Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accreditation Organizations

(CMS-1689-FC)

Summary of Final Rule

The Centers for Medicare & Medicaid Services (CMS) published in the November 13, 2018 *Federal Register* (83 FR 56406-56638)) a final rule with comment period addressing the 2019 Home Health Prospective Payment System (PPS) rate update;[1] 2020 case-mix adjustment methodology refinements, the Home Health Value-Based Purchasing (HHVBP) Model, home health quality reporting requirements, and other items. The rule is available at: https://www.federalregister.gov/documents/2018/11/13/2018-24145/medicare-and-medicaid-programs-cy-2019-home-health-prospective-payment-system-rate-update-and-cy

This is a final rule with comment period. CMS is seeking comments on the definition of "infusion drug administration calendar day" at §486.505. These comments are due by December 31, 2018.

This rule is generally effective on January 1, 2019. The Patient-Driven Groupings Model (PDGM) case-mix methodology refinements and the change in the unit of payment from 60-day episodes of care to 30-day periods of care will apply to home health services (30-day periods of care) beginning on or after January 1, 2020.

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

I. Overview

Update to Home Health Prospective Payment System (HH PPS): CMS updates the national standardized 60-day episode rate with a market basket increase of 3.0 percent, reduced by a 0.8 percent productivity adjustment, for a net 2.2 percent update for home health agencies (HHAs) submitting quality data and 0.2 percent for those that do not submit quality data. The 2019 home health wage index is updated using fiscal year (FY) 2015 hospital cost report data. CMS finalizes a proposal to implement the new rural add-on policy mandated by the Bipartisan Budget Act (BBA) of 2018 (P.L. 115-123). This policy varies the rural add-on payment based on whether the HHA is located in one of three rural county classifications: (1) high home health utilization, (2) low population density, and (3) all others. CMS also finalizes its proposal to lower the fixed dollar loss (FDL) ratio from 0.55 to 0.51 and maintain the loss-sharing ratio of 0.80.

Implementation of the Patient-Driven Groupings Model (PDGM) for 2020: The BBA of 2018 mandated that CMS stop using the number of therapy visits provided to determine payment under the HH PPS. It also required that CMS change the unit of payment from 60-day episodes of care to 30-day periods of care, and that this change be implemented in a budget neutral manner beginning on January 1, 2020. For home health services beginning on or after January 1, 2020, CMS finalizes its proposal, with modifications, to revise its case-mix methodology and payment categories by using the Patient-Driven Groupings Model (PDGM). The PDGM groups home health patients into payment categories using primarily clinical characteristics and other patient information and eliminates the therapy service use thresholds that are currently used to case-mix adjust payments. In response to comments, CMS created 7 additional clinical groups to replace the Medication Management, Teaching, and Assessment (MMTA) group as CMS believes greater specificity will help distinguish differences in care and allow for greater transparency in resource use. The PDGM will have 432 case-mix groups (up from the 216 proposed)– the current system has 153 payment groups.

Home Health Value-Based Purchasing (HHVBP): Two measures are removed from the HHVBP and three others replaced beginning with performance year (PY) 4 (2019 reporting; payment in 2021). The measures removed are Outcome and Assessment Information Set (OASIS) based measures: Influenza Immunization Received for Current Flu Season, Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing. The latter three are replaced with two new

composite measures. Changes are also made in the weighting of measures for calculating the Total Performance Score and to the scoring of improvement points

Home Health Quality Reporting Program (HH QRP): The policy for removing previously adopted measures from the HH QRP is updated to align with other quality reporting programs. In keeping with the Meaningful Measures Initiative, removes seven measures from the HH QRP beginning with 2021 payment. The number of years of data used to calculate the Medicare Spending per Beneficiary measure is increased from one year to two years.

Medicare Coverage of Home Infusion Therapy Services: CMS finalizes new regulations that address health and safety requirements for home infusion therapy suppliers and provide a framework for CMS to approve home infusion therapy accreditation organizations, as required for implementing the new Part B benefit category for home infusion therapy services that was created by the 21st Century Cures Act and begins January 1, 2021. Under the statute, suppliers of home infusion therapy must be accredited by a CMS-approved accreditation organization. Requirements for such organizations, the process for their approval by CMS, and ongoing CMS oversight parameters are finalized. Information on temporary transitional payments for home infusion therapy services for 2019 and 2020 as mandated by section 50401 of BBA 2018 is provided. **The definition of "infusion drug administration day" is finalized despite considerable opposition, and CMS requests comments about the statutory interpretations underpinning this definition.**

Impact: The HH PPS updates are estimated to increase home health payments by a net of $420 million, or 2.2 percent, in 2019—the combined effect of the update, the new rural add-on provision, and the change in the FDL ratio. This $420 million increase does not take into account approximately $60 million in temporary transitional payments to home infusion suppliers in 2019. It also does not account for the reduction in payments to HHAs resulting from the HHVBP model; CMS does not provide an estimate for 2019, but continues to expect an estimated $378 million in savings over five years (2018 -2022) from reduction in unnecessary hospitalizations and skilled nursing facility (SNF) usage in this program. Implementation of the PDGM for 2020 will be budget neutral.

II. Background

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. 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.

CMS also reviews updates to the HH PPS. In the 2017 HH PPS final rule, CMS implemented the last year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates, and the non-routine medical supply (NRS)

conversion factor. CMS also made changes to the methodology used to calculate outlier payments and changes in payment for furnishing Negative Pressure Wound Therapy.

In the past, CMS has highlighted concerns about the use of therapy thresholds in the current payment system. CMS cited several studies that conclude that home health companies may be responding to financial incentives to put patients into higher payment categories by providing more therapy visits. In an analysis of home health data between 2008 and 2013, MedPAC reported a 26 percent increase in the number of episodes with at least 6 therapy visits, with only a 1 percent increase in the number of episodes with five or fewer visits.[2] A 2016 study by Fout et. al., found that the number of therapy visits increased sharply just over Medicare HH payment thresholds at 6, 7, and 16.[3] Furthermore, a Congressional investigation into therapy practices of the four largest publicly-traded home health companies found that three out of the four companies investigated "encourages therapists to target the most profitable number of therapy visits, even when patient need alone may not have justified such patterns."[4]

In the 2018 HH PPS proposed rule, CMS proposed an alternative case-mix model, called the Home Health Groupings model (HHGM) that included proposals to change the unit of payment from 60 days to 30 days and to eliminate the therapy thresholds in the case-mix system. This system would use clinical characteristics and other patient information to place patients into payment categories. Ultimately, CMS did not finalize that proposal, but proposed in the 2019 HHS PPS proposed rule to implement case-mix methodology refinements similar to what was proposed last yearincluding changing the unit of payment from 60 days to 30 days. These changes are finalized in this rule effective January 1, 2020 and would be implemented in a budget neutral manner, as required by section 51001 of the BBA of 2018. CMS renamed its case-mix methodology refinements and refers to it as the Patient-Driven Groupings Model or PDGM. The PDGM is discussed in more detail in section III.F of the final rule and this summary.

CMS also notes the requirements established in the Section 50401 of the BBA of 2018 which established a home infusion therapy services temporary transitional payment beginning January 1, 2019. This benefit provides payments for eligible suppliers covering certain items and services furnished in coordination with transitional home infusion drugs. This is a temporary payment and would end before the full implementation of the home infusion therapy benefit began on January 1, 2021.

Home infusion therapy services is discussed in more detail in section VI of the final rule and this summary.

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[2] Medicare Payment Advisory Commission (MedPAC). "Home Health Care Services." *Report to Congress: Medicare Payment Policy.* Washington, D.C., March 2015. P. 223. Accessed on March 28, 2017 at: http://www.medpac.gov/docs/default-source/reports/mar2015_entirereport_revised.pdf?sfvrsn=0.

[3] Fout B, Plotzke M, Christian T. (2016). Using Predicted Therapy Visits in the Medicare Home Health Prospective Payment System. *Home Health Care Management & Practice, 29(2), 81-90.* http://journals.sagepub.com/doi/abs/10.1177/1084822316678384.

[4] Committee on Finance, United States Senate. *Staff Report on Home Health and the Medicare Therapy Threshold*. Washington, D.C., 2011. Accessed on March 28, 2017 at https://www.finance.senate.gov/imo/media/doc/Home_Health_Report_Final4.pdf.

III. Provisions of the Final Rule: Payment under the Home Health Prospective Payment System and Responses to Comments

A. Monitoring for Potential Impacts – Affordable Care Act Rebasing Adjustments

CMS reported in detail on its monitoring of the impact of rebasing in the proposed rule, and notes in the final rule that it will continue to monitor the impacts due the rebasing adjustments and other future policy changes and provide the industry with periodic updates in future rulemaking or in announcements on the HHA Center webpage at https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html

B. 2019 HH PPS Case-Mix Weights

CMS finalizes its annual recalibration of the HH PPS case-mix weights using 2017 claims data with linked OASIS data. CMS sets out the detailed methodology it uses to recalibrate the case-mix weights and the steps involved (see Tables 3-5in the final rule). Table 6 in the final rule presents the resulting 2019 case-mix payment rates for each of the 153 payment groups.

The final case-mix budget neutrality factor for 2019 is 1.0169, calculated as the ratio of total payments when 2019 case-mix weights are applied to 2017 utilization, to total payments when 2018 case-mix weights are applied to 2017 utilization.

Some commenters stated that recalibrating the case-mix weights annually was too frequent and wanted more detail on how the recalibration works and why the model is recalibrated each year. CMS replies that annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns.

CMS finalizes the recalibrated scores for the case-mix adjustment variables, clinical and functional thresholds, payment regression model, and case-mix weights, as shown in Tables 3 through 6 in the final rule. The 2019 scores for the casemix variables, the clinical and functional thresholds, and the case-mix weights were developed using complete 2017 claims data as of June 30, 2018.

C. 2019 Home Health Payment Rate Update

1. Rebasing and Revising of the Home Health Market Basket

CMS finalizes without change its proposal to rebase and revise the home health market basket to reflect 2016 Medicare cost report data data, the latest available and most complete data on the actual structure of HHA costs. CMS notes that rebasing is necessary to capture changes in the overall cost structure because as the index measures the changes in prices but doesn't capture any changes in the quantity or mix of goods and services. The current home health market basket is based on 2010 Medicare cost report data.

Specifically, CMS finalizes its proposal to rebase the detailed wages and salaries and benefits cost-weights to reflect 2016 BLS Occupational Employment Statistics data on HHAs. In addition, CMS finalizes its proposal to break out the All Other (residual) cost category weights into more detailed cost categories, based on the 2007 Benchmark U.S. Department of Commerce, Bureau of Economic Analysis (BEA) Input-Output (I-O) Table for HHAs. The 2010-based home health market basket used the 2002 I-O data.

To derive the cost weights for the home health market basket, CMS uses data from freestanding HHAs whose cost reporting period began on or after October 1, 2015 and before October 1, 2016. The eight major expense categories used are unchanged from the previous 2014-based payment rebasing.

Table 7 in the final rule (reproduced below) shows the major cost categories and their respective cost weights as derived from the Medicare cost reports. CMS states that the decrease in wages and salaries cost weight of 1.2 percentage points and the decrease in the benefits cost weight of 1.3 percentage points is attributable to employed compensation and direct patient care contract labor costs. The average number of FTEs per provider decreased significantly from 19.8 visits in 2010 to 17.9 visits in 2016. Its analysis of the decrease in the cost weight showed that this reduction occurred across provider groups and was not clustered among certain providers.

Table 7 – Major Cost Categories as Derived from the Medicare Cost Reports		
Major Cost Categories	**2010 Based**	**2016 Based**
Wages and Salaries (inc. allocated direct patient care contract labor)	66.3	65.1
Benefits (including allocated direct patient care contract labor)	12.2	10.9
Transportation	2.5	2.6
Professional Liability Insurance (Malpractice)	0.4	0.3
Fixed Capital	1.5	1.4
Moveable Capital	0.6	0.6
"All Other" residual	16.5	19.0

* Figures may not sum to 100.0 due to rounding

CMS provides detail on the calculations and the lines used from the cost report for each major expense category in the final rule.

Using the same methodology it had used for 2010-based home health market basket, CMS breaks out wages and salaries into (1) wages and salaries, including allocated contract services' labor, and (2) benefits, including allocated contracted services' labor. CMS also further divides the "All Other" residual cost weights estimated from the 2016 Medicare cost report data into nine detailed categories. To do this, CMS finalizes its proposal to use the 2007 Benchmark I-O "Use Tables/Before Redefinitions/Purchaser Values" for NAICS 621600, Home Health Agencies, published by BEA.[5] CMS eliminates the stand-alone category for Postage (given its small weight) and include those expenses in the Other Services cost category.

[5]These data are publicly available http://www.bea.gov/industry/io_annual.htm

Table 8 in the final rule (reproduced below) lists the final 2016-based home health market basket cost categories, cost weights, and price proxies. The wage and price indexes are used to update the rate of change for each expenditure category. With the exception of the price index for professional liability insurance costs, CMS uses price proxies based on the BLS data. CMS states that all of its price proxies meet its criteria of reliability, timeliness, availability, and relevance. The indexes are a combination of Consumer Price Indexes (CPIs), which measure changes in the process of final goods and services bought by the typical consumer, and Produced Price Indexes (PPIs) measure changes in prices received by domestic producers for their goods and services.

Table 8: Cost Categories, Weights, and Price Proxies in Final 2016-Based Home Health Market Basket

Cost Categories	Weight	Price Proxy
Compensation, including allocated contract services' labor	76.1	
Wages and Salaries, including allocated contract services' labor	65.1	Home Health Blended Wages and Salaries Index (2016)
Benefits, including allocated contract services' labor	10.9	Home Health Blended Benefits Index (2016)
Operations & Maintenance	1.5	CPI-U for Fuel and utilities
Professional Liability Insurance	0.3	CMS Physician Professional Liability Insurance Index
Administrative & General & Other Expenses including allocated contract services' labor	17.4	
Administrative Support	1.0	ECI for Total compensation for Private industry workers in Office and administrative support
Financial Services	1.9	ECI for Total compensation for Private industry workers in Financial activities
Medical Supplies	0.9	PPI Commodity data for Medical, surgical & personal aid devices
Rubber & Plastics	1.6	PPI Commodity data for Rubber and plastic products
Telephone	0.7	CPI-U for Telephone services
Professional Fees	5.3	ECI for Total compensation for Private industry workers in Professional and related
Other Products	2.8	PPI Commodity data for Finished goods less foods and energy
Other Services	3.2	ECI for Total compensation for Private industry workers in Service occupations
Transportation	2.6	CPI-U for Transportation
Capital-Related	2.1	
Fixed Capital	1.4	CPI-U for Owners' equivalent rent of residences

Table 8: Cost Categories, Weights, and Price Proxies in Final 2016-Based Home Health Market Basket		
Cost Categories	**Weight**	**Price Proxy**
Movable Capital	0.6	PPI Commodity data for Machinery and equipment
Total	100.0 *	

*Figures may not sum due to rounding.

CMS finalizes its proposal to rebase the home health blended Wages and Salaries index and the home health blended Benefits index, similar to its approach for the 2010-based home health market basket. CMS provides a detailed discussion of the price proxies used and their construction. These changes, however, do not result in material differences in the calculation of annual growth from 2016 to 2019 when using the 2016 home health benefits blend compared with the 2010 home health benefits blend. The annual increases in the two price proxies from 2016 to 2019 are the same (when rounded to one decimal place).

CMS provides a detailed explanation of the other price proxies it uses for the 2016-based home health market basket (show in Table 8 above). All are the same proxies that it used for the 2010-based home health market basket.

Table 14 in the final rule shows the results of the rebasing using the 2016-based market basket compared with the 2010-market basket. Notably, the forecasted rate of growth for 2019 for the 2016-based home health market basket is 3.0 percent, the same rate of growth as estimated using the 2010-based home health market basket.[6] This pattern is similar for other forecast years

With respect to the labor-related share, CMS finalizes revisions to reflect the 2016-based home health market basket compensation (wages and salaries plus benefits) cost weight. Based on the 2016-home health market basket, the labor-related share is 76.1 percent and the non-labor related share is 23.9 percent. Using the 2010-based home health market basket, these figures would have been 78.5 percent and 21.5 percent, respectively. The revision is made in a budget neutral manner.

CMS received limited comments on these issues. One commenter had concerns that the data used for rebasing does not reflect current costs. CMS replies that it issuing the most recent and comprehensive data for the rebasing effort from 2016, which is more current than the 2010 data. In addition, CMS notes that it using data from freestanding HHAs (which account for 90 percent of HHAs) because they better reflect HHAs' actual cost structure. Several commenters recommended that CMS build into the 2019 market basket update an increase to reflect general health care wage increases. CMS explains that its 2019 market basket update of 3.0 percent reflects the expected compensation price increases and that its cost categories are proxied by price indicies that reflect the occupation mix of home health staff.

[6] The growth rates CMS shows in Table 14 are based upon IHS Global Inc.'s (IGI) 3rd quarter 2018 forecast. In the proposed rule, CMS used IGI's 1st quarter 2018 forecast, which resulted in a 2016-based home health market basket growth rate of 2.8 percent.

2. 2019 Home Health Market Basket Update

CMS reviews the methodology for updating the HH PPS rates and finalizes a 2019 update of 2.2 percent (HH market basket increase of 3.0 percent less 0.8 multifactor productivity (MFP) adjustment).[7] The 2019 final update is based on IHS Global Insight Inc.'s (IGI) third quarter 2018 forecast.

HH market basket increase:	3.0 percent.
Multi-factor productivity (MFP) adjustment:	-0.8 percent
MFP adjusted HHA market basket update:	2.2 percent

The 2.2 percent market basket update is reduced by 2.0 percentage points for HHAs that do not submit quality data required by the Secretary. Thus, the updates for 2019 would be:

For HHAs reporting the required quality data:	2.2 percent
For HHAs not reporting the required quality data:	0.2 percent

3. 2019 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 2019, CMS will use FY 2015 hospital cost report data as its source for the updated wage data. CMS will continue to use the Office of Management and Budget's (OMB's) February 28, 2013 revisions to the delineations of Metropolitan Statistical Areas and the creation of Micropolitan Statistical Areas, and Core-based Statistical Areas (CBSAs).[8] The wage index for 2019 is available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html

Similar to prior years, several commenters were concerned about how the wage index is calculated and implemented for HHAs compared to other prospective payment systems within the same CBSAs. In particular, commenters note that hospitals are given the opportunity to appeal their annual wage index, but HHAs in the same geographic area are not given that privilege. In response, CMS states that it continues to believe that the regulations and statutes that govern the HH PPS do not provide a mechanism for allowing HHAs to seek geographic reclassification or to utilize the rural floor provision that exists for Inpatient Prospective Payment System hospitals.

[7] Section 1895(b)(3)(B)(vi) of the Act requires that the market basket percentage under the HHA prospective payment system be adjusted (except 2018 where MACRA specified the update) by changes in economy-wide productivity.

[8] OMB issued Bulletin No. 17-01 which announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area. OMB's most recent bulletin (No. 18-03) published on April 10, 2018 has no impact on the geographic delineation used to wage adjust HH PPS payments.

4. 2019 Payment Update

CMS finalizes two wage index budget neutrality adjustments. One applies to the standardized episode payment rate for episodes other than those involving the Low-Utilization Payment Adjustment (LUPA); and the other is specific to the national per visit rate for LUPA episodes.

- A wage index budget neutrality adjustment of 0.9985 will apply to the standardized episode payment rate, which is computed by dividing total payments for non-LUPA episodes using the 2019 wage index by the total payments for such episodes using the 2018 wage index.
- A wage index budget neutrality adjustment of 0.9996 will apply to national per visit payments for LUPA episodes, computed by dividing total payments for LUPA episodes using the 2019 wage index by the total payments for such episodes using the 2018 wage index.

The methodology and payment amounts for the national standardized 60-day episode payment and the national per visit amounts for HHAs submitting and those not submitting quality data are reviewed. Tables 16 to 23 in the final rule show details on the updates; the table that follows is a summary of the calculations.

2019 60-day National, Standardized 60-Day Episode Payment Amount, for HHAs Submitting and Not Submitting Quality Data		
	HHAs submitting quality data	HHAs not submitting quality data
National standardized amount (Tables 18 and19)		
2018 amount	$3,039.64	
Wage index budget neutrality factor	x 0.9985	
Case-mix budget neutrality factor	x 1.0169	
HH payment update percentage	x 1.022	x 1.002
2019 payment amount	**$3,154.27**	**$3,092.55**

Computations are presented for the LUPA and the per-visit amounts for each type of service. (These are amounts paid in lieu of the 60-day episode payment when there are four visits or fewer in an episode). CMS reminds the reader that the LUPA per-visit amounts are not calculated using case-mix rates. The per-visit amounts for those HHAs submitting the required quality data are as follows:

2019 National, Per-Visit Amounts for HHAs that do Submit Quality Data (see CMS Table 18)						
	Home health aide	Medical social services	Occu-pational therapy	Physical therapy	Skilled nursing	Speech-language pathology
2018 per visit rates	$64.94	$229.86	$157.83	$156.76	$143.40	$170.38
Wage index budget neutrality factor	0.9996					
Payment update	1.022					
2019 per visit rates	**$66.34**	**$234.82**	**$161.24**	**$160.14**	**$146.50**	**$174.06**

As with the payments for a 60-day episode of care, HHAs that do not submit required quality data will have the payment update for per-visit services reduced from 2.2 percent to 0.2 percent (see Table 19), resulting in the following payment rates.

2019 National, Per-Visit Amounts for HHAs that do not Submit Quality Data (see CMS Table 19)						
	Home health aide	Medical social services	Occupa-tional therapy	Physical therapy	Skilled nursing	Speech-language pathology
2019 per visit rates	$65.04	$230.23	$158.08	$157.01	$143.63	$170.65

LUPA Add-On Factors: CMS makes no 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.

Non-routine Medical Supply (NRS) payment rates: CMS updates the conversion factors for particular severity levels (the NRS conversion factor update).

2019 NRS Conversion Factor for HHSs that do and do not Submit the Required Quality Data (Tables 20 and 22)		
	HHAs that submit quality data	HHAs that do not submit quality data
2018 NRS Conversion Factor	$53.03	
2019 Payment Update	1.022	1.002
2019 NRS Conversion Factor	$54.20	$53.14

CMS also finalizes the NRS payment amounts for 2019 for each of the six severity levels based on that conversion factor for those that do and do not submit the required quality data (see Tables 21 and 23). For HHAs that submit quality data, NRS payment amounts range from $14.62 at severity level 1 (the lowest) to $570.48 at severity level 6 (the highest).

Several commenters expressed concerns with the reduction in the labor-related shares, suggesting such a change will result in less care for patients. CMS notes that the reduction is consistent with the employed compensation and the direct patient care contract labor costs as reported in the Medicare cost report data. In addition, CMS notes that the decreased labor share is implemented in a budget neutral manner. CMS finalizes the application of the wage index budget neutrality factor, the case-mix adjustment budget neutrality factor and the home health payment update percentage in updating the home health payment rates for 2019 as proposed.

D. Rural Add-on Payments for 2019 through 2022

Section 50208(a)(1)(D) of the BBA of 2018 added a new subsection (b) to section 421 of the MMA to provide rural add-on payments for episodes and visits ending during 2019 through 2022. This subsection mandates implementation of a new methodology that would vary the add-on amounts into three distinct categories. This is unlike previous rural add-ons, which were

applied to areas uniformly. In 2018, for example, all HHAs in rural areas received a 3 percent payment add-on.

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 6 individuals or fewer per square mile of land area; and

(3) All other category: rural counties and equivalent areas not in the above categories.

To classify counties into these three categories, CMS used the 2015 HH PPS wage index file, which includes the names of the constituent counties for each rural and urban area designation. CMS used2015 claims data and 2015 data from the Medicare Beneficiary Summary file to examine home health episodes for purposes of classifying counties as high utilization.[9] For the low population density category, CMS used 2010 Census data as mandated in statute.

The proposed rule outlines how CMS categorized the rural counties and is restated here. Of the 3,246 total counties and equivalent areas, CMS found 2,006 could be considered rural for purposes of determining HH rural add-on payments. Of these, 510 rural counties or equivalent areas are classified into the "high utilization" category, 334 rural counties into the "low population density category", and the remaining 1,162 rural counties into the "all other" category. CMS notes that using its statutory authority (as defined in section 421(b)(2)(B)(iii) of the MMA) it excluded certain counties and equivalent areas from being placed in the "high utilization category" based on a low volume. Specifically, CMS excluded data from rural counties and equivalent areas that had 10 or fewer episodes during 2015 from the "high utilization category."

The rural add-on payment percentages and varying durations to which these add-on percentages apply for the three specified rural categories are specified in the statute. These are shown in Table 25 of the final rule (reproduced below). The HHAs located in low population density areas will receive the highest add-on values for the longest duration.

Table 25: HH PPS Rural Add-on Percentages, 2019-2022				
Category	2019	2020	2021	2022
High utilization	1.5%	0.5%		
Low population density	4.0%	3.0%	2.0%	1.0%
All other	3.0%	2.0%	1.0%	

When services are provided in a rural area, CMS will increase the national standardized 60-day episode payment rate, the national per-visit rates, and the NRS conversion factor by the relevant

[9] CMS assigned each home health episode to the state and county code of the beneficiary's mailing address.

rural add-on percentage. The HH pricer module, within the CMS' claims processing system, will apply these add-on amounts prior to applying any case-mix and wage index adjustments.

As specified in statute this determination is only made a single time and that determination applies for the entire duration of the period for which rural add-on payments are in place. That would mean, for example, that a rural county or equivalent area classified into the "high utilization" category will remain in that category through 2022 even after the rural add-on payments for that category at the end of 2020. In addition, there is no administrative or judicial review of the classification determinations made for rural add-on payments (as specified under section 421(b)(1) of the MMA).

The statute also specifies that for home health services furnished on or after January 1, 2019, the claim should contain the code for the county (or equivalent area) in which the home health services was furnished.[10] This information is necessary to calculate the rural add-on payment. CMS finalizes its proposal that HHAs enter the Federal Information Processing Standard (FIPS) state and county code, rather than the Social Security Administration state and county code, on the claim. It notes that many HHAs are already familiar with this format, as a number of states already required HHAs to use FIPS state and county codes for state-mandated reporting programs.

In conjunction with the proposed rule, CMS posted an Excel file that contains the rural county or equivalent area names, their FIPS state and county codes, and their designation into one of the three rural add-on categories. Also posted are the data used to categorize each county or county equivalent. While a final rule update to these files has not been posted to date, CMS finalized the designations of rural counties (or equivalent areas) into their respective categories that are shown in the Excel files published in conjunction with the proposed rule. These can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices-Items/CMS-1689-P.html

Many commenters urged CMS to continue providing rural add-on payments after 2022 so that beneficiaries in rural communities continue to have access to home health services. Several commenters suggested that CMS establish a workgroup to examine rural costs and how best to address those costs with an add-on payment. MedPAC stated that the rural payment add-on policy for 2019 is an improvement that better targets Medicare's scarce resources. In reply, CMS notes that these are statutory requirements, and thus, it does not have the authority to provide a 3 percent rural add-on for episodes and visits ending on or after January 1, 2019 across all rural areas, or to extend rural add-on payments beyond the duration of the period for which rural add-on payments are in place under section 421(b)(1) of the MMA.

E. 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

[10] Section 50208(a)(2) of the BBA of 2018 amended section 1895(c) of the Act by adding this requirement.

approach. Under that methodology, CMS converts the national per-visit rates into per 15-minute unit rates And limits the amount of time (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 notes that it plans to publish the cost-per-unit amounts for 2019 in the rate update change request, which it will issue after the publication of the 2019 HH PPS final rule.

2. Fixed Dollar Loss (FDL) Ratio

The FDL ratio[11] and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level 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).

For 2019 CMS finalizes its proposal to lower the FDL ratio from 0.55 to 0.51 and maintain the loss-sharing ratio of 0.80. CMS believes that this is appropriate given the percentage of outlier payments projected for 2019 and the need to ensure that outlier payments do not exceed 2.5 percent of total payments. Its simulations show that the FDL ratio needs to be reduced from 0.55 to 0.51 to better approximate the 2.5 percent statutory maximum. For the final rule, CMS verified its estimate using updated data.

CMS also provided a clinical example in the proposed rule of how care for a patient with amyotrophic lateral sclerosis (ALS) or commonly referred to as Lou Gehrig's disease, could qualify for an additional outlier payment, which would serve to offset unusually high costs associated with providing home health to a patient with unusual variations in the amount of medically necessary care.[12] The example serves to illustrate a point that while patients must require skilled care to be eligible to receive services under the Medicare home health benefit, that coverage does not turn on the presence or absence of an individual's potential for improvement, but rather on the beneficiary's need for skilled care.

In response to comments about whether the 2.5 percent target for outlier and the 10-percent cap on outlier payments are sufficient, CMS notes that these are statutory requirements, and thus it cannot change these. CMS will consider whether to add supply costs to the outlier calculations and evaluate whether such a policy change is appropriate for future rulemaking. A commenter also suggested that CMS consider demonstrations related to home health cases that may qualify for an outlier payment (such as patient with ALS). CMS states that it will consider this as it develops new models through the Center for Medicare and Medicaid Innovation.

[11] 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.

[12] CMS notes this in response to several news stories. See, for example, https://www.npr.org/sections/health-shots/2018/01/17/578423012/home-care-agencies-often-wrongly-deny-medicare-help-to-the-chronically-ill

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

CMS finalizes the PDGM with modifications discussed below. The PDGM will be effective for 30-day periods of care that start on or after January 1, 2020. CMS also finalizes its proposal to change in the unit of payment from 60 to 30 days, effective for 30-days period of care that start on or after January 1, 2020. CMS finalizes the corresponding regulations text changes.

1. Summary of the Proposed PDGM Model

The PDGM uses 30-day periods rather than the 60-day episode used in the current payment system and eliminates the use of the number of therapy visits provided to determine payment as required by the BBA of 2018. For the current HH PPS case-mix weights, CMS uses Wage Weighted Minutes of Care (WWMC), which uses Home Health Service Industry data from the Bureau of Labor Statistics (BLS). For the PDGM, CMS proposed shifting to a Cost-Per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from the Medicare Cost Reports.

In the PDGM, CMS proposed that 30-day periods would be classified as "early" or "late" depending on when they occurred within a sequence of 30-day periods and be further classified by admission source, clinical grouping, functional level, and a comorbidity adjustment. The proposed rule also outlined the methodology CMS used to create the PDGM (82 FR 25297 through 35298).

- Early or Late Episode. The 30-day periods would be classified as "early" or "late" depending on when they occur within a sequence of 30-day periods. The first 30-day period would be classified as early and all subsequent 30-day periods in the sequence would be classified as late. The comprehensive assessment would still be completed within 5 days of the start of care date and no less frequently than during the last 5 days of every 60 days beginning with the start of care date.

- Admission Source and Timing. Each period would be classified into one of two admission source categories: community or institutional. The 30-day period would be categorized as institutional if an acute or post-acute stay occurred in the prior 14 days to the start of the period of care. The 30-day period would be categorized as community if there were no acute or post-acute care stay in the 14 days prior to the start of the period of care.

- Clinical Grouping. Based on the principal diagnosis reported on claims, the 30-day payment amount would include grouping periods into one of six clinical groups based on the principal diagnosis listed on the home health claim. The proposed six clinical groups were Musculoskeletal Rehabilitation; Neuro/Stroke Rehabilitation; Wounds (post-op wound aftercare and skin/non-surgical wound care); Complex Nursing Interventions; Behavioral Health Care (including Substance Use Disorders); and Medication Management, Teaching and Assessment (MMTA).

- Functional Level. Based on certain functional OASIS items, each 30-day period would be placed into one of three functional levels: low, medium, or high. The level would indicate if, given responses on certain functional OASIS items, a 30-day period was predicted to have higher costs or lower costs. CMS proposed that each of the six clinical groups would be further classified into one of the three functional levels with roughly 33 percent of periods in each level.

- Comorbidity Adjustment. Based on secondary diagnoses, CMS proposed that 30-day periods would receive a comorbidity adjustment if any diagnosis codes listed on the home health claim were included on a list of comorbidities that occurred in at least 0.1 percent of 30-day periods and associated with increased average resource use. A 30-day period may receive "no" comorbidity adjustment, a "low" comorbidity adjustment, or a "high" comorbidity adjustment.

Commenters provided broad support to moving from the current payment system to a system that used a broader patient clinical profile. Some commenters recommended delaying the implementation of the PDGM and others suggested CMS implement the model incrementally or conduct a demonstration of the model. CMS notes that the BBA of 2018 requires a change to the unit of payment and elimination of the therapy thresholds for all payments under the HH PPS instead of requiring CMS to conduct a demonstration. CMS believes that implementing the PDGM incrementally could cause more burden and confusion than implementing all aspects of the PDGM at one time. CMS intends to work with stakeholders on ways to provide sufficient guidance and training to ensure a smooth transition to the PDGM.

In response to comments about limited industry involvement in the development of the PDGM, CMS summarizes the activities that allowed stakeholder input. In addition, on February 1, 2018, CMS convened another technical expert panel (TEP) to gain input about the case-mix adjustment methodology summarized in the proposed rule (82 FR 35270). As required by the BBA, CMS issued a report on the recommendations from the TEP members (available at https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html.) In response to a concern about a need for a site of service adjustment for patients in assisted living, CMS plans to analyze data after implementation of the PDGM to determine whether a site of service adjustment may be warranted.

Several commenters expressed concerns about the PDGM and its impact on delivery and payment innovations, such as Accountable Care Organizations and Bundled Payments for Care Improvement (BPCI) Models. CMS notes that BPCI Models 2 and 3 ended September 30, 2018, before PDGM implementation. CMS will determine whether any refinements are needed to the BPCI Advanced Model, and any ACO programs and models, such as the Medicare Shared Savings Program as a result of PDGM implementation. Any changes necessary to the payment methodology used in the Medicare Shared Savings Program will be done through notice and comment rulemaking. CMS does not believe the PDGM will disrupt the HHVBP Model or the Home Health star ratings. CMS also thinks that many aspects of the PDGM could be used in a unified post-acute care (PAC) PPS prototype in which payments would be based according to individual characteristics, as specified by the IMPACT Act. CMS notes that Medicare Advantage (MA) plans do not have to use the FFS payment methodology; some plans could

change their payment models to incorporate the PDGM but others may not change their payment models.

2. Methodology Used to Calculate the Cost of Care

CMS finalizes its proposal to calculate the cost of a 30-day period of home health care under the PDGM using the cost per minute plus non-routine supplies (CPM+ NRS) approach based on information from HHA Medicare cost reports and home health claims. The current payment system uses the wage-weighted minutes of care (WWMC) approach based on data from the BLS.

Several commenters objected to the use of Medicare cost report data because changes in the utilization and provider payment and supplies are not accurately reflected in cost reports. CMS believes that cost reports better reflect changes in utilization, provider payments and supply for Medicare-certified HHAs that occur over time as compared to the WWMC approach based on BLS average hourly wages for the entire home health care service industry. CMS notes that the correlation coefficient between the two approaches to calculating resource use is 0.8537 (n=8,521,924).[13] In response to commenters request for additional data, CMS posted files on the HHA Center page that include the case-mix weights produced using the proposed CPM+NRS approach and those produced using the current WWMC approach in calculating resource use.[14] Using the data in these files, the coefficient between the CPM+NRS versus WWMC is 0.9806. CMS also delineates the steps used to generate the measures of resource use under the CPM+NRS approach.

CMS disagrees with concerns raised about the accuracy of cost reports and notes that each cost report is required to be certified by the Officer or Director of the home health agency as being true, correct, and complete with potential penalties should any information be false or a misrepresentation. CMS also disagrees that the cost reports reward inefficient providers with high costs or facility-based HHAs and discusses how including or excluding any single HHA on average would not dramatically impact the results of the payment regression. Based on its calculations each provider, on average, contributed 841 30-day periods to the payment regression, which is only 0.010 percent of all 30-day periods. CMS also discusses the reasons the NRS are not geographically adjusted (previously discussed in the 2008 HH PPS proposed rule (72 FR 25427 through 25430)).

3. Change from a 60-day to a 30-day Unit of Payment

Section 51001 of the BBA of 2018, requires the Secretary to apply a 30-day unit of service for purposes of implementing the HHS PPS. CMS interprets the term "unit of service" to be synonymous with "unit of payment" and uses this term in this final rule with regards to payment under the HH PPS.

[13] Correlation coefficients are used to measure how strong the relationship is between two variables. Zero means no relationship and the closer to 1 the stronger is the relationship.
[14] The files are available at https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html.

a. 30-day Unit of Payment

In addition to calculating a 30-day payment amount in a budget-neutral manner, the BBA of 2018 requires the Secretary to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and to take into account behavior changes in calculating a 30-day payment amount. A budget-neutral 30-day payment amount is calculated before the provisions of section 1895(b)(3)(B) of the Act are applied (the HH applicable percentage increase, the adjustment for case-mix changes, the adjustment if quality data is not reported, and the productivity adjustment).

CMS finalizes its proposal to make three assumptions about behavior change that could occur in 2020 in calculating the budget-neutral 30-day payment amount:

- Clinical Group Coding: The principal diagnosis code for 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 1 primary diagnosis and 24 secondary diagnoses. The OASIS only allows 1 primary diagnosis and 5 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 to receive a full 30-day payment.

CMS estimates what the 30-day payment amount would be for 2019 (using 2017 home health utilization data) to achieve budget neutrality with and without behavioral assumptions (see table below). CMS notes these are only illustrative examples and that for 2020, it would propose the actual 30-day payment amount in the 2020 HH PPS proposed rule using 2018 home health utilization data. As required, it would calculate this amount before application of the proposed home health update percentage for 2020. A detailed explanation of how CMS calculated the 30-day budget-neutral payment amount is provided in the 2019 HH PPS proposed rule (83 FR 32389).

The Secretary is also 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 no earlier than in years 2022 through 2028 rulemaking. Temporary adjustments allow CMS to recover excess spending or give back the difference between actual and estimated spending not addressed by permanent adjustments.

Estimates of 30-Day Budget-Neutral Payments Amounts		
Behavioral Assumption	**30-day Budget-Neutral Standard Amount**	**Percent Change from No Behavioral Assumption**
No Behavioral Assumption	$1,873.91	
Clinical Group Coding + Comorbidity Coding	$1,786.54	-4.66%
Clinical Group Coding + Comorbidity Coding + LUPA Threshold	$1,753.68	-6.42%

The majority of commenters requested CMS not apply behavioral assumptions industry wide and recommended CMS do targeted program integrity efforts. CMS reiterates that it does not intend to imply that HHAs would engage in unethical behavior but as previously discussed in the 2016 HH PPS rule, CMS does not believe a targeted program integrity effort would mitigate behavioral changes resulting from a case mix system (80 FR 68421 through 68422).

CMS disagrees with commenters stating that the three behavioral assumptions are arbitrary and not supported by any evidence. CMS discusses in detail the need to adjust prospective payments for behavior changes based on its past experience with the case-mix system for the HH PPS and the implementation of the DRGs and the MS-DRGs under the inpatient prospective payment system. CMS also disagrees that these assumptions are in violation of the Administrative Procedures Act (APA) given that CMS is required to apply behavioral assumptions and described these assumptions in notice and comment rulemaking as required (section 1896(b)(3)(A)(iv) of the Act).

CMS notes that under the PDGM, it expects HHAs will improve the ordering of diagnosis codes to ensure that the home health period of care represents the patient's characteristics and payment is appropriate. In addition, the implementation of ICD-10-CM has expanded the diagnosis code set making it possible for HHAs to more accurately and specifically code conditions. CMS' analysis shows that only about a third of the 30-day periods move into a different clinical group as a result of the clinical coding assumption. CMS provides an example in which it would be appropriate to report a higher paying code as the principal diagnosis instead of as a secondary diagnosis.

In response to concerns about the comorbidity coding assumption, CMS notes that the OASIS item set only allows HHAs to designate up to 5 secondary diagnoses, while the home health claim (8371 institutional claim format-electronic version of the paper UB-04) allows HHAs to report up to 24 secondary diagnoses. CMS assumes that by taking into account additional ICD-10-CM diagnosis codes listed on the home health claim, more 30-day periods of care will receive a comorbidity adjustment that would have received using OASIS.

CMS also discusses the basis for the LUPA threshold assumption. In the 2001 final rule, CMS estimated that approximately 16 percent of 60-day episodes would have received a LUPA (65 FR 41162) and currently only about 7 percent of all 60-day episodes receive a LUPA. CMS discusses its analysis of 2017 data which suggests that about one-third of the LUPA episodes with visits near the LUPA threshold will move up to become non-LUPA episodes.

CMS acknowledges MedPAC's comments providing additional evidence that past experience with the HH PPS demonstrates that HHAs have changed coding, utilization and the mix of services provided in response to new payment systems. MedPAC recommended an additional behavioral assumption to account for responses to the shorter unit of payment that would result in just enough visits to get payment for a second 30-day period of care. CMS does not think additional behavioral assumptions are needed but will consider this if additional adjustments are needed.

Several commenters encourage CMS to closely monitor utilization patterns to ensure that beneficiary access is not negatively impacted as a result of the PDGM. CMS notes that the goal of the PDGM is to more accurately align payment with the cost of providing care and is not meant to penalize or harm providers or beneficiaries. CMS will be monitoring beneficiary access but expects HHAs will continue to provide services in accordance with the existing home health condition of participation (CoP) requirements.

To assist HHAs in evaluating the effects of the PDGM, a Home Health Claims-OASIS Limited Data Set (LDS) can be requested from CMS by following the instructions on the CMS website: htpps://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA-NewLDS.html.

b. Split Percentage Payment Approach for a 30-day Unit of Payment

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, 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, CMS finalizes the following proposals:

- 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 states 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.

CMS considered proposing a phase-out of the split percentage approach by reducing the percentage of the upfront payment over a period of time and requiring a NOA to be submitted upon full elimination of the split-percentage payment. CMS did not propose this alternative because it wants to clearly signal its intent to potentially eliminate the split percentage payment approach over time. CMS appreciates the comments it received about timeframe options for phasing out the split percentage approach. Some commenters indicated that RAPs for late period could be phased out, but that RAPs for early periods should remain. CMS plans to continue to monitor the need for RAPs after implementation of the PDGM.

Several commenters believed that newly enrolled HHAs have the same or more case flow concerns as existing HHAs and that the split-percentage payments should not be eliminated for them. CMS believes that the opportunity to receive full payment every 30 days may mitigate case flow concerns for newly enrolled HHAs. In response to concerns about HHAs acquired or opened on or after January 1, 2019, CMS clarifies that this policy is applicable to newly enrolled HHAs and does not apply to HHAs with a CMS Certification Number (CCN) that is effective on and after January 1, 2019. CMS also reminds commenters that existing HHAs, those certified for participation in Medicare with effective dates prior to January 1, 2019 should continue with the same RAP submission process.

4. Episode of Timing Categories

CMS finalizes its proposal to classify the 30-day periods as "early" or "late" depending on when they occur within a sequence of 30-day periods. The first 30-day period will be classified as early. All subsequent 30-day periods in the sequence (second or later) will be classified as late. Similar to the current definition of a "home health sequence", CMS finalizes that 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.

Commenters were concerned about the definition of "early" and "late" 30-day periods because many patients need more than 30 days of intense care and after an acute episode, patients may need increased care after the initial 30 days. In response, CMS discusses in detail the data analysis provided in the proposed rule demonstrating the timing categories used to construct the PDGM (83 FR 3240). CMS notes that in response to the 2008 HHS PPD final rule, commenters expressed concern that a heavier weighting of a "late" episode would lead to gaming by

providers, with patients receiving services longer than appropriate (72 FR 38366). CMS concludes that based on its analysis of home health resource use, review of the literature, comments from MedPAC and from the public, more resources are used in the first 30 days. CMS notes it will reassess the appropriateness of this policy and evaluate whether changes are needed once the model has been implemented.

In response to commenters' suggestion that a readmission to home health within the 60-day gap be treated as an "early" stay", CMS states that it expects the addition of both the source of admission as well as the timing categories will reflect agencies' average costs for home health patients. The source of admission category will account for a readmission to home health within 14 days of an acute care hospital stay (discussed below in section III.F.5).

In response to concerns about provider burden, especially the operational aspects of the timing element, CMS has developed claims processing procedures to reduce the administrative burden. Providers will not have to determine whether a 30-day period is early or late, they will have the option to provide this information. As discussed in detail in the proposed rule, information from the Medicare systems will be used during claims processing to automatically assign the appropriate timing category (83 FR 32394). The Medicare system will identify claims that are not submitted and processed sequentially, and recode claims to represent the correct sequence and correct the payment according to the changed sequence. In addition, when any new 30-day period is added to those history records for each beneficiary, the coding on previously paid periods will be checked to determine if the new added period causes a need to change the sequence of periods. If a need for a change is identified, the Medicare systems will initiate automatic adjustments to previously paid periods. CMS plans to develop materials regarding timing categories, including topics related to claims adjustments and claims processing issues, and develop training materials to facilitate the transition to the PDGM.

Several commenters expressed concerns about the potential for provider behavior changes due to financial incentives in the PDGM. CMS notes that public comments in response to both the 2018 and 2019 HH PPS proposed rule present conflicting predications regarding provider behavior in response to implementation of the PDGM. CMS reiterates that it expects HHAs to furnish care in accordance with each beneficiary's HH plan of care as required by HH CoPs at §484.60.

5. Admission Source Category

CMS finalizes its proposal to establish two admission sources for grouping 30-day periods of care: institutional and community. The admission category will be determined by the health care setting utilized in the 14 days prior to the home health admission. The institutional category will include patients admitted from either acute care or PAC settings. CMS finalizes this would include beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility (IPF) stays[15], 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.

[15] In response to comments, CMS includes inpatient psychiatric facility stays (IPF) in the institutional category for the payment system under the PDGM,

- The institutional category will also include patients that had an acute 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 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 categorize 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.

For purposes of a RAP, CMS finalizes it will only adjust the final home health claim submitted for source of admission. For example, if a RAP for a community admission was submitted and paid, and then an acute or PAC Medicare claim was submitted before the final home health claim was submitted, CMS will not adjust the RAP but it will adjust the final home health claim to reflect it was an institutional admission. In addition, admission source occurrence codes will only be included on the final claim and not on any RAPs submitted.

Many commenters expressed concerns about the home health admission source grouping because the home health admission may not always correspond to the beneficiary's needs and corresponding provider costs. Commenters were also concerned that the admission source component outweighed clinical and functional factors. In response, CMS reiterate the analytic findings present in the HH PPS proposed rule demonstrating clear differences in resource utilizes by beneficiaries with differing sources of admission (83 FR 32340). CMS will monitor the outcomes of this change, including any impacts to community entrants, and make further refinements as necessary.

CMS acknowledges the concerns regarding provider behavioral changes and it expects HHAs will provide the appropriate care to all beneficiaries, including beneficiaries with medically complex conditions admitted from the community. CMS will monitor any impacts to community entrants and make further refinements as necessary.

Several commenters recommended CMS incorporate other clinical settings into the definition of institutional category, including hospices, ambulatory surgery centers (ASCs), and outpatient facilities, including emergency departments (EDs). As discussed in the proposed rule, the volume of patients with admissions from the EDs and observational stays is low relative to community and institutional admissions. CMS believes creating a third community admission source category for observational stays and EDs could introduce unnecessary complexity into the PDGM (83 FR 32340). CMS is also concerned that a third admission source category for observational stays and EDs could create an incentive to encourage outpatient encounters prior to beginning a HH episode. CMS notes that a discharge from as ASC and hospice would not meet the definition of institutional.

In response to concerns about the operational aspects of the admission source category, CMS reiterates the process described in the proposed rule (83 FR 32375). Medicare 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 system receives 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.

CMS will create occurrence codes that would allow HHAs to manually indicate on home health claims an institutional admission source prior to an acute or PAC Medicare claim. HHA could also use the occurrence codes for beneficiaries with acute or PAC stays, paid by other payers such as the Veterans Administration (VA). If an occurrence code is submitted on the home health claim, the claim will be categorized as an institutional admission. The Medicare systems will adjust community-admitted home health claims on a claim-by claim, flow basis if an acute/PAC Medicare claim for an institutional stay occurring within 14 days of the home health admission is received. A 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.

CMS states that if medical review finds no acute or PAC Medicare claims in the National Claims History, and there is no documentation of an acute or PAC stay, either Medicare or non-Medicare, within 14 days of the home health admission, it will correct the overpayment. If it finds that an HHA is systematically including occurrence codes but no documentation exists in the medical record of an institutional stay, it will refer the HHA to the zone program integrity contractor (ZPIC) for review.

6. Clinical Grouping

CMS proposed grouping 30-day periods of care into one of six clinical groups based on the principal diagnosis that describes the primary reason for which the beneficiary is receiving home health services. The principal diagnosis was the basis for the clinical grouping; secondary diagnosis codes and patient characteristics would be used to further case-mix adjust the period through the comorbidity and functional level. To inform the development of the clinical groups, CMS conducted an extensive review of diagnosis codes to identify the primary reasons for home health services and developed six clinical groups that reflected the reported principal diagnosis, clinical relevance, and coding guidelines.[16] The six proposed clinical groups were: Musculoskeletal Rehabilitation; Neuro/Stroke Rehabilitation; Wound-Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care; Behavioral Health Care; Complex Nursing Intervention;

[16] More information on the analysis and development of the groupings can be found in the HHGM technical report available on the HHA Center webpage at https://www.cms.gov/center/provider-Type/Home-Health-Agency-HHA-Center.html.

and Medication Management, Teaching and Assessment (MMTA). CMS solicited comments on whether there were compelling reasons why the MMTA clinical group should be divided into subgroups, despite analysis indicating this would not result in significant differences in case-mix weights.

Many commenters expressed concern that the MMTA group was too large a clinical group and recommended more specificity within this group despite analysis showing a lack of variation in resource use across subgroups. Based on comments, CMS finalizes its proposal, with modifications, and creates seven additional clinical groups to replace the comprehensive MMTA (Table 27, reproduced below). With the addition of the seven new groups, the PDGM will now contain 432 case-mix groups.

Table 27: Final Clinical Groups Used in the PDGM

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 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

In response to comments suggesting additional diagnosis codes, CMS discusses the many reasons a diagnosis code is not assigned to one of the clinical groups including the code is vague or unspecified for assignment, a non-home health service, and a code that unlikely requires home health services. As discussed in detail in the final rule, CMS did review, add, and re-group certain codes based on commenter feedback and encourages HHAs to review the list of diagnosis codes in the PDGM Grouping Tool available on the CMS web site at: https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html. CMS will continue to review ICD-10-CM code assignments and commenters are encouraged to

continue to submit comments about diagnosis coding under the PDGM to HomehealthPolicy@cms.hhs.gov.

CMS disagrees with the need to group patients based on their need for therapy. CMS expects the ordering physician, in conjunction with a therapist, to develop and follow a plan of care for any home health patient, regardless of clinical group, when therapy is deemed reasonable and necessary. Thus, therapy may be included in the plan of care for a patient in any of the clinical groupings. CMS also discusses how the PDGM takes into account the functional level and comorbidities of the patient after the clinical grouping designates the primary reason for the period and how patients requiring multiple home health disciplines will have further case-mix adjustments.

7. Functional Levels and Corresponding OASIS Items

In the 2018 HH PPS proposed rule, CMS proposed each 30-day period would be placed into one of three functional levels: low, medium, or high. Functional status generally reflects an individual's ability to carry out activities of daily living (ADLs) and to participate in various life situations and in society.[17] CMS requires the collection of data on functional status in home health through the Outcome and Assessment Information Set (OASIS). Under the current HH PPS, a functional score is derived from responses to OASIS and this score contributes to the overall case-mix adjustment for a home health episode payment.

CMS finalizes its proposal to assign points for each of the responses to the proposed OASIS functional items (Table 28, reproduced below) to sum up the points to create a functional score for the period of care. A home health period of care will receive points based on each of the responses associated with the functional OASIS items which will be converted into a table of points corresponding to increased resource use. The sum of all these points results in a functional score which is used to group home health periods into a functional level with similar resources. CMS will use three functional levels of low, medium and high based on the 2017 data for each of the clinical groups. Table 29 (reproduced below) shows the functional thresholds for each functional level by clinical group. CMS states that approximately one-third of home health periods from each of the clinical groups will be within each functional level.

TABLE 28: OASIS Points Table for Those Items Associated with Increased Resource Use Using a Reduced Set of OASIS Items, 2017*

Variable	Response Category	Points (2017)	Percent of Periods in 2017 with this Response Category
M1800: Grooming	1	4	56.9%
M1810: Current Ability to Dress Upper Body	1	6	60.0%
M1820: Current Ability to Dress Lower Body	1	5	59.3%
	2	11	20.9%
M1830: Bathing	1	3	18.0%
	2	13	53.1%
	3	21	23.6%
M1840: Toilet Transferring	1	4	

[17] Clauser, S. PhD. And Arlene S. Bierman, M.D., M.S. (2003). "Significance of Functional Status Data for Payment and Quality". Health Care Financing Review. 24(3), 1-12.

TABLE 28: OASIS Points Table for Those Items Associated with Increased Resource Use Using a Reduced Set of OASIS Items, 2017*			
Variable	**Response Category**	**Points (2017)**	**Percent of Periods in 2017 with this Response Category**
			32.1%
M1850: Transferring	1	4	37.8%
	2	8	59.2%
M1860: Ambulation/Locomotion	1	11	25.2%
	2	13	52.8%
	3	25	14.8%
M1032 (M1033 for OASIS C-1): Risk of Hospitalization	4 or more items checked	11	17.8%
*Source: 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).			

Table 29: Thresholds for Functional Levels by Clinical Group, 2017*		
Clinical Group	**Level of Impairment**	**Points (2017 Data)**
MMTA	Low	0-37
	Medium	38-53
	High	54+
Behavioral Health	Low	0-38
	Medium	39-53
	High	54+
Complex Nursing Interventions	Low	0-36
	Medium	37-57
	High	58+
Musculoskeletal Rehabilitation	Low	0-39
	Medium	40-53
	High	54+
Neuro Rehabilitation	Low	0-45
	Medium	46-61
	High	62+
Wound	Low	0-43
	Medium	44-63
	High	64+
*Source: 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018)		

CMS will update the functional points and functional thresholds for 2020 using 2018 home health claims and the most current version of the OASIS data set. CMS expects to make annual recalibration of the PDGM case-mix weights.

In response to recommendations to add additional OASIS items, such as caregiver availability and support, CMS discusses its analyses of the OASIS items to identify items to use in the case-mix adjustment. It examined every OASIS item for potential inclusion in the alternative case-mix adjustment methodology. Each OASIS item included in the model had a positive relationship with resource use such that as functional status declines (as measured by a higher response category), periods have more resource use, on average. When CMS re-examined the OASIS caregiver items for possible inclusion in the functional level case-mix adjustment, it found inverse patterns in resource use (82 FR 35319).

In response to concerns about the IMPACT Act, CMS notes that the analysis presented in the proposed rule was based on 2017 home health episodes and did not include IMPACT Act functional items. In support of the IMPACT Act, CMS has proposed to add the functional items, Section GG "Functional Abilities and Goals" to the OASIS data set effective January 1, 2019. CMS does not have the data to determine the effect on these new items on resource costs however, it will continue to examine the effect of all OASIS items, including the "GG" functional items, on resources to determine if refinements are needed.

CMS disagrees with concerns about the functional impairment thresholds and reminds the reader that the current HH PPS groups' scores are based on functional OASIS items with similar average resource use with the same distribution of episodes classified as low, medium, or high. CMS also reminds HHAs that the provision of home health services should be based on patient characteristics and care needs. In response to concerns about the elimination of therapy thresholds, CMS notes that section 51001(a)(3) of the BBA of 2018 prohibited the use of therapy thresholds as part of the overall case-mix adjustment for CY 2020 and subsequent years.

8. Comorbidity Adjustments

CMS finalizes its proposals for the comorbidity adjuster, including the home health specific list of comorbidity subgroups and comorbidity subgroup interactions. One of three mutually exclusive categories of comorbidity adjustment will be applied to each period: No Comorbidity Adjustment, Low Comorbidity Adjustment, and High Comorbidity Adjustment. No comorbidity adjustment means no secondary diagnoses exists or a secondary diagnosis did not meet the criteria for a comorbidity adjustment.

CMS finalizes that home health 30-day periods of care can receive a comorbidity payment adjustment 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 (Table 30) associated with higher resource use, or
- High comorbidity adjustment: There are two or more secondary diagnoses reported within the same comorbidity subgroup interaction (Table 31) that are associated with higher resource use.

CMS notes that with dividing the MMTA clinical group into subgroups (discussed above in section III.F.6), the number of comorbidity subgroups in both the low and high comorbidity adjustment is higher than described in the proposed rule. Based on analysis of 2017 home health claims there are 13 comorbidity subgroups that would receive the low comorbidity adjustment and 34 comorbidity subgroup interactions that would receive the high comorbidity adjustment.

CMS finalizes that a 30-day period of care can receive either a payment for a low or high comorbidity adjustment. 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. If a 30-day home health period of care does not have any reported comorbidities that fall into one of the two payment adjustments, there will be no comorbidity adjustment applied.

In 2020, CMS will analyze the most recently available claims to update the comorbidity list to include those comorbid conditions and interaction subgroups that represent more than 0.1 percent of periods and have at least as high as the median resource use. CMS will also continue to evaluate reported secondary diagnoses and interactions between comorbidities to identify their impact on resource use and will make additional refinements to this case-mix adjustment variable as appropriate.

CMS agrees with commenters that it will need to continue to monitor how the comorbidity adjustment affects home health patients and providers and it will consider future refinements as necessary. CMS notes that over time, if the average number of comorbidities in the aggregate becomes the standard within the Medicare home health patient population, this will be factored into the base rate because the base rate represents the average home health payment for the average patient. CMS anticipates it will annually recalibrate the PDGM case-mix weights, including the comorbidity adjustment. This could mean additions or subtractions of comorbidity subgroups and/or comorbidity subgroup interactions in the low and/or high comorbidity adjustment groups.

In response to concerns that the comorbidity adjustments are insufficient payment for providers, CMS notes that the payments are the result of actual resource utilization reported on home health claims. CMS repeats the details of the analysis discussed in the proposed rule (83 FR 32407).

9. Changes in the Low-Utilization Payment Adjustment (LUPA) Threshold

Under the current payment system, if an HHA provides four visits or less in an 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 Low-Utilization Payment Adjustments (LUPAs).

CMS finalizes its proposal to vary the LUPA threshold for each 30-day period of care depending 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. Table 32 in the final rule, lists the LUPA thresholds for the PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes based on the 2017 home health data. This information will be updated in the 2020 HH PPS proposed rule using 2018 home health data.

In response to commenters' concerns about increased burden associated with different LUPA thresholds, CMS responds it does not understand why case-mix-specific LUPA thresholds would cause additional administrative burden and costs. It notes that there is no change in how LUPA episodes are billed under the PDGM. Some commenters suggested a system of varying LUPA thresholds than would include a narrower range of thresholds, but the commenters did not provide specifics on their recommendations nor any rationale supporting this recommendation. CMS notes that it set the LUPA threshold at the 10^{th} percentile value of visits or 2 visits,

whichever is higher, for each payment group in order to target approximately the same percentage of LUPA as under the current system. CMS will analyze this methodology once the PDGM is implemented to determine whether any changes to the LUPA threshold are warranted.

10. HH PPS Case-Mix Weights Under the PDGM

Section 1895(b)(4)(B) of the Act requires the Secretary to establish appropriate case-mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services. CMS finalizes the case-mix adjustment methodology for the PDGM (with modifications as discussed in each prior section as appropriate), which results in a total of 432 unique case-mix payment groups known as Home Health Resource Groups (HHRGs).

CMS discusses the methodology it used to determine case-mix weights under the PDGM. Table 33 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 case-mix weight for each HHRG payment group is provided in Table 34.

CMS finalizes its proposal to generate PDGM case-mix weights for each of the different PDGM payment groups by regressing resource use on a series of indicator variables for each of the five categories (timing, admission source, clinical grouping, functional level, and comorbidity) using a fixed effects model. CMS will annually recalibrate the PDGM case-mix weights to ensure that they reflect the most recent utilization data available for annual rulemaking.

In response to comments, CMS does not finalize its proposal to revise the frequency of the updates to the HHS PPS Grouper software used to assign the appropriate HIPPS code used for the case-mix adjustment on the claim. CMS will continue to provide an update on October 1 to capture HH PPS policies that become effective on January 1 and will also release Grouper software in January of each year.

11. Low-Utilization Payment Adjustment (LUPA) Add-On Payments and Partial Episode Payment (PEP) Adjustments under PDGM

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. CMS finalizes its proposal that under the PDGM, the LUPA add-on factors will remain the same as the current payment system. In response to a comment, CMS clarifies that the LUPA add-on payment amount under the PDGM will only be paid to LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of additional periods of care.

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.

For 30-day periods of care, CMS will maintain the current process for PEP adjustments. When a new 30-day period begins due to 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.

12. Payments for High-Cost Outliers Under the PDGM

CMS finalizes its proposal to maintain the current methodology for payment of high-cost outliers under the PDGM except that outlier payments will be determined on a 30-day basis to align with the 30-day unit of payment under the PDGM. CMS plans to evaluate and model projected outlier payments within the framework of the PDGM and consider modifications to the outlier policy as appropriate.

Commenters expressed concerns about limiting the outlier policy to a 10 percent cap and suggested modification to the 8-hour cap on the amount of time per day that is counted toward the estimation of an episode's costs for calculation of the outlier. CMS notes that the requirement that the total amount of outlier payments not exceed 2.5 percent of total home health payments and the 10 percent cap on outlier payments at the home health agency level are statutory requirements (1895(b)(5) of the Act). Regarding the 8-hour limit, CMS notes that the daily and weekly cap on the amount of skilled nursing and home health aide services combined is a limit defined within the statute. In the 2018 HH PPS final rule, CMS stated that because outlier payments are predominately driven by the provisions of skilled nursing services, the 8-hour cap on services aligns with the statute, which requires that skilled nursing and home health aide services combined be furnished less than 8 hours each day. CMS believes that maintaining the 8-hour cap is appropriate under the PDGM.

Using 2017 claims data and 2019 payment rates, CMS estimates that outlier payments under the PDGM with 30-day periods of care would comprise approximately 4.77 percent of total HH PPS payments in 2019. To meet the statutory requirement to target up to, but no more that 2.5 percent of total payments as outlier payments, CMS estimates that the fixed dollar loss (FDL) ratio under the PDGM would need to change from 0.55 to 0.71. CMS notes it will update the estimate of outlier payments as a percent of total HH PPS payments using the most current data available at the time of 2020 rate-setting.

G. Changes Regarding Certifying and Recertifying Patient Eligibility

1. Regulations Text Changes Regarding Information Used to Satisfy Documentation of Medicare Eligibility for Home Health Services

In the proposed rule, CMS reviewed the documentation requirements necessary to certify patient eligibility for home health services. The certifying physician is responsible for determining whether the patient meets the eligibility criteria (i.e., homebound status and need for skilled services) and for developing an effective plan of care. As a condition for payment, statute requires that prior to certifying a patient's eligibility for the Medicare home health benefit, the certifying physician must document that the physician or an allowed non-physician practitioner had a face-to-face encounter with the patient.[18] CMS requires documentation in the certifying physicians' medical records and/or the acute/post-acute care facility's medical records (if directly admitted to home health) be used as a basis for certification of home health eligibility (as described in regulations at §424.22(c)).

CMS noted that while the face-to-face encounter must be related to the primary reason for home health services, patient's skilled need and homebound status can be substantiated through an examination of all submitted medical record documentation (e.g., progress notes, diagnostic findings, medication and nursing notes). HHAs must obtain as much documentation as necessary to assure themselves that the Medicare home health patient eligibility criteria have been met. This information must be available upon request from CMS and the documentation must be sufficient, otherwise CMS will not make payment for the home health services provided.

For physician certifications and recertifications made on or after January 1, 2019, section 51002 of the BBA of 2018 allows for the Secretary to use documentation in the medical record of the HHA as supporting material in addition to using the documentation in the medical record of the certifying physician or of the acute or post-acute care facility.[19] CMS believes the BBA of 2018 provisions are consistent with its existing policy in this area which is currently reflected in sub-regulatory guidance in the Medicare Benefit Policy Manual (Pub.100-02, chapter 7, section 30.5.1.2) and the Medicare Program Integrity Manual (Pub. 100-08, chapter 6, section 6.2.3).[20]

In this final rule, CMS adopts changes to the regulations text at 42 CFR 424.22(c) to align with current sub-regulatory guidance that allows medical record documentation from the HHA to be used to support the basis for certification and/or recertification of home health eligibility, if the following requirements are met:

- The documentation from the HHA can be corroborated by other medical record entries in the certifying physician's and/or the acute/post-acute care facility's medical record for the patient, thereby creating a clinically consistent picture that the patient is eligible for Medicare home health services as specified in §424.22 (a)(1) and (b).

[18]Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act as amended by section 6407 of the Affordable Care Act
[19]Section 51002 of the BBA of 2018 amended sections 1814(a) and 1835(a) of the Act
[20] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf and https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c06.pdf

- The certifying physician signs and dates the HHA documentation demonstrating that the documentation from the HHA was considered when certifying patient eligibility for Medicare home health services. HHA documentation can include, but is not limited to, the patient's plan of care required in accordance with 42 CFR 409.43 and the initial and/or comprehensive assessment of the patient required in accordance with 42 CFR 484.55.

CMS states that HHAs have the discretion to determine the type and format of any documentation used to support home health eligibility. CMS notes that it has received reports from HHAs that they typically include this supporting information in the plan of care. As such, CMS believes that no additional burden is incurred by either the HHA or the certifying physician, and that most HHAs may already have a process in place to provide this information to the certifying physician or the acute/post-acute care facility.

Overall, commenters were supportive of incorporating existing subregulatory guidance into regulations text as it provides them with reassurance that HHA-generated documentation can play an important role in confirming eligibility for Medicare home health services. CMS stresses in response to a comment that the HHA-generated documentation is not meant to supersede, override or negate the physician's opinion or any physician orders in the established home health plan of care.

2. Elimination of Recertification Requirements to Estimate How Much Longer Home Health Services Will be Required

As discussed in the proposed rule, in response to requests for reducing burden with respect to home health care, several commenters requested that CMS consider eliminating the requirement that the certifying physician include at each home health recertification an estimate of how much longer skilled services will be required, as set forth at §424.22(b)(2) and in subregulatory guidance in the Medicare Benefit Policy Manual (Chapter 7, Section 30.5.2). Commenters stated that this estimate is duplicative of the Home Health Conditions of Participation (CoP) requirements for the content of the home health plan of care, set out at 42 CFR 484.60(a)(2).

CMS stated in the proposed rule that it agreed with the commenters and this estimate required at each recertification is not currently used for quality, payment, and or program integrity purposes, and in this rule finalizes its proposal to eliminate the regulatory requirement as set forth at 42 CFR 424.22(b)(2), that the certifying physician, as part of the recertification process, provide an estimate of how much longer skilled services will be required. All other recertification content requirements under §424.22(b)(2) remain unchanged.

CMS believes that elimination of this recertification requirement will result cost savings of $14.2 million as this will reduce the amount of time physicians spend on the recertification process.

H. Change Regarding Remote Patient Monitoring

CMS provides background and notes the importance of remote patient monitoring and its applicability to the home health setting. It cites literature which shows that for patients with

chronic conditions, such as chronic obstructive pulmonary disease and congestive heart failure, the use of this technology results in lower mortality, improved quality of life, and reductions in hospital admissions.[21] CMS notes that it had not had specific policies surrounding the use of patient monitoring by HHAs other than the statutory requirement that services furnished via a telecommunications system may not substitute for in-person home health services ordered as part of a plan of care certified by a physician.

To facilitate its adoption, CMS finalizes its proposed a definition of remote patient monitoring under the Medicare home health benefit, and a proposal to include such costs as allowable on the HHA cost report. Specifically, CMS defines remote patient monitoring under the Medicare home health benefit as "the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA."

Although the cost of remote patient monitoring is not separately billable under the HHS PPS and may not be used as a substitute for in-person home health services, CMS believes that the expenses of remote patient monitoring, if used by the HHA to augment the care planning process, should be reported on the cost report as an allowable administrative cost (operating expenses) that are factored into costs per visit.[22] CMS finalizes it proposal to amend the regulations at 42 CFR 409.46 to include the costs of remote patient monitoring as an allowable administrative cost (that is, operating expense), if remote patient monitoring is used by the HHA to augment the care planning process. These costs will then be factored into the costs per visit calculations, and could then be used, for example, to compare costs to payments as part of any payment analysis.

Commenters were overwhelmingly positive regarding CMS' proposals to define remote patient monitoring in regulation for the Medicare home health benefit and to include the costs of remote patient monitoring as an allowable expense on the HHA cost report. Several commenters requested that CMS clarify whether agency intends that all qualified health professionals, specifically, physical therapists, speech language pathologists, and occupational therapists, acting within their scope of practice, may use remote patient monitoring to augment the plan of care during a home health episode. CMS replies that its definition does not specify which skilled professionals may utilize remote patient monitoring under home health, and believes therapists involved in care planning, as well as other skilled professionals acting within their scope of practice, may utilize remote patient monitoring to augment this process.

In summary, CMS finalizes its proposal to define remote patient monitoring under the Medicare home health benefit as "the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient or caregiver or both to the home health agency." CMS adds the following language to the

[21] CMS cites evidence from a systematic review by the Agency for Healthcare Research and Quality (AHRQ). See Department of Health and Human Services, Agency for Healthcare Research and Quality, Telehealth: Mapping the Evidence for Patient Outcomes from Systematic Reviews, Technical Brief Number 26 (Washington, D.C.: June 2016).

[22] CMS cites that costs associated with remote patient monitoring are reported on line 23.20 on Worksheet A of the HHA cost report, as direct costs associated with telemedicine. These costs, however, are not allocated to costs per visit.

regulations text to ensure a more complete description of remote patient monitoring services, while also ensuring that such services cannot be reported as a visit without the provision of another skilled service: Visits to a beneficiary's home for the sole purpose of supplying, connecting, and/or training the patient on the remote patient monitoring equipment, without the provision of another skilled service are not separately billable. These services do constitute services included in the expense of providing remote patient monitoring allowed as administrative costs.

CMS also finalizes its proposal to amend the regulations at 42 CFR 409.46 to include the costs of remote patient monitoring as an allowable administrative cost (that is, operating expense), if remote patient monitoring is used by the HHA to augment the care planning process.

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 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[23] is mandatory. Several changes to the model were subsequently made in the 2017 and 2018 HH PPS final rules (81 FR 76741-76752) and (82 FR 51700-51711).

B. Changes to HHVBP Quality Measures

The 2016 HH PPS final rule established a "starter set" of 24 quality measures already reported via the Outcome and Assessment Information Set (OASIS) patient assessment instrument.[24] Four of these measures were subsequently removed in the 2017 HH PPS final rule effective beginning with PY 1. The resulting measure set for PY 1 (2016 data for 2018 payment adjustment) includes 20 measures consisting of 5 process of care measures, 10 outcome measures, and 5 Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey (HHCAHPS) measures. In the 2018 HH PPS final rule, one of these measures ("Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care") was removed beginning with PY 3 (2018 data for 2020 payment).

[23] 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.

[24] 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.

In this rule, CMS finalizes its proposal to remove two measures from the HHVBP measure set and replace three others beginning with PY 4 (2019 data for 2021 payment). Commenters were generally supportive of these proposals. The two measures removed are:

- "Influenza Immunization Received for Current Flu Season" is removed based on concern about the measure specifications from stakeholders and a Technical Expert Panel (TEP); the measure does not exclude patients who were offered but refused a flu vaccine or patients for whom a vaccine is contraindicated. CMS notes that although the influenza immunization measure is being removed from the HHVBP, HHAs will still have an incentive to ensure appropriate immunization because the measure remains in the HH QRP and HHA performance on this measure will be publicly reported.
- "Pneumococcal Polysaccharide Vaccine Ever Received" is removed because the Advisory Committee on Immunization Practices clinical guidelines for this vaccine have changed.[25] Although CMS is also finalizing removal of this measure from the HH QRP (see below), HHAs are encouraged to provide pneumococcal vaccinations for their patients.

Three OASIS-based measures are replaced with two related composite measures, based on the recommendation of a TEP convened in November 2017. The measures Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing are removed, and the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, described further below, are added. CMS believes that the composites will create a more comprehensive assessment of HHA performance across a broader range of Activities of Daily Living (ADL) outcomes. In addition, while the measures being removed assess improvement, the new composites assess the magnitude of patient changes, including both improvement and decline.

The new composite measures combine several existing and endorsed HH QRP outcome measures, and will be included within the Patient and Family Engagement domain.

"Total Normalized Composite Change in Self Care" assesses the magnitude of change based on a normalized amount of possible change for each of six OASIS-based quality outcomes:

- Improvement in Grooming (M1800)
- Improvement in Upper Body Dressing (M1810)
- Improvement in Lower Body Dressing (M1820)
- Improvement in Bathing (M1830)
- Improvement in Toileting Hygiene (M1845)
- Improvement in Eating (M1870)

"Total Normalized Composite Change in Mobility" similarly assesses change in three OASIS-based quality outcomes:

- Improvement in Toilet Transferring (M1840)

[25] The previous guidelines recommended a single dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23) among all adults aged 65 years and older and high-risk adults ages 19-64 years. The current guidelines recommend that Pneumococcal conjugate vaccine (PCV13) and PPSV23 be given to all immunocompetent adults ages 65 and older, with intervals depending on age and previous vaccination.

- Improvement in Bed Transferring (M1850)
- Improvement in Ambulation/Locomotion (M1860)

For each of these composites, the magnitude of possible change depends on the number of possible responses in the underlying OASIS items. CMS describes the technical steps used to calculate, normalize, and risk adjust scores for these measures. Table 37 in the final rule provides an overview of the results of the prediction models using 2014 and 2015 data; for both measures in both years the R-square value is about 30 percent. That is, the models consistently predict about 30 percent of the variability in the composite measures. CMS will use data for episodes ending in 2017 for the prediction model when the measure is implemented. Missing values for an item will be scored as zero, although CMS notes that missing item values are unlikely because HHAs must provide responses to all OASIS items to have the OASIS assessment accepted into the CMS data repository.

The baseline year for these two composite measures is finalized to be 2017. CMS says that it committed to consistently use the 2015 baseline period for the starter set of quality measures used in the model, but that these new composite measures were not part of the starter set and using more recent baseline data will result in a more accurate performance score.

As proposed, the composite measures will each have a maximum score of 15 points. The three ADL improvement measures that are being replaced currently have a maximum cumulative score of 30 points. Thus, a 30-point maximum is maintained for ADL-related measures in the HHVBP Model.

In its comments, MedPAC expressed concern about the composite measures' reliance on reporting elements completely within the control of HHAs, which may incentivize them to change their coding practices in order to improve measure performance. CMS responds by noting that in this rule it is also finalizing its proposed reduction in the weight of OASIS-based measures in calculating the HHVBP total performance score. (See section IV.C below.) That change will give greater weight to claims-based and patient survey measures over the self-reported OASIS measures. Responding to another commenter, CMS acknowledges that not all of the OASIS items that comprise the Total Normalized Composite Change in Self Care composite measure are currently included in the measure set for the HHVBP Model. It notes, however, that these are existing OASIS items in areas of great importance to patients and families for which HHAs should already be focused on improvement.

Regarding many comments suggesting that patient stabilization measures should be recognized in the HHVBP and not just patient improvement measures, CMS reiterates the analysis of existing stabilization measures that it discussed in the 2016 HH PPS final rule. At that time CMS found that performance on available stabilization measures was already very high and would therefore not allow for meaningful distinctions in HHA quality performance. Since then, CMS has not identified any other stabilization measures that would allow for meaningful comparison of HHA performance.

Table 38 in the final rule describes the 16 measures adopted for PY 4 (2019 data for 2021 payment), including details on data source, and the numerator and denominator for each measure (or, in the case of the composites, the measure computation and risk adjustment). The following table provides a summary of these measures.

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

C. Reweighting of HHVBP Model Measures

CMS finalizes its proposal to change the weighting of the HHVBP Model measures when calculating a Total Performance Score (TPS) beginning with PY 4 (2019 data for 2021 payment). Currently, the sum of points for reporting of new measures is weighted at 10 percent of the TPS, and the sum of points for all other measures in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience classifications is weighted at 90 percent. Within both parts, all measures are weighted equally. The change creates new weights by measure category for the measures that are not new measures (i.e., the component that is weighted at 90 percent). The OASIS-based and claims-based measure categories will each be weighted at 35 percent, while the HHCAHPS category will be weighted at 30 percent. Points awarded for data reporting for each new measure will continue to receive equal weight and account for the remaining 10 percent of the TPS. Corresponding changes are adopted to the regulatory text at 42 CFR 484.320(c).

Under the final policy, if scores are missing for individual measures within a category, the weights of the remaining measures will be adjusted proportionately so that the category total weight remains the same. If an HHA is missing all the measures for one of the three categories, the weights of the other categories will be adjusted.

In addition, CMS finalizes that the claims-based measure "Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health" will be given a weight that is three times the weight of the other claims-based measure "Emergency Department Use without Hospitalization." CMS says this is because HHAs have more control over the unplanned hospitalization measure, and because improvement on this measure will have a greater impact on Medicare expenditures.

Table 50 in the final rule, reproduced below, shows the current and newly finalized weights for each measure under all scenarios (i.e., scores for 1, 2, or all 3 categories). Table 40 of the final rule offers a numerical example of calculating the TPS under the current and new weights.

CMS believes that the reweighting will better support improvement in the claims-based measures. Figures 1 and 2 of the final rule show changes in performance on HHVBP Model measures in model and non-model states. In general, CMS reports that there has been steady improvement in performance on OASIS-based measures in both model and non-model states, while performance on claims-based measures has been relatively flat.

MedPAC suggested in its comments that the OASIS measures be given less weight than the HHCAHPS measures because patient experience is important to assessing quality of care. CMS responds by stating that under the finalized weights the HHCAHPS category weight declines only slightly (from 31.25 percent to 30 percent, or 6.25 percent for each measure) while the OASIS category declines from 56.25 percent to 35 percent, and the non-composite OASIS-based measures are weighted at 5 percent each. CMS also notes that smaller HHAs are not required to submit HHCAHPS scores due to low volume and it is appropriate to give more weight to the categories with broader reporting.

Responding to other comments, CMS believes that with its emphasis on claims-based measures of ED use and unplanned hospitalizations, the reweighting will encourage HHAs to increase coordination with other providers to reduce ED visits and hospital stays which may improve care for all beneficiaries, including vulnerable populations. CMS does not agree with some commenters that HHAs need more time to adapt to the HHVBP before reweighting, saying that the measures have been part of the model from its start, and noting the evaluation of the model will consider changes in the model and changes in the HH PPS.

TABLE 50: CURRENT AND FINALIZED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES FOR THE HHVBP MODEL[123]

	Current Weights				Finalized Weights: All Changes			
	All Measures (n=1,026)	**No HHCAHPS (n=465)**	**No claims (n=20)**	**No claims or HHCAHPS (n=99)**	**All Measures (n=1,026)**	**No HHCAHPS (n=460)**	**No claims (n=20)**	**No claims or HHCAHPS (n=73)**
Large HHAs	*1023*	*382*	*20*	*49*	*1023*	*380*	*20*	*39*
Small HHAs	*3*	*83*	*0*	*50*	*3*	*80*	*0*	*34*
OASIS (35% weight)[1]								
Flu vaccine ever received[2]	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Pneumococcal vaccine[2]	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Improve Bathing[3]	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Improve Bed Transfer[3]	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Improve Ambulation[3]	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%
Improve Oral Meds	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%
Improve Dyspnea	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%
Improve Pain	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%
Discharge to Community	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%
Composite self-care	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%
Composite mobility	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%
Total weight for OASIS measures	*56.25%*	*81.82%*	*64.26%*	*100.00%*	*35.00%*	*49.98%*	*53.82%*	*99.96%*
Claims (35% weight)								
Hospitalizations	6.25%	9.09%	0.00%	0.00%	26.25%	37.50%	0.00%	0.00%
Outpatient ED	6.25%	9.09%	0.00%	0.00%	8.75%	12.50%	0.00%	0.00%
Total weight for claims measures	*12.50%*	*18.18%*	*0.00%*	*0.00%*	*35.00%*	*50.00%*	*0.00%*	*0.00%*
HHCAHPS (30% weight)								
Care of patients	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Communication between provider and patient	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Discussion of specific care Issues	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Overall rating of care	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Willingness to recommend HHA to family or friends	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Total weight for HHCAHPS measures	*31.25%*	*0.00%*	*35.70%*	*0.00%*	*30.00%*	*0.00%*	*46.15%*	*0.00%*

NOTES:

[1] Under the finalized weights, the weights of the measure categories, when one category is removed, are based on the relative weight of each category when all measures are used. For example, if the two measure categories, Claims and OASIS, are expressed then each category represents 50% because each of these categories has the same weight (35%) when all 3 categories are represented (the OASIS percentage is shown as 49.98% in Table 50 due to rounding). However, if only OASIS and HHCAHPS are expressed, OASIS represents 53.82% while HHCAHPS represents 46.15%, which represents the same relative proportion as 35% and 30%, the OASIS and HHCAHPS weights, respectively, when all three categories are present.

[2] The flu vaccine ever received and pneumococcal polysaccharide vaccine measures are finalized to be removed from the applicable measure set beginning in CY 2019/PY4.

[3] The Improvement in Bathing, Improvement in Bed Transfer and Improvement in Ambulation measures are finalized to be removed from the applicable measure set and replaced with the two new composite measures beginning in CY 2019/PY4. These new composite measures (Composite Self-Care and Composite Mobility) will be weighted 1.5 times more than the other OASIS-based measures so that the total weight for the functional-based OASIS measures is unchanged.

D. Performance Scoring Methodology

CMS finalizes its proposal to reduce the maximum number of improvement points that can be earned on each measure in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience classifications from 10 points to 9 points, beginning with PY 4. The proposal was made in response to previous public comments supporting a focus on achievement of specified quality scores after the initial 3 years of implementation. CMS also notes that the Inpatient Hospital Value-Based Purchasing Program scoring system assigns a maximum of 10 points for achievement and 9 points for improvement.

Under the final rule, a unique improvement range will be measured for each HHA defined as the difference between the HHA's baseline period score and the state benchmark used in achievement scoring. If the HHA's performance during the performance period is equal to or higher than the benchmark score, the HHA will receive the maximum improvement score of 9 points. The HHA could still receive the maximum score for achievement; this is generally 10 points but for the two new composite measures, the maximum score is 15 points. If the measure score is lower than it was in the baseline period, zero points are awarded for improvement. If the measure score exceeds the baseline level but is below the benchmark, the following formula will be used to determine the improvement score:

$$9 \times \left(\frac{\text{HHA Performance Period Score - HHA Baseline Period Score}}{\text{Benchmark - HHA Baseline Period Score}} \right) - 0.5$$

The final rule repeats the numerical examples of calculating achievement and improvement scores that were included in the proposed rule.

E. Update on Public Display of Total Performance Scores

CMS continues to consider public reporting of HHVBP Model results after allowing analysis of at least eight quarters of performance data on the model, and comparison of the results with other reported quality data. No proposal was offered but comments were sought (and received) on what information should be made publicly available. The information that might be considered for public reporting is what is included in the Annual Total Performance Score and Payment Adjustment Report: the agency name, address, TPS, payment adjustment percentage, performance information for each measure, state and cohort information, and percentile ranking.

Some commenters suggested certain elements for public reporting, while others stated that the TPS methodology is still evolving and these data would only be available for the subset of HHAs participating in the HHVBP Model. Commenters also pointed out that the measures used in the model are already publicly reported on Home Health Compare.

CMS thanks commenters and says it will work to ensure any data that are publicly reported from the annual reports are thoroughly explained and give patients, physicians, discharge planners, and

other referral sources the knowledge they need to choose higher-performing HHAs. Any changes will be proposed in future rulemaking.

F. Impact Analysis of HHVBP Model

CMS does not believe the changes adopted in this final rule would affect prior estimates of the overall impact of the HHVBP Model. In the 2017 HH PPS final rule, CMS estimated that model would reduce payments for 2018 through 2022 by approximately $378 million.

The final rule includes estimates of the distribution of payment adjustments under the model using performance year data for 2016, the first year of HHVBP. The estimates take into account the changes finalized in this rule to remove and replace measures, reduce maximum improvement points from 10 to 9, and change the weighting of HHVBP measures beginning in PY 4 (2019). Table 47 in the final rule, summarized below, displays the estimated distribution of payment adjustments being used in PYs 4 and 5 of the HHVBP model. The table is unchanged from the proposed rule (where it was numbered Table 62).

Payment Adjustment Distribution by Percentile of Quality TPS (from Final Rule Table 47)			
	Lowest, 10th percentile	Median	Highest, 90th percentile
7% payment adjustment (year 4)	-3.3%	-0.2%	+3.7%
8% payment adjustment (year 5)	-3.8%	-0.3%	+4.2%

Table 48 in the final rule shows the estimated distribution of payment adjustments by state and stratified by small/large volume HHAs. It is also unchanged from the proposed rule (Table 63). Among other impacts the table shows that under the final rule changes, the number of HHAs with a sufficient number of measures to receive a payment adjustment for PY 4 (for 2021 payment) would be reduced by 31 (from a current total of 1,610). The table also shows that five states (AZ, MD, NC, TN, WA) would only have one cohort because they do not have sufficient smaller-volume HHAs.

Table 49 (unchanged from proposed rule Table 64) shows the estimated distribution of payment adjustments across all states by HHA characteristics (size of HHA, percent of Medicare-Medicaid dual eligibles, patient acuity, percent of rural beneficiaries, ownership, and free-standing versus facility-based HHAs). The median change in the payment adjustment resulting from the final rule changes is greatest for HHAs with a higher proportion of dual-eligible beneficiaries (-0.4%), those with a percentage of rural beneficiaries less than 90% (-0.4%) and HHAs with higher-acuity patients (-0.3%).

Table 50, which is reproduced above, shows the current and newly finalized weights for measures in the HHVBP Model. As noted, the table includes the weightings for HHAs that have scores for all measures and for HHAs for which the claims measures or HHCAHPS measures are missing and the remaining classifications are re-weighted. Under the final rule changes, the number of HHAs that do not have enough measures to receive a payment adjustment drops from

99 to 73 (shown in the column "no claims or HHCAHPS"), and the majority of these are smaller HHAs (16 of the 26 HHAs).

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

A. Background

CMS reviews 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 Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, P.L. 113-185) imposed new reporting requirements for post-acute care (PAC) providers, including HHAs. This includes standardized patient assessments for HHAs, SNFs, Inpatient Rehabilitation Facilities (IRFs) and Long-Term Care Hospitals (LTCHs).

B. Accounting for Social Risk Factors in the HH QRP

CMS discusses the status of its consideration of whether and how to account for social risk factors in the HH QRP and other quality programs. Social risk factors might include dual eligibility/low-income subsidy; race and ethnicity; and geographic area. In last year's rulemaking CMS sought comment not only on which factors might be used to adjust or stratify measures, but also whether existing sources of information are available or whether new data collection would be required, and on operational considerations.

As a next step, in the proposed rule for 2019 CMS said that it is considering options to reduce health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. Readers are referred to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details regarding potential stratification of certain outcome measures in the hospital inpatient quality reporting program.

CMS reports that commenters offered recommendations on which risk factors to consider, on statistical methods, and for rewarding better outcomes for beneficiaries with social risk factors. One comment suggested exploring the influence of neighborhood factors that could be linked to a patient using address information, and MedPAC recommended that CMS adjust payment through peer grouping and targeting technical assistance to low-performing providers.

C. Removal Factors for Previously Adopted HH QRP Measures

Elsewhere in the final rule, CMS discusses the Meaningful Measures Initiative,[26] which it launched in October 2017 as part of its effort to reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care. Meaningful Measures is a component part of the agency's Patients Over Paperwork Initiative and is aimed at identifying the highest

[26] See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.

priority areas of quality measurement and quality improvement that are most vital to improving patient outcomes. Consistent with these goals, CMS reviewed the HH QRP measure set to identify how to move the program forward in the least burdensome manner possible while continuing to incentivize quality improvement.

Based on that review, CMS in this rule finalizes its proposal to replace the current six criteria that it uses to consider removing measures from the HH QRP with the seven factors adopted by the various other Medicare provider quality reporting programs,[27] and to add a new eighth factor. The finalized eight factors consider whether 1) performance on the measure is so high and unvarying that meaningful distinctions can no longer be made; 2) performance or improvement on the measure does not result in better patient outcomes; 3) the measure does not align with current clinical guidelines or practice; 4) another more broadly applicable measure is available; 5) a measure that is more proximal in time to desired patient outcomes on the topic is available; 6) another available measure is more strongly associated with the desired patient outcomes; 7) collection or public reporting of the measure leads to negative unintended consequences other than patient harm; and 8) the costs associated with a measure outweigh the benefit of its continued use in the program.

CMS reiterates that none of the factors results in automatic removal; these are considerations taken into account on a case-by-case basis. With respect to Factor 8 for example, CMS might remove a measure that is of limited use because publicly reported data cannot be easily interpreted by beneficiaries. In contrast, it might retain a measure that is burdensome for HHAs to report if the benefit to beneficiaries justifies the reporting burden. Further, readers were reminded that measure removal is subject to notice and comment rulemaking unless a measure is determined to cause a patient safety concern.

Commenters generally agreed with adopting the new measure removal factors. Regarding new Factor 8, CMS responds to commenters by acknowledging the challenges in weighing costs and benefits of a measure, considering that stakeholders will have different perspectives. In evaluating this factor for a measure, it intends to take into account input from patients, caregivers, advocates, providers, researchers, vendors and other stakeholders with relevant insight. Considerations will also involve the "holistic balance" of costs, benefits, data, input from stakeholders and CMS' policy objectives.

With respect to Factor 1 on topped out measures, CMS responds to a comment by indicating that it monitors for gaps in quality related to the topics that removed measures address and it would consider reintroducing a measure if it discovered such a gap. Regarding Factor 4 on replacement with a more broadly applicable measure, CMS says that it intends to only consider measure replacement if the broader measure is at least comparable in terms of how well it addresses quality outcomes as the measure it is replacing.

[27] The current six removal criteria adopted for the HH QRP are not listed in either the proposed or final rules for 2019, but they are identical to the first six of the eight finalized factors listed above. The six criteria can be found in the 2017 HH PPS final rule (81 FR 76755).

D. Removal of Measures Beginning with the 2021 HH QRP

In keeping with the Meaningful Measures Initiative, CMS finalizes its proposals to remove seven measures beginning with the 2021 HH QRP out of the 31 currently adopted measures. The measures being removed are summarized in the table below, and the final measure set for the 2021 HH QRP is displayed in a separate table that follows.

CMS notes that it cannot update the OASIS submission system prior to January 1, 2020, which is midway through the HH QRP data collection period. As a result, for the five measures finalized for removal that are calculated using OASIS data, HHAs must continue to submit data for episodes that occur during the 3rd and 4th quarters of 2019 (i.e., the first two quarters of the 2021 program year). For the two claims-based measures, CMS will stop collecting claims data for these measures for episodes that begin on or after July 1, 2019.

With respect removal of the pneumococcal vaccine measure, CMS rejects comments suggesting that the current measure be retained until an updated version reflecting the new guidelines is available. This is because the updated version requires information that HHAs often do not have, such as whether the patient was previously vaccinated, the type of vaccine received, and the sequencing of vaccine administration. CMS encourages HHAs to provide these vaccines to their patients when possible and appropriate.

Measure	**Rationale for Removal**	**Data Submission and Public Reporting Changes**
1. Depression Assessment Conducted	*Factor 1, performance is high and unvarying*. 2017 performance scores were 96.8% (mean) and 99.2% (median) and the 75th and 90th percentile scores were both 100%.	OASIS Item M1730 (Depression Screening) no longer submitted for this measure beginning 1/1/20 but reporting continues as a risk adjustor for other measures.[28] Publicly reported until no data available.
2. Diabetes Foot Care and Patient/Caregiver Education Implemented During All Episodes of Care	*Factor 1, performance is high and unvarying.* 2017 performance scores were 97% (mean) and 99.2% (median) and the 75th and 90th percentile scores were both 100%.	OASIS Item M2401 row a (diabetic foot care at transfer to an inpatient facility) no longer submitted beginning 1/1/20. Publicly reported until no data available.
3. Multifactor Fall Risk Assessment Conducted for All Patients (NQF #0537)	*Factor 1, performance is high and unvarying.* 2017 performance scores were 99.3% (mean) and 100% (median) and the 75th and 90th	OASIS Item M1910 (falls risk assessment) no longer submitted beginning 1/1/20. Publicly reported until no data available.

[28] The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in measure calculation are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), Improvement in Management of Oral Medications (NQF #0176), and Improvement in Status of Surgical Wounds (NQF #0178).

Measure	Rationale for Removal	Data Submission and Public Reporting Changes
	percentile scores were both 100%.	
4. Pneumococcal Polysaccharide Vaccine (PPV) Ever Received	*Factor 3, measure does not align with current clinical guidelines or practice.* The Advisory Committee on Immunization Practices clinical guidelines for this vaccine have changed. (See discussion above with respect to the HHVBP program.)	OASIS Items M1051 (Pneumococcal Vaccine) and M1056, (Reason Pneumococcal Vaccine not received) no longer required beginning January 1, 2020. Publicly reported until no data available.
5. Status of Surgical Wounds	*Factor 4, a more broadly applicable measure is available*. A majority of HHAs are not able to report on this narrowly defined measure (36% of HHAs reported it in 2016). The pressure ulcer measures are seen as a broader assessment of HHA care with respect to skin integrity.	OASIS Items M1340 (Does patient have a Surgical Wound?) and M1342 (Status of Most Problematic Surgical Wound) no longer required beginning 1/1/20 but reporting continues as a risk adjustor for other measures.[29] Publicly reported until no measure data are available.
6. Emergency Department (ED) Use Without Hospital Readmission During First 30 Days of HH (NQF #2505)	*Factor 4, a more broadly applicable measure is available.* Reportable for only 63% of HHAs in 2017. ED Use Without Hospitalization During 60 days is broader and includes the 30-day interval.	Publicly reported until no measure data are available.
7. Rehospitalization During First 30 Days of HH (NQF #2380)	*Factor 4, a more broadly applicable measure is available.* Reportable for only 63% of HHAs in 2017. Acute Hospitalization during the First 60 Days of HH is broader and includes the 30-day interval.	Publicly reported until January 2020.

[29] The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in measure calculation are those listed in footnote above for OASIS Item 1730 except that these items are NOT used for the measure Improvement in Status of Surgical Wounds (NQF #0178). These items are also used for the measure Discharged to the Community Needing Wound Care or Medication Assistance that is used by HH surveyors.

Summary Table: Final Measure Set for the 2021 HH QRP

Short Name	Measure Name & Data Source
OASIS-based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167)
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674)
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)
Pressure Ulcers*	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Timely Care	Timely Initiation of Care (NQF #0526)
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)	

E. IMPACT Act Update

CMS previously indicated its intention (82 FR 51731) to specify two measures no later than January 1, 2019 under the IMPACT Act domain of accurately communicating the existence and provision of the transfer of health information and care preferences and to propose to adopt them for the 2021 HH QRP, with data collection beginning on or about January 1, 2020.

As a result of the subsequent input by a TEP and pilot measure testing conducted in 2017, CMS is still engaged in development work on these measures including supplementary measure testing and further opportunity for public comment. It now intends to specify the measures no later than January 1, 2020, and to propose to adopt them beginning with the 2022 HH QRP, with data

collection beginning in January 2021. For more information on the pilot testing, readers are referred to: 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.

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

CMS finalizes proposed revisions to the regulatory text at 42 CFR 484.250(a) to clarify that not all OASIS data described in §484.55(b) and (d) related to the comprehensive assessment are needed for purposes of complying with the HH QRP. OASIS data may be submitted for other purposes, such as payment, survey, the HHVBP Model, or care planning. OASIS data not submitted for purposes of the HH QRP are not used for purposes of HH QRP compliance.

Specifically noted in the rule, CMS did not propose any changes to the HHCAHPS survey requirements for 2019. Data submission deadlines are posted at https://homehealthcahps.org.

G. Public Display of HH QRP Quality Measure Data

CMS previously finalized public reporting of data on five measures beginning in 2019. The measures are listed here along with the reporting periods. In this rule, CMS finalizes a modified reporting period for the Medicare Spending Per Beneficiary measure from 1 year of claims data (2017) to 2 years (2016 and 2017). It says this will increase the number of HHAs with sufficient data for public reporting from 90.7% to 94.9%. In addition, the 2-year time frame is used for this measure in other post-acute care provider public reporting programs. Responding to comments, CMS says that the benefit of increasing the number of HHAs in public reporting outweighs concerns about using the longer measurement period (e.g., use of less recent performance data). CMS believes that use of a 2-year performance period will still reflect HHA improvement efforts.

Measures Previously Finalized for Public Reporting in 2019	
Measure	**Reporting Period for Public Display**
Assessment-based Measures	
Percent of Residents or Patients with Pressure Ulcers that Are New or Worsened (Short Stay) (NQF #0678)	4 rolling quarters beginning with data collected for discharges in 2017
Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP	
Claims-based Measures	
Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP	3 years of claims data: 2015- 2017
Discharge to Community— (PAC) HH QRP	2 years of claims data: 2016- 2017
Medicare Spending Per Beneficiary (PAC) HH QRP	2 years of claims data: 2016- 2017 (newly finalized)

H. Impact Analysis of HH QRP

The removal of five OASIS-based measures from the HH QRP is estimated to reduce the annual burden associated with OASIS data collection by $60 million annually across the 11,623 HHAs that report OASIS data to CMS, or $5,149 per HHA. (Relative to 2016, at a 7 percent discount rate, the estimated annualized savings total $46 million beginning in 2020.)

CMS reports that 1,311 HHAs, about 11 percent of the 11,776 active Medicare-certified HHAs, did not receive the full annual percentage increase for the 2018 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 (83 FR 56559)

Currently, Fee-for-Service (FFS) Medicare covers home infusion therapy services delivered under the durable medical equipment component of Part B (Part B-DME). However, significant changes in home infusion therapy services payment will occur beginning January 1, 2019, as a result of section 50401 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123, BBA 2018). BBA 2018 added a distinct "temporary transitional payment" for home infusion therapy-related professional services for 2019 and 2020. Beginning January 1, 2021, major benefit design, coverage, and payment changes will be implemented in accordance with Section 5012 of the 21st Century Cures Act (Pub. L. 114-255, Cures Act); the Cures Act created a separate Part B home infusion therapy services benefit for 2021 and subsequent years. Cures Act provisions address practitioner involvement, professional service details, standards for accrediting suppliers, designation of accrediting organizations, and payment parameters. CMS is finalizing proposals related to implementing both the temporary transitional payment and the new Part B home infusion therapy services benefit. While CMS aligns the two sets of changes where possible, some regulations are specific to only one set. The more extensive, permanent, Cures Act changes are described first and in more detail in the preamble, followed by aspects of the temporary transitional payment.

CMS asserts that home infusion therapy delivery includes several components regardless of the benefit under which the services are covered: the drug itself, drug delivery equipment and supplies (e.g., infusion pump, tubing), and related professional services.[30] Currently, the Part B-DME benefit covers only certain diseases and drugs delivered through specified external infusion pumps. The Part B-DME supplier also is expected to provide limited professional services that are not separately reimbursed (i.e., training in handling the drug and using the pump). Some suppliers choose to provide additional professional services (e.g., catheter care, patient assessment) for which there also is no separate reimbursement. Both the temporary transitional payment and the new home infusion therapy services benefit expand the professional services that must be delivered to beneficiaries receiving home infusion therapy services. Under both the

[30] In this summary section, "drug" includes both drugs and biologicals.

temporary payment and permanent new benefit approaches, the Part B-DME benefit will continue to provide coverage for the home infusion drug, equipment, and supplies.

B. Health and Safety Standards for Home Infusion Therapy Services

1. Background

Accreditation of home infusion therapy suppliers under Part B heretofore has been indirect, done as part of the overall accreditation by Medicare-approved accrediting organizations (AOs) for home health agencies (HHA).[31] The Cures Act requires the Secretary to designate AOs no later than January 1, 2021 that will directly accredit suppliers to provide infusion therapy services under the new FFS Medicare benefit. Before setting specific home infusion standards, CMS reviewed related professional publications as well as the standards of other payers and of six existing AOs, including five with Medicare-approved, home health-based, infusion therapy services accreditation programs.[32] Standards from two more AOs were not identified by CMS in time for review; neither accredit HHAs.[33] CMS concluded that standards for core content areas (e.g., infection control) were very similar across the AOs reviewed and would suffice to protect Medicare beneficiaries. CMS, therefore, proposed only those new standards required in statute.

2. Health and Safety Requirements for Suppliers of Home Infusion Therapy Services: (42 CFR part 486, Subpart I)

CMS proposed to add requirements for suppliers of the new Part B home infusion therapy services benefit. Assessing compliance with these requirements, if finalized, would be a required function of any AO that achieves designation by the Secretary to accredit home infusion therapy suppliers who seek to provide the new infusion services benefit. A qualified home infusion therapy supplier would be required to:

- Be accredited by an AO designated by the Secretary;
- Furnish infusion therapy services to individuals with acute or chronic conditions on a 7-day-a-week, 24-hour-a-day basis;
- Ensure that each patient is under the care of an applicable provider (physician, nurse practitioner, physician assistant) and has a plan of care established by a physician;
  - The plan must prescribe in detail the home infusion therapy services to be furnished;
  - The plan must be periodically reviewed by the physician (CMS did not propose a specific timeline for review); and
- Consistent with the care plan, a qualified home infusion therapy supplier will provide professional services (including nursing); patient training and education (beyond the minimum drug and pump training provided by the Part B-DME supplier); and remote monitoring and monitoring services.

[31] Additional AOs have accreditation programs, that are not Medicare-approved, that function outside of the Medicare home health accreditation process.
[32] Those six AOs are The Joint Commission, Accreditation Commission for Health Care, Compliance Team, Community Health Accreditation Partner, Healthcare Quality Association on Accreditation, and National Association of Boards of Pharmacy.
[33] The two additional AOs are The Centers for Pharmacy Practice Accreditation and URAC.

Direct monitoring occurs during home visits for professional services delivery (e.g., vital signs). Remote monitoring can be performed via multiple communication methods guided by patient preferences (e.g., telephone, electronic mail), provided beneficiary privacy and security are protected.

Some commenters addressed the plan of care review timeline, suggesting alignment with existing State laws to avoid duplication, or every 30 days. CMS agreed that duplication should be avoided and declined to further specify review timelines. Some commenters asked that certain pharmaceutical standards (e.g., FDA-enforced sterile compounding and dispensing) be added to the proposed standards. CMS agrees that all home infusion therapy services should be provided in accordance with national professional practice standards. CMS addresses this issue by modifying proposed §486.525 to require that all home infusion therapy suppliers provide services in accordance with nationally recognized standards and with all applicable state and federal laws and regulations (e.g., Federal Food, Drug, and Cosmetic Act). Other commenters suggested an expanded list of professional services; CMS disagrees with expansion, having specifically proposed language mirroring that of the statute. CMS finalizes the health and safety regulations as proposed, with the modification to specify at §486.525(b) that suppliers will provide home infusion therapy services in keeping with national standards and applicable laws and regulations.

C. Accrediting Organization Applications, Standards, and Oversight (83 FR 56563)

1. AO Application Process and Requirements

To begin the Medicare-approved home infusion therapy services AO designation process, CMS proposed to publish a notice in the Federal Register, after publication of the CY 2019 HHPPS final rule, inviting AOs that are "national in scope" to submit their applications. CMS proposed that each AO's application would describe an accreditation program that is separate from that AO's home health accreditation program (i.e., has distinct survey processes and standards for home infusion therapy suppliers); would meet all application content requirements as proposed in §488.1010 (83 FR 32516 to 32518); and would include supplier requirements that are at least as stringent as Medicare's requirements in §486.500 through §486.525 (83 FR 32514-32515). Besides the AO's application contents, the Secretary is statutorily directed when making AO designation decisions to consider the AO's capacity for timely review of supplier applications; the AO's ability to take into account rural supplier issues; and the reasonableness of the AO's fees for suppliers seeking accreditation. The Secretary is given discretion to determine other factors for use in designation decision-making.

CMS proposed that continued infusion therapy payments (e.g., Part B-DME) to existing suppliers would be contingent upon their current AOs (Medicare-approved home-health AOs) submitting applications to become Medicare-approved home infusion therapy services AOs (i.e., no grandfathering of AOs). Proposed AO application processing would include:

- Assignment to a CMS technical review team to assess completeness.

- A 30-day public comment period on the application, announced by a CMS notice published in the Federal Register.
- Review completion within 210 days of application receipt.
- Final decision publication in the Federal Register, specifying reasons for any denial.

CMS finalizes the proposed application processing provisions without modification after receiving no specific comments (§488.1010(d)). Numerous comments were received addressing more general issues.

Operational. Some questioned the use of HHA rules to address the substantial home infusion therapy changes proposed; CMS notes that current Medicare approval of home infusion suppliers is linked to Medicare-approved Home Health AOs. Questions were raised about operational timelines; CMS clarifies that payment to suppliers for the new Part B home infusion therapy services benefit will become contingent on accreditation on January 1, 2021 and notes that AO applications will be accepted as soon as the Federal Register invitation to potential AOs is published. CMS emphasizes that the proposed accreditation process is applicable to the new Part B home infusion therapy services benefit and is not intended to apply to the temporary transitional payment, whose suppliers will continue to be pharmacies providing home infusion therapy under accreditation from currently existing (Medicare-approved home health) AOs.

AO Designation Eligibility. Multiple comments and questions addressed the eligibility of existing AOs to become home infusion therapy services AOs. Several commenters contended that the five Medicare-approved home health AOs who currently accredit home health suppliers should be automatically designated as Medicare-approved home infusion therapy services AOs ("grandfathered"), allowed to continue comingled home health and home infusion accreditation programs, and not be required to go through the infusion therapy AO application process. These commenters asserted that not providing for grandfathering would be disruptive to patient care. They also urged CMS not to consider an application from a specific AO, a request that CMS declines; CMS notes that this AO belongs to the putative "grandfather" group. Some commenters stated that grandfathering is necessary as CMS has delayed proposing the home infusion therapy services regulations so that statutory deadlines cannot otherwise be met.

CMS provides multiple detailed responses (83 FR 56565 through 56567). Ultimately, CMS asserts that any national AO may apply if the AO (1) provides home infusion supplier accreditation through a distinct program (i.e., separate from HHA-linked programs); (2) have health and safety standards meeting or exceeding those finalized above (e.g., plan of care compliance); and (3) agrees to accredit only those suppliers that provide all services required by the health and safety standards regulations. CMS closes by noting that those AOs seeking grandfathering have stated that their accreditation programs already meet or exceed the proposed infusion AO standards, which should allow the existing AOs to rapidly complete their applications by transferring information from their current AO program documents to the infusion AO application form. CMS finalizes the proposals describing the application process and requirements without modifications.

Finally, CMS addresses a comment about accreditation transferability. Commenters opined that Congress intended for CMS to accept existing AO accreditation of suppliers as being

sufficient as of January 1, 2019 when the temporary transitional payments begin. They interpreted section 1834(u)(5)(D) of the Act to require CMS to deem any home infusion supplier already accredited by a home infusion therapy AO designated (or otherwise recognized and accepted) by CMS prior to January 1, 2019, to be deemed accredited through January 1, 2023. CMS agrees but emphasizes that this provision applies only to those AOs that are ultimately approved by CMS as home infusion AOs; the eight AOs currently providing HHA-linked accreditation receive no special consideration.

2. Establishing Regulations (42 CFR 488 Subpart L)

Applicability of Pre-existing Regulations. To implement a comprehensive, consistent set of regulations specific to home infusion therapy AOs, CMS proposed to add 42 CFR 488 Subpart L covering AO oversight and approval. CMS had considered using pre-existing regulations dealing generally with survey and certification procedures (§488.1 through 488.13), but found that multiple sections were not applicable to home infusion therapy AOs and suppliers. CMS received no comments and proceeds with adding Subpart L.

Validation Survey Process. CMS also considered proposing a formal validation (follow-up) survey process to the multiple provisions of Subpart L that deal with AO surveys of suppliers, but ultimately chose not to do so. An important concern was that small sample sizes (i.e., the limited number of home infusion therapy suppliers) could impair the validity and generalizability of the survey data. CMS concludes by stating that required data submission by AOs finalized under Subpart L will support ongoing AO performance monitoring.[34]

3. Specific Regulations: Subpart L—Accreditation of Home Infusion Therapy Suppliers

Definitions are provided at §488.1005. The regulations address AO application and reapplication procedures, ongoing oversight of approved AOs, and procedures for termination and appeals. CMS provides a detailed sequential discussion of the proposed regulations (83 FR 56570-56579) from which illustrative examples and summary comments are extracted below.

(a) AO Application and Reapplication Procedures (§488.1010)

As proposed, §488.1010(a) lists the information to be submitted with the AO application. Examples include: material documenting the AO's ability to take into account the capacities of rural home infusion therapy suppliers; a table that crosswalks each Medicare health and safety requirement (e.g., plan of care compliance) to the exact language of the AO's comparable requirements and standards; a detailed description of the AO's survey process; surveyor conflict of interest management policies; and procedures for addressing disputes about survey findings filed by suppliers. Proposed §488.1010(b) through (d) require the AO to agree to submit additional information as requested by CMS; allow for voluntary AO application withdrawal up until a final accreditation decision is published in the Federal Register; and require application review to be completed by CMS within 210 days after submission.

[34] Required information includes all accreditation decisions, all complaints against the AO's accredited suppliers, all remedial or adverse actions taken by AOs against suppliers, and CMS-specified annual summary data.

Multiple commenters, including home infusion therapy suppliers, raised general concerns about the time and cost burden for AOs to obtain initial CMS approval and the added time and cost burden after receiving approval for ongoing administration. CMS responds that the burden is necessary to comply with statutory requirements for an AO designation process. Commenters raised a specific concern that a 90-day notice from an AO to its accredited suppliers of the AO's planned voluntary withdrawal as an accreditor is too short to allow an otherwise compliant supplier to secure accreditation from a different CMS-approved home infusion therapy AO. CMS agrees with commenters and adopts their suggestion for a 180-day notice. CMS finalizes §488.1010(a) through (d) with the modification (at §488.1010(a)(23)(i) to extend the notice period for AO notification of suppliers about voluntary AO withdrawal as an accreditor plus a conforming change at §488.1045(a).

(b) Resubmitting a Request (§488.1015)

CMS received no comments and finalizes as proposed that an AO may resubmit its application after denial or after voluntary withdrawal providing the AO had (1) addressed the issues leading to denial or voluntary withdrawal; and (2) resubmitted the application in its entirety.

(c) Public Notice and Comment (§488.1020)

CMS received no comments and finalizes as proposed to publish a notice in the Federal Register upon receipt of a complete AO application package and upon reaching a final accreditation decision. The latter notice will specify the basis for CMS' decision.

(d) Release and Use of Accreditation Surveys (§488.1025)

CMS received no comments about the provisions of this section. CMS finalizes as proposed that in the AO agreement with each accredited supplier, the supplier acknowledges that the AO may release to CMS a copy of the supplier's most current accreditation survey and any related materials including corrective action plans. Also finalized is a provision allowing CMS to deny supplier accreditation based on the agency's review of the survey materials, independent of the AO's accreditation decision. Lastly finalized is a prohibition on CMS from disclosing home infusion therapy survey reports or survey related information.[35]

(e) Ongoing CMS Oversight of Approved AOs (§488.1030)

CMS proposed standardized requirements to support consistent and ongoing review of Medicare-approved AOs and their home infusion therapy accreditation programs. CMS proposed to conduct three types of reviews of AOs.

- Performance review: targets AO survey activity and Subpart L requirements and conducted as part of routine, ongoing CMS oversight of AOs.

[35] CMS would be permitted to publicly disclose an accreditation survey and related information, upon written request, to the extent that the accreditation survey and survey information is related to a CMS enforcement action.

- Comparability review: targets comparison of AO standards with Medicare requirements to assure AO standards meet or exceed Medicare requirements, triggered by changes in Medicare requirements or AO standards.
- CMS-approved accreditation program review: opened when substantial noncompliance is suspected or demonstrated by a performance or comparability review.

CMS Standards Changes. CMS would provide written notice of Medicare requirement changes to approved AOs which then would have at least 30 days to review their standards for equivalency and to submit any needed changes for CMS approval.[36] Once revised AO standards were received by CMS, comparability would be determined within 60 days of receipt and conveyed to the AO.[37] An AO failing to respond to the initial CMS notice or failing to implement CMS-approved revisions could be subject to an accreditation program review.

AO Initiated Standards Changes. CMS proposed that an approved AO desiring to change its standards or survey process would notify CMS at least 60 days before scheduled implementation and the AO would be prohibited from implementation without first receiving CMS approval. Implementation without approval could lead to an accreditation program review. The AO's revised standards proposal would be required to include a crosswalk between their revised standards and current Medicare requirements (facilitating comparability review). CMS would send a comparability decision to the AO within 60 days of receiving their proposed standards revisions and reasons for any denial would be required.[38] AO implementation of standards determined not to be comparable by CMS could trigger an accreditation program review.

CMS-approved Accreditation Program Review. When evidence is found of substantial noncompliance by an AO with Medicare requirements, CMS proposed to initiate an accreditation program review and so notify the AO; contents of the notice are specified at §488.1030(d). An AO generally would be permitted to submit a corrective action plan to be implemented during a program review probationary period of 180 days or less from action plan submission. CMS would complete corrective action plan review within 30 days of receipt. CMS proposed to allow extension of the probationary period for up to another 180 days or the AO's approval expiration date whichever is earlier. Within 60 days after probation ends, CMS would inform the AO whether or not it has returned to approved status. Should CMS elect to rescind AO approval, the AO would be notified and a notice published in the Federal Register. CMS proposed to immediately revoke approval if continued approval places beneficiaries in immediate jeopardy or is hazardous to public health.

Several commenters asked for clarification that the non-compliance that triggers a CMS-approved program accreditation review under §488.1030 must not only be "substantial" but also be "material." CMS responds that the two words are so similar that to include both in regulation text would be duplicative. Further, CMS notes that other Medicare AO approval program processes do not use both substantial and material in their descriptions, and that new language

[36] The initial response period must be specified in the notice by CMS and may be 30 days or greater. Before the original deadline expires, an AO may request an extension.
[37] If comparability results are not provided to the AO within 60 days, the AO's revisions would be deemed comparable and AO approval would continue.
[38] No response by CMS within 60 days would trigger deemed approval of the AO's proposed revisions.

used solely for the home infusion therapy AO accreditation program would introduce undesirable inconsistency for CMS, AOs, and suppliers. CMS declines to revise the terminology of §488.1030 to substantial and material from the proposed substantial. No other comments were received on this section and CMS finalizes the entire section as proposed without modifications.

(f) Ongoing Responsibilities of a CMS-approved AO (§488.1035) and Onsite AO Operations Observation (§488.1040)

CMS proposed that approved AOs have corresponding ongoing responsibilities, primarily related to providing routinely required or specifically requested information to CMS and to responding timely to CMS notices. CMS also proposed that the agency be permitted to conduct an onsite inspection of AO offices and operations at any time as part of ongoing oversight. Reasons for such visits would be limited (e.g., during a probationary period, for assuring the accreditation program is fully implemented), and the AO must be notified of the planned visit. No comments were received and CMS finalizes the regulations as proposed without modifications.

(g) Termination and Appeal (§488.1045)

AO Termination. CMS proposed that when an approved AO voluntarily terminates its accreditation program, written notice must be provided to CMS and to each of the AO's accredited home infusion therapy suppliers at least 180 days in advance of the termination date. A second notice to suppliers would be required 10 days prior to the termination date. The notices to suppliers must describe the implications for supplier payments if the supplier's accreditation were to lapse. For involuntarily termination by CMS of an AO's accreditation program, CMS proposed that the AO be required to notify all of its suppliers within 30 days of publication of the termination notice in the Federal Register. The AO would also be required to inform the suppliers about implications for supplier payments if the supplier's accreditation were to lapse. For both voluntary and involuntary AO terminations, CMS proposed that the AO's suppliers would retain their accreditation status until their scheduled expiration dates. To continue Medicare reimbursement, a supplier accredited by a terminated AO would be required to apply for accreditation from another AO at least 60 days before the supplier's accreditation expires; the supplier must notify CMS of its new accreditation application.

Voluntary Supplier Withdrawal. CMS proposed that an approved AO would be required to complete three steps before an accredited supplier's request for withdrawal of accreditation would become effective.

(1) The AO would be required to directly contact the supplier for written confirmation of the supplier's request to withdraw from the AO's accreditation program.
(2) The AO would be required to provide written notice to the supplier of the statutory requirement for accreditation of Medicare home infusion therapy services suppliers and the payment consequences of lapsed accreditation.
(3) The AO would be required to submit a final notice of supplier withdrawal from accreditation to CMS within five days after the withdrawal becomes effective.

Concern was expressed by a commenter that the three steps required of an AO before an accredited supplier's request to the AO for withdrawal of accreditation would become effective

would be extremely burdensome for the AO. The commenter believed that the supplier would be responsible for already knowing the applicable CMS regulations. CMS disagrees that the three-step process is excessively burdensome, particularly in light of readily available electronic office technology and methods of communication (e.g., templated letters and reply forms, electronic mail). Several commenters expressed concern that the initial notice from a terminated AO could fail to reach or be overlooked by one of the AO's suppliers, leading the supplier to miss the deadline by which the supplier must notify CMS of the supplier's application submission to a new AO. The commenters requested that CMS shorten the deadline for suppliers by which they must inform CMS of their replacement AO application from 60 days to 5 days. CMS reviews the timelines and information-sharing options in detail, concluding it to be unlikely that a supplier would not learn of its AO's impending withdrawal for a prolonged period, thereby encroaching on the time available to the supplier to apply to a new AO and inform CMS of the new AO application (and potentially lead to a supplier lapse in accreditation with loss of payments). For example, the supplier's accreditation date would not be changed by the original AO's withdrawal, and CMS would announce the AO's upcoming withdrawal through multiple channels, not just the Federal Register notice (e.g., Medicare Learning Network newsletter). CMS declines to adopt the commenters' request to shorten the period by which the supplier would be required to notify CMS of its application to a new AO. All provisions of §488.1045 are finalized without modification.

Reconsideration. CMS proposed a process by which an AO could appeal an unfavorable decision from CMS (e.g., application denial). The AO would be required to submit a reconsideration request with details of the dispute within 30 days of being notified of the adverse effect by CMS. CMS would provide an administrative hearing opportunity and notify the AO of hearing details 10 or more days in advance. More process details are provided at §488.1050. Notably the hearing officer could not issue subpoenas and would be required to produce a written report of findings and recommendations within 45 days after the hearing ends. The hearing officer's decision is final. CMS received no comments and finalizes the provisions at §488.1050 as proposed.

D. Payment for Home Infusion Therapy (83 FR 56579)

1. Temporary Transitional Payment CYs 2019 and 2020 (BBA 2018)

a. Background

Section 50401 of the BBA 2018 established a home infusion therapy services temporary transitional payment for professional services (including skilled nursing), training and education, remote monitoring, and monitoring services furnished in coordination with transitional home infusion drug administration. The temporary transitional payment becomes effective on January 1, 2019 and remains in effect until succeeded by the FFS Medicare Cures Act home infusion therapy services benefit payment on January 1, 2021. The temporary transitional payment is made to an "eligible home infusion supplier" separately from the Part B-DME benefit payment for an external infusion pump, supplies, and the home infusion drug.

b. Definitions to Operationalize the Temporary Transitional Payment

Drugs covered under the temporary transitional benefit are termed transitional home infusion drugs. As provided in statute:

- Transitional home infusion drugs include those covered under the Local Coverage Determinations (LCDs) for External Infusion pumps.
- Also included are subsequent drug additions to the LCDs and compounded infusion drugs not otherwise classified (J codes J7799 and J7999).
- The drug(s) is administered to an individual under a physician-ordered plan of care and who is under the care of an applicable provider (physician, physician assistant, nurse practitioner).

Eligible home infusion supplier is defined in the statute as a pharmacy enrolled in Medicare Part B that provides external infusion pumps and external infusion pump supplies, and that maintains all pharmacy licensure requirements in the state where the infusion drugs are being administered. Current Part B-DME home infusion suppliers will qualify as eligible home infusion suppliers (absent events such as loss of licensure).

CMS proposed to define an infusion drug administration calendar day as a date of service on which professional services are furnished to administer a home infusion drug(s) to an individual in the home. CMS adapted statutory language to propose that for purposes of the temporary transitional payment, the home infusion drug(s) administered would have to be a transitional home infusion drug(s). Further, where services begin on one calendar day and continue into to the next, the drug administration calendar day would be that on which the home visit to provide home infusion therapy professional services ends. A date on which home infusion drug therapy professional services are furnished but a drug(s) is not administered would not be an infusion drug administration calendar day. Thus, an infusion drug administration calendar day requires both that a drug be administered and that professional services (typically skilled nursing) are provided in the home on the date for which payment would be provided.

Many commenters disagreed with the proposed definition of an infusion drug administration calendar day. Objections offered included: violation of Congressional intent; coverage of only a small fraction of home infusion services actually delivered; impairing access to home infusion therapy; and supporting inefficient care by mandating unnecessary skilled nursing visits. CMS disagrees with the objections and offers a detailed analysis of the statutory language in support of the drug calendar day definition. CMS also emphasizes the temporary transitional payment is a new, separate amount paid in addition to the linked Part B-DME benefit covering the drug and equipment and does not preclude home health services being performed on the drug calendar day. CMS states home infusion service data (Medicare and other payers) suggest that home infusion therapy services are most often furnished twice weekly for the first week then weekly thereafter throughout the remainder of the course of therapy. CMS also notes that each drug calendar day will trigger both a 21 percent coinsurance payment (for the temporary transitional payment) and a 20 percent copayment for the Part B-DME payment to the beneficiary. CMS also notes not anticipating provider behavioral changes (i.e., increased visit frequency to trigger a drug administration day and associated payment). The full discussion is available at 83 FR 56580-56583. CMS concludes by finalizing without modification the proposed definition of

infusion drug administration calendar day. However, CMS includes a statement of concern and of intent to ensure access to home infusion therapy services as provided for by BBA 2018. **Also, CMS seeks comment on the statutory interpretations that underpin the finalized definition of an infusion drug administration calendar day; the comment period ends on December 31, 2018.**

c. Temporary Transitional Payment Categories and Payment Amounts

Three payment categories and the assignments of specific drugs to each category as well as the temporary transitional payment levels are defined in statute. Therefore, these aspects of the temporary transitional payment are not changed from the proposed rule and are not recapitulated in the final rule. The payment categories and some examples of drugs in each category are shown below, adapted from the proposed rule.

Home Infusion Therapy Services Transitional Payment Payments by Category (Modified from Proposed Rule Table 56)		
HCPCS Code	**Description**	**Units (#)**
Category 1		
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	1
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour	3
Category 2		
96369	Subcutaneous infusion, for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)	1
96370	Subcutaneous infusion, for therapy or prophylaxis (specify substance or drug); each additional hour	3
Category 3		
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	1
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	3

Transitional Home Infusion Drug J-codes and Therapy Services Payment Categories (Modified from Proposed Rule Table 55)	
J-code	**Category 1 Drug***
J0133	acyclovir
J0285, J0287, J0288, J0289	amphotericin B
J1250	dobutamine hydrochloride
J1325	epoprostenol
J2270, J2274	morphine sulfate
J code	**Category 2****
J1555 JB	cuvitru

Transitional Home Infusion Drug J-codes and Therapy Services Payment Categories (Modified from Proposed Rule Table 55)	
J1559 JB	hizentra
J code	**Category 3*** **
J9039	blinatumomab
J9190	fluorouracil
J9370	vincristine sulfate

* Includes antifungals and antiviral drugs, uninterrupted long-term infusions, pain management, inotropic, and chelation drugs

** Includes subcutaneous immunotherapy infusions

*** Includes certain chemotherapy agents

2. Responses to Solicitation of Public Comments Regarding Payment for Home Infusion Therapy Services for CY 2021 and Subsequent Years

CMS notes having solicited public comments in the proposed rule pertaining to multiple aspects of implementation of the separate Medicare benefit category and payment created by the Cures Act (e.g., approaches to capturing patient acuity, prior authorization, and the propriety of an outlier payment). The benefit is effective January 1, 2021. CMS specifically requested comments on whether the definition of "infusion drug administration calendar day", as proposed (and now finalized) for use with the temporary transitional payment for home infusion therapy professional services created by BBA 2018, should be retained for use with the Cures Act benefit.

Several commenters were concerned about retaining the definition of "infusion drug administration calendar day" for use with the Cures Act's home infusion therapy services benefit. CMS notes that the BBA 2018 language regarding infusion drug administration calendar day includes terms also used in the Cures Act description of the home infusion therapy services benefit (e.g., "home infusion drugs" and "qualified home infusion therapy supplier"). CMS does not state if or how the term infusion drug administration calendar day will be applied to the Cures Act home infusion therapy services benefit beginning January 1, 2021. CMS states having received suggestions on multiple aspects of the Cures Act benefit implementation, including billing, payment basis and adjustments, prior authorization, and the relationship between the home infusion and home health benefits; this input will be considered as CMS moves forward with policies for 2021. CMS finishes with some additional thoughts as follows: (1) the Cures Act provisions about covered drugs are far less prescriptive than the BBA 2018 provisions, so that the full list of covered infusions under the new benefit has not yet been fully decided; and (2) CMS convened a Technical Expert Panel in August 2018, at which the panelists concurred that some patients are in fact not candidates for home infusion therapy, even though initially thought to be so by the physician prescribing the infusion. CMS further notes that some patients (in conjunction with their associated caregivers) may not be trainable or may be unwilling to assume any degree of independence related to home infusion therapy. Infusion therapy can be provided in several other settings (and is covered there to various degrees by FFS Medicare); such patients are better served by receiving infusions in sites other than their homes.

VII. Changes to the Accreditation Requirements for Certain Medicare-Certified Providers and Suppliers

CMS accepts accreditation of a provider/supplier by a Medicare-approved accrediting organization (AO) as evidence that the provider/supplier is in "substantial compliance" with applicable statutes and regulations and thereby eligible to care for beneficiaries and to receive payment from Medicare. CMS proposed two changes to regulations governing Medicare-approved AOs (§488.5).

- As part of the AO application to CMS for approval or re-approval, the AO would include a written statement agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the AO's CMS-approved accreditation program, the AO must continue the facility's current accreditation until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.
- Surveyors from all Medicare-approved AOs would be required to complete the relevant program-specific CMS online trainings consistent with requirements established by CMS for state agency surveyors, in addition to any other training completed by the surveyors.

CMS proposed the first change upon receiving multiple provider/supplier complaints about premature termination of accreditation by their AOs after the provider/supplier notifies the AO of the provider/supplier's planned withdrawal from the AO's accreditation program. Multiple commenters expressed support for this change. A few were opposed, stating that the change would undermine the AO's autonomy to enforce their own policies or would circumvent the AO's termination policies and procedures. CMS disagrees, asserting that if an accredited provider or supplier has paid the agreed upon accreditation fees, successfully gone through the survey process, and is in good standing with their AO, but has, for whatever reason, decided to switch accreditation to another AO or to submit to a survey by a state agency, there is no justifiable reason for the current AO to cancel that provider/supplier's accreditation prior to the expiration date. CMS finalizes the proposal without modification (see §488.5(a)(17)(iii)).

The second change was proposed by CMS as a strategy intended to reduce the disparity rate between surveys conducted by AOs and validation surveys (performed within the next 60 days or less) by a state agency surveyor by standardizing education across surveyors. CMS received many comments opposing the addition of this requirement, including:

- No proven linkage between surveyor training and disparity rate,
- Proposal too vague, lacking operational detail (e.g., required training duration),
- Proposal is ambiguous and will increase training variation among surveyors,
- Other variables contribute to disparity rate (e.g., duration of survey, number and composition of survey team),
- Issue better addressed during CMS review of AO performance,
- State surveyor lacks depth of experience relative to provider type surveyed,
- Multiple citations for the same deficiencies during a single visit by state but not AO surveyors, leading to disparate total citation numbers
- No appeal process for AO after validation survey results released, and
- Added burden of additional training and of documenting training.

CMS agrees that the proposal lacked operational detail and that evidence clearly linking surveyor training to disparity rates is lacking. CMS does not finalize the proposal to require AO surveyors to complete CMS online surveyor training.

VIII. RFIs on Promoting Interoperability and Price Transparency

In the proposed rule CMS made two requests for information (RFIs). One RFI was on the topic of promoting electronic interoperability; the other was on price transparency. CMS says it received 28 and 15 timely responses to these RFIs, respectively. The responses received are not described in the final rule.

IX. Regulatory Impact Analysis

CMS provides a regulatory impact analysis (RIA) because this final rule is a major rule that meets the threshold of an economic impact of $100 million or greater. Some portions of the analysis (e.g., HHVBP, home infusion therapy) are discussed in the earlier sections of this summary, as are relevant collection of information requirements. The overall impact of the changes in the HH PPS system on HHAs in 2019 is summarized here.

Summary of overall regulatory impact analysis		
Policy	**2019 impact**	
	Percentage	**Dollars**
HH PPS update	+ 2.2%	+$420 million
Decrease of FDL ratio	+0.1%	+$20 million
New rural add-on provision	-0.1%	- $20 million
Net impact	+2.2%	+$420 million

CMS estimates that the net impact of the HH PPS policies in this rule is an increase of 2.2 percent, or $420 million, in Medicare payments to HHAs for 2019. This estimate does not take into account the approximately $60 million in additional payments ($48 million from Medicare and $12 million from beneficiaries) to home infusion suppliers in 2019 from the temporary transitional payments to eligible home infusion suppliers for items and services associated with the furnishing of transitional home infusion drugs. It also does not take into account the reduction in payments to HHAs resulting from the HHVBP model—the overall impact of this model is an estimated $378 million in savings over five years (2018 -2022) from reduction in unnecessary hospitalizations and SNF usage.

Table 44 in the final rule provides details on the impact of each change 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 2019 wage index and revised labor share, case-mix weights, the new rural add-on payment provisions, and the effects of the revised FDL ratio used to calculate outlier payments. Proprietary free-standing HHAs (almost 80 percent of all agencies) would experience an average increase of payments of 2.3 percent. Government-based HHAs would experience a 2.8 percent increase. HHAs located in the New England region would experience the smallest

increase in payments of 1.4 percent compared with a 3.0 percent increase for HHAs located in the West South Central.

Table 45 in the final rule provides details on the impact of the PDGM on HHAs in 2020 by facility type and ownership, by rural and urban area, by census region and by the number of HHA first episodes. The PDGM is implemented in a budget neutral manner, but the effect of the PDGM varies by specific types of providers and location. Proprietary free-standing HHAs would experience a reduction in payments of -0.9 percent, on average. Voluntary/nonprofit free-standing HHAs are expected to average a 1.8 percent increase and government-based HHAs are expected to experience a 0.6 percent increase. Rural HHAs are expected to receive 3.8 percent increase compared with a -0.6 decrease in payment for urban HHAs. Smaller HHAs (<100 episodes) are expected to fare better, a 2.4 percent increase, compared with a reduction in payments for larger agencies (1,000 or more) of 0.4 percent.

Table 46 in the final rule provides additional information on how the PDGM impact HHAs' payments in 2020 for patients with selected clinical conditions. The table shows the ratio of average PDGM payment to average current (30-day equivalent) payment. For instance, for patients categorized as behavioral health, HHAs under the PGPM would receive 85 percent (ratio of 0.85) of what they currently receive. In contrast, for patients categorized as having wounds HHAs would receive 25 percent more (ratio of 1.25) under the PGPM model, on average, compared with what they currently receive.