of care in future rulemaking.

There were comments recommending that CMS require home infusion suppliers to document a variety of different element in the plan of care. CMS responded that required elements of the regulations already established in rulemaking (§486.520(b) and §414.1515) capture the majority

of the commenters' recommendations. Any additional regulatory plan of care elements would be required to go through notice and comment rulemaking.

There were comments recommending that CMS add a requirement that the same physician be responsible for signing the DME detailed written order (DWO) and the home infusion therapy plan of care to avoid risk for medication errors resulting from conflicting orders being obtained by the individual providers involved in the patient's care. CMS declined to establish such a requirement because the statute does not specify that the home infusion plan of care must be established by the same physician who orders the DME and signs the DWO. Regardless of whether the physician ordering the home infusion drug is the same physician ordering the home infusion therapy services, there must be care coordination between both entities in order to meet the plan of care requirements under §486.520(a).

CMS is finalizing its policies as proposed with minor modifications to the regulatory text that are not substantive.

4. Qualified Home Infusion Therapy Suppliers and Professional Services

A "qualified home infusion therapy supplier" is a pharmacy, physician, or other provider of services or supplier licensed by the State in which it furnishes items or services that must:

- furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;
- ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour a day basis;
- be accredited by an organization designated by the Secretary; and
- meet such other requirements as the Secretary determines appropriate.

CMS does not enumerate a list of "professional services" that may be necessary for the care of an individual patient. The rule specifies that no payment can be made for Medicare services under Part B that are not reasonable and necessary for the diagnosis or treatment of illness.

Payment for an infusion drug administration calendar day is a bundled payment, which reflects not only the visit itself, but any necessary follow-up work (which could include visits for venipuncture), or care coordination provided by the qualified home infusion therapy supplier on days in which professional services are not being provided in the home. Care coordination furnished by the DME supplier responsible for furnishing equipment and supplies, including the home infusion drug, is paid for under the DME benefit. Care coordination furnished by the physician who establishes the plan of care is separately billable under the PFS.

Several commenters expressed concern about care coordination between different entities providing services under various benefits. One commenter noted that under the commercial payer structure, the pharmacy is the entity contracted to supply the drugs, equipment, and supplies. There were commenters recommending that the Secretary add a new requirement that the home infusion therapy supplier be enrolled in the DME program as a pharmacy that provides external infusion pumps and supplies, and that maintains all pharmacy licensure and

accreditation requirements, and that all components of the home infusion benefit should be billed by the same provider, including professional services, drugs, pumps, and supplies.

CMS declined to establish the requested requirement indicating that the statute does not require that the DME supplier also furnish home infusion therapy services. The final rule references section 1861(iii)(3)(D)(ii) of the Act that allows a qualified home infusion therapy supplier to sub-contract with a pharmacy, physician, provider of services, or supplier to provide these services suggesting the provision would allow for the type of care coordination requested by the commenters. Further, other provisions of statute address care coordination requirement of concern to the commenters. Section 1861(iii)(1)(B) of the Act states that the home infusion therapy plan of care must be established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs. The DME Quality Standards require the supplier furnishing the infusion drug to consult with the physician prescribing the infusion drug as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluation to the prescribed equipment item(s), and/or service(s) (84 FR 34692).

Additional comments stated that the home infusion therapy benefit was established to make up for the drug pricing change from AWP to ASP plus 6 percent. Commenters stated that the home infusion therapy benefit was intended for services provided remotely by a pharmacist to be reimbursed without regard to overlap with the DME benefit or contingent on the patient's nursing needs. CMS responded that Medicare does not generally implement new benefits in order to subsidize other existing benefits. Additionally, Medicare does not make duplicative payment for services and would not require two different benefits to furnish the same services to a single beneficiary.

5. Home Infusion Therapy and the Interaction with Home Health

The proposed rule indicated that during 2019 and 2020, home health services covered under the Medicare home health benefit continue to include in-home services covered under the new home infusion therapy benefit. The final rule outlines the process for billing services under either the home health benefit or the home infusion therapy benefit:

When the home health agency and the home infusion therapy provider are the same entity:

- If the home visit is exclusively for furnishing items and services related to the administration of the home infusion drug, the home health agency would submit a home infusion therapy services claim under the home infusion therapy benefit.
- If the home visit includes the provision of other home health services in addition to, and separate from, home infusion therapy services, the home health agency would submit both a home health claim under the home health PPS and a home infusion therapy claim under the home infusion therapy benefit. The home health agency must separate the time spent furnishing services covered under the home health PPS from the time spent furnishing services covered under the home infusion therapy.

DME is excluded from the consolidated billing requirements governing the home health PPS (42 CFR 484.205) and therefore, the DME items and services (including the home infusion drug and related services) will continue to be paid for outside of the home health PPS.

When the home health agency and the home infusion therapy provider are different entities, the home health agency would continue to bill under the home health PPS on the home health claim, and the qualified home infusion therapy supplier would bill for the services related to the administration of the home infusion drugs on the home infusion therapy services claim.

Home health agencies expressed several concerns about the home infusion therapy benefit including additional beneficiary coinsurance under the home infusion therapy benefit for services previously covered under the home health benefit; home health agencies needing to be accredited to furnish home infusion therapy services; and home health agencies being required to furnish pumps, related supplier and home infusion medications. One commenter recommended that the home infusion benefit should only be available for beneficiaries who are not homebound, and infusion services for otherwise eligible home health beneficiaries should remain under the home health benefit.

CMS indicated that section 1861(m) of the Act excludes home infusion therapy from home health services effective January 1, 2021. Therefore, home infusion therapy will no longer be provided to homebound patients under the home health benefit. Home infusion therapy services will now be provided under the home infusion benefit for both homebound and non-homebound beneficiaries. CMS indicates that home health agencies are not required to furnish pumps, related supplier and home infusion medications but are already required to arrange for the DME and related infusion services for patients under a home health plan of care. In the case of a home health agency that becomes accredited as a home infusion therapy supplier, the home health agency would continue to meet the requirements under the Home Health Conditions of Participation as well as the home infusion therapy supplier requirements as set out in Part 486, Subpart I, of which DME services, including pharmacy services associated with the preparation and dispensing of home infusion drugs are not included.

6. Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

CMS solicited comments on the statutory requirement that prior to furnishing home infusion therapy, the physician who establishes the plan of care for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department). Commenters suggested a variety of verbal and written requirements as well as requests to minimize the paperwork burden and confusion that written documents or patient attestations could impose on physicians and patients. CMS does not respond to the individual suggestions in the comments but will take them into consideration as it develops future policy through notice-and comment rulemaking.

D. Payment Categories and Amounts for Home Infusion Therapy Services for 2021

CMS proposed to carry forward the three temporary transitional payment categories for the home infusion therapy services payment in 2021 except it proposed that payment equal 5 hours of infusion per day rather than 4 hours. The law indicates that the payment cannot exceed 4 hours per day under the transitional system and 5 hours per day under the permanent system. Subsequent drugs added to the DME LCD for external infusion pumps, and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be grouped into the appropriate payment category by the DME MACs.

Payment for an infusion drug administration calendar day would not vary within each category but would vary between each category. CMS indicates that the values of the CPT infusion code amounts, in accordance with the different payment categories, reflect variations in nursing utilization, patient acuity, and complexity of drug administration, as they are directly proportionate to the clinical labor involved in furnishing the infusion services in the patient's home. The rule states that the proposed policy is consistent with statutory requirement to vary payment by patient acuity and the complexity of drug administration.

CMS proposed increasing 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 and established patient evaluation and management (E/M) service for a given year. Any changes in the plan of care or drug regimen, including the addition of drugs or biologicals that may change the payment category, would not trigger a first visit payment amount. There must be a gap in receiving home infusion therapy services of more than 60 days in order to bill a first visit again. CMS proposed to apply this policy uniformly to patients receiving home infusion therapy services under both the temporary and permanent benefits. CMS plans to monitor home infusion therapy service lengths of visits, both initial and subsequent, in order to evaluate whether the data substantiates the increase to the initial visit payment amount or if it should be reevaluated.

Some commenters recommended that CMS reimburse all home infusion professional services at the proposed rate for payment category 3 (1 hour at CPT 96413 and 4 hours at CPT 96415). Another commenter stated that the CPT description for the category three CPT codes are more expansive than only chemotherapy drugs but CMS only includes chemotherapy drugs among those that are paid the category 3 payment amounts. The majority of commenters supported the 5-hour payment rate; however, these commenters continued to disagree with the definition of "infusion drug administration calendar day" and indicate that the codes should be billable each day the drug is infused rather than each day professional services are furnished in the patient's home.

CMS responded that paying a single amount at the category 3 rate for the professional services for all home infusion drugs would not take into account types of infusion therapy, including the variation in utilization of nursing services, patient acuity, and complexity of drug administration as required by the statute. The final rule recognizes that the CPT codes associated with payment for category 3 home infusion drugs also includes other highly complex drugs and biologicals beyond chemotherapy drugs. However, the only drugs included in LCD L33794 appropriate for this category are the cancer chemotherapy drugs. CMS believes that a single unit of payment

equal to 5 hours of infusion therapy services in a physician's office is a reasonable approach to account for the bundled services included under the home infusion therapy benefit. It reiterated its prior responses to the definition of "infusion drug administration calendar day."

Final Decision: CMS is finalizing its proposal to maintain the three payment categories currently being utilized under the temporary transitional payments for home infusion therapy services. Each category payment amount will be in accordance with the six CPT infusion codes under the PFS and equal to 5 hours of infusion services in a physician's office. CMS will apply an adjustment to increase the initial visit payment by the new patient rate over an existing patient rate using the physician E/M payment amounts for a given year. The adjustment will be budget neutral resulting in a small decrease to the payment amounts for any subsequent visits.

CMS is further seeking comments on the criteria CMS could consider to allow coverage of additional drugs under the DME benefit. In order for a drug to be covered as a supply under the Medicare DME benefit, the drug itself must require administration through an external infusion pump. The DME Supplier Standards require that the supplier train the patient and/or caregiver to operate the equipment safely and effectively in the home. As such, the patient and/or caregiver must be able to use the equipment on his/her own. For this reason, the DME LCDs for External Infusion Pumps do not currently include drugs that the patient and/or caregiver would not be able to infuse in the home without a healthcare professional present. The new permanent home infusion therapy benefit includes payment for professional services. For this reason, CMS is soliciting comments on improving policies for coverage of eligible drugs for home infusion therapy. For example, CMS ask whether coverage could include instances where diseases or conditions prevent a patient from being able to self-infuse, such as due to a neurodegenerative disease).

The below combines final rule tables 30/31/32 with the categories for each of the home infusion drugs and the associated drug administration codes that would be used for payment as well as the proposed payment amounts based on the 2019 PFS.

TABLE 28/29/31: INFUSION DRUG J-CODES PAYMENT CATEGORIES FOR 2021				
HCPCS	**Drug**	**Codes**	**First Visit***	**Subsequent Visit***
Category 1		**96365, 96366**	**$255.25**	**$153.54**
J0133	Injection, acyclovir, 5 mg			
J0285	Injection, amphotericin b, 50 mg			
J0287	Injection, amphotericin b lipid complex, 10 mg			
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg			
J0289	Injection, amphotericin b liposome, 10 mg			
J0895	Injection, deferoxamine mesylate, 500 mg			
J1170	Injection, hydromorphone, up to 4 mg			
J1250	Injection, dobutamine hydrochloride, per 250 mg			
J1265	Injection, dopamine hcl, 40 mg			
J1325	Injection, epoprostenol, 0.5 mg			
J1455	Injection, foscarnet sodium, per 1000 mg			
J1457	Injection, gallium nitrate, 1 mg			
J1570	Injection, ganciclovir sodium, 500 mg			
J2175	Injection, meperidine hydrochloride, per 100 mg			

TABLE 28/29/31: INFUSION DRUG J-CODES PAYMENT CATEGORIES FOR 2021				
HCPCS	**Drug**	**Codes**	**First Visit***	**Subsequent Visit***
Category 1		**96365, 96366**	**$255.25**	**$153.54**
J2260	Injection, milrinone lactate, 5 mg			
J2270	Injection, morphine sulfate, up to 10 mg			
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg			
J3010	Injection, fentanyl citrate, 0.1 mg			
J3285	Injection, treprostinil, 1 mg			
Category 2		**96369, 96370**	**$357.44**	**$215.00**
J1555	JB Injection, immune globulin (cuvitru), 100 mg			
J1561	JB Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg			
J1562	JB Injection, immune globulin (vivaglobin), 100 mg			
J1569	JB Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg			
J1575	JB Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin			
Category 3		**96413, 96415**	**$422.70**	**$254.26**
J9000	Injection, doxorubicin hydrochloride, 10 mg			
J9039	Injection, blinatumomab, 1 microgram			
J9040	Injection, bleomycin sulfate, 15 units			
J9065	Injection, cladribine, per 1 mg			
J9100	Injection, cytarabine, 100 mg			
J9190	Injection, fluorouracil, 500 mg			
J9360	Injection, vinblastine sulfate, 1 mg			
J9370	Injection, vincristine sulfate, 1 mg			

*For each of the payment categories, CMS proposes to pay 1 unit of the initial infusion hour and 4 units for each subsequent hour. Payment amounts are based on 2020 PFS proposed rule payments amounts. The final home health PPS rule includes the proposed 2020 PFS payment amount because the 2020 PFS final rule was not yet public at the time the final rule was released.

E. Required Payment Adjustments for 2021 Home Infusion Therapy Services

1. Home Infusion Therapy Geographic Wage Index Adjustment

CMS proposed 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 calculated by multiplying the physician work, PE and MP GPCIs by the corresponding national cost share weight: work (50.886 percent), PE (44.839 percent), and MP (4.295 percent). The GAF is updated at least every 3 years per statute and reflects a 1.5 percent work GPCI floor for services furnished in Alaska as well as a 1.0 PE GPCI floor for services furnished in frontier states (Montana, Nevada, North Dakota, South Dakota and Wyoming).

CMS' policy would apply the GAF to the home infusion therapy single payment amount based on the zip code of where the beneficiary is receiving the service. The list of GAFs by locality for this final rule is available as a downloadable file at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html (last link at the bottom of the page).

CMS considered adjusting the single payment amount based on the hospital wage index, the GPCI or just the practice expense component of the GPCI. However, CMS believes the GAF is the best option for geographic wage adjustment because there are already mechanisms in place to geographically adjust using the GAF and applying this option would require fewer system changes.

CMS proposed that the application of the geographic wage adjustment be budget neutral. The budget neutrality factor will be recalculated for 2021 in next year's rule using 2019 utilization data from the first year of the temporary transitional payment period. One commenter supported CMS' proposal that it is finalizing without change.

2. Consumer Price Index

Consistent with the statute, CMS proposed 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 multifactor productivity. The rule does not present any comments on this policy.

F. Other Optional Payment Adjustments/Prior Authorization for 2021 Home Infusion Therapy Services

1. Prior Authorization

Section 1834(u)(4) of the Act allows CMS to adopt prior authorization for home infusion therapy services. CMS does not believe that prior authorization for home infusion therapy services is necessary at this time, as services are contingent on the requirements under the DME benefit. CMS will monitor the provision of home infusion therapy services and revisit the need for prior authorization if issues arise. One commenter opposed use of prior authorization in the home infusion therapy benefit.

2. Payments for High-Cost Outliers for Home Infusion Therapy Services

Section 1834(u)(1)(C) of the Act allows CMS to adopt adjustments for outlier situations and other factors as the Secretary determines appropriate. CMS does not believe that high cost outlier payments are necessary at this time and plans to monitor the need for such payments and, if necessary, address in future rule making. MedPAC commented agreeing that it is premature at this time to develop outlier payments for home infusion therapy services.

G. Billing Procedures for 2021 Home Infusion Therapy Services

CMS continues to believe that, as a qualified home infusion therapy supplier is only required to enroll in Medicare as a Part B supplier, and is not required to enroll as a DME supplier, it is more practicable to process home infusion therapy service claims through the A/B MACs and the Multi-Carrier System for Medicare Part B claims. DME suppliers, also enrolled as qualified home infusion therapy suppliers, would submit DME claims through the DME MACs and home infusion therapy service claims to the A/B MACs for processing.

CMS plans to require qualified home infusion therapy suppliers to submit all home infusion therapy service claims on the 837P/CMS-1500 professional and supplier claims form to the A/B MACs. DME suppliers, concurrently enrolled as qualified home infusion therapy suppliers, would need to submit two claims: 1) one claim for the DME, supplies, and DME drugs on the 837P/CMS-1500 professional and supplier claims form to the DME MAC; and 2) a separate 837P/CMS-1500 for the professional services to the A/B MAC.

Because the home infusion therapy services are contingent upon a home infusion drug J-code being billed, home infusion therapy suppliers must ensure that the appropriate drug associated with the visit is billed with the visit no more than 30 days prior to the visit. CMS plans to add the home infusion G-codes to the PFS, incorporating the required annual and geographic wage adjustments. Home infusion therapy suppliers would include a modifier on the appropriate G-code to differentiate the first visit from all subsequent visits, as well as a modifier to indicate when a patient has been discharged from service.

DME suppliers expressed concerns about needing to be enrolled with both the A/B MAC and the DME MAC; particularly that the 855B A/B enrollment form does not include a category for "home infusion therapy supplier" and that DME suppliers are not required to be in the same state as the patient. DME suppliers can distribute drugs and supplies across a broad geographical region to Medicare beneficiaries who spend parts of the year in different states. These commenters encouraged CMS to allow for jurisdictional enrollment and billing of home infusion therapy services without the requirement to have a physical location within the jurisdiction; and allow for DME suppliers, also accredited as qualified home infusion therapy suppliers, to complete a single A/B MAC application identifying all areas that they schedule and dispatch the nursing component of home infusion therapy.

CMS responded that DME suppliers that become accredited as a home infusion therapy supplier would complete an additional enrollment with the A/B MACs in order to submit home infusion therapy service claims. Until such time as CMS creates a "home infusion therapy supplier" type on the 855B enrollment form currently under consideration, suppliers can enroll using the "other" option. CMS will take other enrollment suggestions under consideration as it continues developing guidance for suppliers.

In 2020, CMS estimates a decrease of 1.9 percent in home infusion therapy payments as a result of changes to PFS payments for drug administration. However, these impacts are based on PFS proposed rule rates as final rule rates were unavailable at the time the home health rule's release.

Table 36 in the final rule provides details on the estimated impact of the 2021 payment of home infusion therapy services. CMS notes payment amounts are contingent on the 2020 PFS rates, which were not available for this analysis. There will be significant decreases in payment for home infusion therapy services in 2021 because statutorily excluded drugs on the self-administered drug list that trigger coverage of home infusion therapy under the transitional system in 2019 and 2020 will no longer do so in 2021. Some of these reductions will be offset in 2021 as the transitional payment in 2019 and 2020 that is based on 4 hours of drug administration will be increased to 5 hours in 2021. CMS estimates an overall decrease of 3.6 percent ($2 million) in payments to home infusion therapy suppliers in 2021. The estimated

impact is greater in rural areas and varies by region and by BBA payment category, with category 2 showing a decrease of 41.3 percent (due to the exclusion of Hizentra) while the categories 1 and 3 show increases of 15.9 percent and 13.3 percent, respectively.

VII. Waiver of Proposed Rulemaking

CMS uses its authority to waive proposed rulemaking for "good cause" to finalize submission of a "no-pay" RAP within five calendar days after the start of each 30-day period of care for 2021 and to apply a payment reduction if the "no-pay" RAP is not submitted timely. (See section III.G above.) These changes are in accordance with the proposed policy for submission of an NOA in 2021, which in this final rule is delayed until 2022. CMS notes that if the NOA policy would have been finalized as proposed for 2021, the payment reduction for an untimely filed NOA would also have applied. Therefore, finalizing a "no-pay" RAP policy, as opposed to an NOA policy, with an untimely submission payment reduction in 2021 is not substantively different from what was proposed.

In addition, proposed rulemaking is waived with respect to technical changes in regulatory text at §486.505 (in the definition of "applicable provider" the term "nurse practitioner" replaces "nurse provider" and §414.1550(a)(1) and (2).

VIII. Regulatory Impact Analysis

CMS provides a regulatory impact analysis (RIA) because the final rule is a major rule that meets the threshold of an economic impact of $100 million or greater. Some portions of this analysis (e.g., HHVBP, HH QRP, home infusion therapy) are discussed in the earlier sections of this summary. The overall impact of the changes in the HH PPS system on payments to HHAs in 2020 is summarized here.

Summary of overall regulatory impact analysis		
Policy	**2020 impact**	
	Percentage	**Dollars**
HH PPS update	+ 1.5%	+$290 million
New rural add-on provision	-0.2%	- $40 million
Net impact	+1.3%	+$250 million

CMS estimates that the net impact of the HH PPS policies in this final rule is an increase of 1.3 percent, or $250 million, in Medicare payments to HHAs for 2020. This estimate does not take into account the estimated $1.2 million decrease (-1.9%) in Medicare payments to home infusion suppliers in 2020 as determined under the Physician Fee Schedule (PFS). Finally, the estimate does not take into account the effects on payments to HHAs in 2020 resulting from the HHVBP model.

Table 35, reproduced below from the final rule, provides details on the impact by facility type and ownership, by rural and urban area, by census region and by facility size. It breaks out the payment effects of the 2020 wage index, the rural add-on payment, and the effects of the

implementation of the PDGM case-mix methodology. Proprietary free-standing urban HH facilities (about 80 percent of all facilities) show an average increase of payments of 0.3 percent, with all other categories significantly higher.

TABLE 35: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTY, CY 2020

	Number of Agencies	CY 2020 Wage Index	CY 2020 Rural Add-On	CY 2020 Case-Mix Weights (PDGM)	CY 2020 HH Payment Update Percentage[1]	Total
All Agencies	10,185	0%	-0.2%	0.0%	1.5%	1.3%
Facility Type and Control						
Free-Standing/Other Vol/NP	1,014	-0.2%	-0.1%	2.5%	1.5%	3.7%
Free-Standing/Other Proprietary	8,157	0.0%	-0.1%	-1.1%	1.5%	0.3%
Free-Standing/Other Government	233	-0.1%	-0.4%	2.5%	1.5%	3.5%
Facility-Based Vol/NP	549	-0.1%	-0.2%	3.6%	1.5%	4.8%
Facility-Based Proprietary	63	0.2%	-0.3%	2.9%	1.5%	4.3%
Facility-Based Government	169	0.4%	-0.4%	4.4%	1.5%	5.9%
Subtotal: Freestanding	9,404	-0.1%	-0.1%	-0.3%	1.5%	1.0%
Subtotal: Facility-based	781	0.0%	-0.2%	3.7%	1.5%	5.0%
Subtotal: Vol/NP	1,563	-0.2%	-0.1%	2.8%	1.5%	4.0%
Subtotal: Proprietary	8,220	0.0%	-0.1%	-1.1%	1.5%	0.3%
Subtotal: Government	402	0.2%	-0.4%	3.6%	1.5%	4.9%
Facility Type and Control: Rural						
Free-Standing/Other Vol/NP	248	-0.3%	-0.7%	3.7%	1.5%	4.2%
Free-Standing/Other Proprietary	820	0.2%	-0.7%	3.4%	1.5%	4.4%
Free-Standing/Other Government	152	0.1%	-0.8%	0.3%	1.5%	1.1%
Facility-Based Vol/NP	245	0.6%	-0.8%	3.4%	1.5%	4.7%
Facility-Based Proprietary	33	0.3%	-0.8%	10.4%	1.5%	11.4%
Facility-Based Government	132	0.3%	-0.8%	4.6%	1.5%	5.6%
Facility Type and Control: Urban						
Free-Standing/Other Vol/NP	766	-0.2%	0.0%	2.3%	1.5%	3.6%
Free-Standing/Other Proprietary	7,337	-0.1%	-0.1%	-1.7%	1.5%	-0.4%
Free-Standing/Other Government	81	-0.3%	0.0%	4.3%	1.5%	5.5%
Facility-Based Vol/NP	304	-0.2%	-0.1%	3.7%	1.5%	4.9%
Facility-Based Proprietary	30	0.1%	-0.1%	-0.4%	1.5%	1.1%
Facility-Based Government	37	0.5%	-0.1%	4.1%	1.5%	6.0%
Facility Location: Urban or Rural						
Rural	1,630	0.2%	-0.7%	3.5%	1.5%	4.5%
Urban	8,555	-0.1%	-0.1%	-0.5%	1.5%	0.8%
Facility Location: Region of the Country (Census Region)						
New England	355	-0.7%	-0.1%	2.5%	1.5%	3.2%
Mid Atlantic	469	-0.2%	-0.1%	3.0%	1.5%	4.2%
East North Central	1,896	-0.1%	-0.1%	-0.9%	1.5%	0.4%
West North Central	681	0.5%	-0.3%	-4.2%	1.5%	-2.5%
South Atlantic	1,612	-0.2%	-0.1%	-4.9%	1.5%	-3.7%
East South Central	410	0.1%	-0.4%	0.5%	1.5%	1.7%
West South Central	2,577	0.2%	-0.2%	4.1%	1.5%	5.6%
Mountain	692	0.1%	-0.1%	-5.4%	1.5%	-3.9%
Pacific	1,448	0.0%	0.0%	3.7%	1.5%	5.2%

	Number of Agencies	CY 2020 Wage Index	CY 2020 Rural Add-On	CY 2020 Case-Mix Weights (PDGM)	CY 2020 HH Payment Update Percentage[1]	Total
Outlying	45	-0.4%	-0.3%	11.9%	1.5%	12.7%
Facility Size (Number of 60-day Episodes)						
< 100 episodes	2,741	0.2%	-0.1%	2.5%	1.5%	4.1%
100 to 249	2,154	0.1%	-0.1%	0.9%	1.5%	2.4%
250 to 499	2,134	0.1%	-0.1%	0.6%	1.5%	2.1%
500 to 999	1,660	0.0%	-0.2%	-0.3%	1.5%	1.0%
1,000 or More	1,496	-0.1%	-0.1%	-0.2%	1.5%	1.1%

Source: CY 2018 Medicare claims data for episodes ending on or before December 31, 2018 for which we had a linked OASIS assessment (as of July 31, 2019).

[1]The CY 2020 home health payment update percentage reflects the home health payment update of 1.5 percent as described in section III.F.1 of the final rule with comment period.

Notes: This analysis omits 307,949 60-day episodes not grouped under the PDGM (either due to a missing SOC OASIS, because they could be assigned to a clinical grouping, or had missing therapy/nursing visits). After converting 60-day episodes to 30-day periods for the PDGM, a further 28 periods were excluded with missing NRS weights, and 2,869 periods with a missing urban/rural indicator; in total 9,336,898 30-day periods were used in the analysis.

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York;
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
P**acific**=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands