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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-P)

Summary of Proposed Rule

On July 2, 2018, the Centers for Medicare & Medicaid Services (CMS) placed on public display a calendar year proposed rule addressing the 2019 Home Health Prospective Payment System rate update;[1] 2020 case-mix adjustment methodology refinements, the Home Health Value-Based Purchasing model, home health quality reporting requirements, and other items. Page references given in this summary are to this published document, which is available 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

Comments on the proposed rule are due by August 31, 2018.

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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 proposes to update the national standardized 60-day episode rate with a market basket increase of 2.8 percent, reduced by a 0.7 percent productivity adjustment, for a 2.1 percent update for home health agencies (HHAs) submitting quality data and 0.1 percent for those that do not submit such data. CMS would update the 2019 home health wage index using fiscal year (FY) 2015 hospital cost report data. CMS develops a proposal to implement the new rural add-on policy mandated by the Bipartisan Budget Act (BBA) of 2018. 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 proposes to lower the 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. The BBA of 2018 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. CMS proposes for home health services beginning on or after January 1, 2020, to revise its case-mix methodology and payment categories by using its Patient-Driven Groupings Model (PDGM). In the PDGM, CMS proposes refinements to the comorbidity case-mix adjustments; all other variables remain as proposed in the HHGM, proposed in the 2018 HH PPS proposed rule. The case-mix methodology groups home health patients into payment categories using primarily clinical characteristics and other patient information and eliminates therapy service use thresholds that are currently used to case-mix adjust payments. A patient can be grouped into one of 216 payment groups under this proposal – the current system has 153 payment groups.

Home Health Value-Based Purchasing (HHVBP): Two measures would be removed from the HHVBP and three others replaced beginning with performance year (PY) 4 (2019 reporting; payment in 2021). The measures that would be 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 would be replaced with two proposed new composite measures. Changes are also proposed in weighting of measures for calculating the Total Performance Score.

Home Health Quality Reporting Program (HH QRP): The policy for removing previously adopted measures from the HH QRP would be updated to align with other quality reporting programs. In keeping with the Meaningful Measures Initiative, CMS proposes to remove seven measures beginning with the 2021 QRP out of the 31 currently adopted measures. Updates are provided regarding IMPACT Act measures, public display of HH QRP measures and accounting for social risk factors in HH QRP measures. The number of years of data used to calculate the Medicare Spending per Beneficiary measure would be increased from one year to two years.

Medicare Coverage of Home Infusion Therapy Services: CMS proposes to add 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, in anticipation of implementing the new Part B benefit category for home infusion therapy services that was created by the 21st Century Cures Act. Under the statute, suppliers of home infusion therapy must be accredited by a CMS-approved accreditation organization. Requirements for such organizations, the process for CMS approval and ongoing CMS oversight are proposed. Information on temporary transitional payments for home infusion therapy services for 2019 and 2020 as mandated by section 50401 of the BBA of 2018 is provided and comments are solicited on payment for home infusion therapy services for 2021 and subsequent years as required by the 21st Century Cures Act.

Impact: The HH PPS updates are estimated to increase home health payments by a net of $400 million, or 2.1 percent, in 2019—the combined effect of the 2.1 percent update, the new rural add-on provision, and the change in the FDL ratio. This $400 million increase does not take into account approximately $60 million in additional Medicare payments to home infusion suppliers in 2019 from temporary transitional payments. 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 expects an estimated $378 million in savings over five years (2018 -2022) from reduction in unnecessary hospitalizations and 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

[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.

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 decided not to finalize this proposal, but CMS is proposing in this year's rule to implement case-mix methodology refinements (similar to what was proposed last year) including changing the unit of payment from 60 days to 30 days. These changes, however, would be effective January 1, 2020 and would be implemented in a budget neutral manner, as required by section 51001 of the BBA of 2018. CMS is renaming its case-mix methodology refinements and refers to it as the Patient-Driven Groupings Model or PDGM.

This PDGM proposal is discussed in more detail in section III.F of the proposed 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.

CMS' proposals with respect to home infusion therapy services is discussed in more detail in section VI of the proposed rule and this summary.

III. Proposed Provisions: Payment under the Home Health Prospective Payment System

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

CMS reports on its monitoring of the impact of rebasing adjustments finalized in the 2014 HH PPS final rule (See Tables 2-4 and Figures 1-3 on pages 35-41 of display copy). It presents 2016 cost report and 2017 claims data and the rebasing adjustments made to HH PPS payment rates in 2014-2017 do not appear to have resulted in significant HHA closures or otherwise diminished access to home health services.

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[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.

Its preliminary review of 2017 claims data shows that the number of episodes and home health users that received at least one episode of care remained virtually the same from 2016 to 2017. CMS notes that the number of HHAs billing Medicare continues to decline, but that there are still 2.8 HHAs per 10,000 FFS beneficiaries, compared with 1.9 in 2001 when the HH PPS was implemented. The portion of FFS beneficiaries using HH services has declined from 9.0 percent in 2013 to 8.4 percent in 2016.

Longer-term trends in the number of visits per episode are reviewed; they have dropped from 21.7 visits per episode in 2009 to 17.9 visits in 2017, with the most notable decreases occurring in skilled nursing and home health aide services. CMS also reviews trends in episode timing. Currently, the first two 60-day episodes of care are considered "early" and the third or later 60-day episodes are considered "late." CMS finds that the percentages of early episodes with 20+ therapy visits has been trending upward since 2009 while the percentage of late episodes with 20+ therapy visits has been trending downward. CMS also notes that the percentage of overall episodes with 20+ therapy visits increase from 4.6 percent in 2008 to 7.6 percent in 2017.

Finally, CMS reports on trends in episodes by admission source, and finds that the percentage of first or only episodes with a community admission source increased from 37.4 percent in 2008 to 41.5 percent in 2017. CMS notes that MedPAC reviewed data going back to 2002-2013 and found high rates of volume growth for patients residing in the community, and suggested the potential for overuse given the lack of cost sharing for home health care.

CMS states that it will continue to monitor the potential impact of rebasing.

B. Proposed 2019 HH PPS Case-Mix Weights

CMS proposes 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 5-7 on pages 44-49 of display copy). Table 8 (pages 51-54 of display copy) presents the resulting proposed 2019 case-mix payment rates for each of the 153 payment groups.

CMS proposes a case-mix budget neutrality factor of 1.0163 for 2019, 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.

C. 2019 Home Health Payment Rate Update

1. Rebasing and Revising of the Home Health Market Basket

CMS proposes to rebase and revise the home health market basket to reflect 2016 Medicare cost report data (MCR) 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 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 proposes to rebase the detailed wages and salaries and benefits cost-weights to reflect 2016 BLS Occupational Employment Statistics (OES) data on HHAs. In addition, CMS proposes 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 proposes to use data from freestanding HHAs whose cost reporting period began on or after October 1, 2015 and before October 1, 2016. CMS proposes to use the same eight major expense categories that were used in the last 2014 based payment rebasing.

Table 9 in the proposed 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 9 – Major Cost Categories as Derived from the Medicare Cost Reports

Major Cost Categories	**2010 Based**	**Proposed 2016 Based**
Wages and Salaries (including 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 in the cost report for each major expense category in the proposed rule (pages 60-63 of the display copy)

Using the same methodology CMS 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 proposes to use the 2007 Benchmark I-O “Use Tables/Before Redefinitions/Purchaser Values” for NAICS 621600, Home Health Agencies, published by

BEA.[5] CMS proposes to eliminate the stand-alone category for Postage (given its small weight) and include those expenses in the Other Services cost category.

Table 10 in the proposed rule (reproduced below) lists the proposed 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 proposes 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), which measure changes in prices received by domestic producers for their goods and services.

Table 10: Cost Categories, Weights, and Price Proxies in Proposed 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	Proposed Home Health Blended Wages and Salaries Index (2016)
Benefits, including allocated contract services' labor	10.9	Proposed 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

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

Table 10: Cost Categories, Weights, and Price Proxies in Proposed 2016-Based Home Health Market Basket		
Cost Categories	**Weight**	**Price Proxy**
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
Movable Capital	0.6	PPI Commodity data for Machinery and equipment
Total	100.0 *	

*Figures may not sum due to rounding.

CMS proposes 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 on pages 73 of the display copy. The result of these changes, however, does not result in material differences in the calculation of annual growth in the proposed 2016 home health benefits blend compared with the 2019 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) with the exception of a 0.1 percentage point difference in 2019 (see Table 15 in proposed rule).

CMS provides a detailed explanation of the other price proxies it proposes to use on pages 78 of the display copy (show in Table 10 above). All are the same proxies that it used for the 2010-based home health market basket.

Table 16 in the proposed 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 proposed 2016-based home health market basket is 2.8 percent, the same rate of growth as estimated using the 2010-based home health market basket. Other forecast years show a similar increase.

With respect to the labor-related share, CMS proposes to revise the labor-related share to reflect the proposed 2016-based home health market basket compensation (wages and salaries plus benefits) cost weight. Based on the proposed 2016-home health market basket, the labor-related share would be 76.1 percent and the proposed non-labor related share would be 23.9 percent. Using the 2010-based home health market basket, the labor related share would have been 78.5 percent and the non-labor related share would have been 21.5 percent. CMS also proposes to implement this proposed revision in a budget neutral manner.

2. Proposed 2019 Home Health Market Basket Update

CMS reviews the methodology for updating the HH PPS rates and proposes a 2019 update of 2.1 percent (HH market basket increase of 2.8 percent less 0.7 multifactor productivity (MFP)

adjustment).[6] The 2019 proposed update is based on IHS Global Insight Inc.'s (IGI) first quarter 2018 forecast.

HH market basket increase:	2.8 percent.
Multi-factor productivity (MFP) adjustment:	-0.7 percent
MFP adjusted HHA market basket update:	2.1 percent

The 2.1 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:	2.1 percent
For HHAs not reporting the required quality data:	0.1 percent

3. Proposed 2019 Home Health Wage Index

CMS proposes to continue to use the pre-floor, pre-reclassified hospital wage index as the wage index to adjust the labor portion of HH PPS rates. For 2019, CMS would 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 (MSAs) and the creation of Micropolitan Statistical Areas, and Core-based Statistical Areas (CBSAs).[7] The proposed 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-Items/CMS-1689-P.html

4. Proposed 2019 Payment Update

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

- A wage index budget neutrality adjustment of 0.9991 would apply to the standardized episode payment rate, which is computed by dividing total payments for non-LUPA episodes using the proposed 2019 wage index by the total payments for such episodes using the 2018 wage index.
- A wage index budget neutrality adjustment of 1.0000 would apply to national per visit payments for LUPA episodes, computed by dividing total payments for LUPA episodes using the proposed 2019 wage index by the total payments for such episodes using the 2018 wage index.

[6] Section 1895(b)(3)(B)(vi) of the Act required 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.

[7] 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.

The methodology and payment amounts for the national standardized 60-day episode payment and the national per visit amounts for HHAs submitting and not submitting quality data are reviewed. See Tables 18-25 on pages 89-94 in the display copy for details on the updates; below is a summary of the proposed calculations.

Proposed 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
Proposed National standardized amount (Tables 18,19)		
2018 amount	$3,039.64	
Wage index budget neutrality factor	x 0.9991	
Case-mix budget neutrality factor	x 1.0163	
HH payment update percentage	x 1.021	x 1.001
Proposed 2019 payment amount	**$3,151.22**	**$3,089.49**

Computations are presented for the LUPA and the proposed 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 proposed per-visit amounts for those HHAs submitting the required quality data are as follows:

Proposed 2019 National, Per-Visit Amounts for HHAs that do Submit Quality Data (see CMS Table 20)						
	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	1.0000					
Payment update	1.021					
Proposed 2019 per visit rates	**$66.30**	**$234.69**	**$161.14**	**$160.05**	**$146.41**	**$173.96**

As with the payments for a 60-day episode of care, HHAs that do not submit required quality data would have the payment update for per-visit services reduced from 2.1 percent to 0.1 percent (see Table 21), resulting in the following payment rates.

Proposed 2019 National, Per-Visit Amounts for HHAs that do not Submit Quality Data (see CMS Table 21)						
	Home health aide	Medical social services	Occupa-tional therapy	Physical therapy	Skilled nursing	Speech-language pathology
Proposed 2019 per visit rates	$65.00	$230.09	$157.99	$156.92	$143.54	$170.55

LUPA Add-On Factors: CMS proposes 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.

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

Proposed 2019 NRS Conversion Factor for HHSs that do and do not Submit the Required Quality Data (Tables 22 and 24)		
	HHAs that submit quality data	HHAs that do not submit quality data
2018 NRS Conversion Factor	$54.14	
Proposed 2019 Payment Update	1.021	1.001
Proposed 2019 NRS Conversion Factor	$54.14	$53.08

CMS proposes 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 23 and 25). For HHAs that submit quality data, NRS payment amounts range from $14.61 at severity level 1 (the lowest) to $569.85 at severity level 6 (the highest).

D. Proposed 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 mandated 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, HHAs in rural areas received a 3 percent add-on to the payment it would have received otherwise.

Section 421(b)(1) of the MMA specifies the three categories for purposes of rural add-on payments, as follows:

(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; and

(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 notes that this file was easier to use because it already included SSA state and county codes not normally included on the HH PPS wage index file; these had been incorporated into that file because of the transition to the new OMB geographic area delineations that year. CMS used 2015 claims data and 2015 data from the Medicare Beneficiary Summary file to examine home

health episodes for purposes of classifying counties as high utilization.[8] For the low population density category, CMS used 2010 Census data as mandated in statute.

Using these data, CMS determined that of the 3,246 total counties and equivalent areas, 2,006 could be considered rural for purposes of determining HH rural add-on payments. CMS classified 510 rural counties or equivalent areas 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."

Section 421(b)(1) of the MMA specifies the rural add-on payment percentages and varying durations that these add-on percentages apply for the three specified rural categories. CMS shows the rural add-on payment percentages and duration of the rural add-on payments in Table 26 of the proposed rule (reproduced below). The HHAs located in low population density areas would receive the highest add-on values for the longest duration.

Table 26: 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 rural areas, CMS will increase the national standardized 60-day episode payment rate, the national per-visit rates, and the NRS conversion factor by the rural add-on percentages. 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 (section 421(b)(2)(A)) of the MMA) this determination is only made for a single time and the determination applies for the entire duration of the period for which rural add-on payments are in place under this section. That would mean, for example, that a rural county or equivalent areas classified into the "high utilization" category would remain in that category through 2022 even after rural add-on payments for that category ends after 2021. 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.[9] This information is necessary to calculate the rural add-on payment. CMS proposes that HHAs enter the FIPS state and county code, rather than the SSA states and county code, on the claim. It notes that many HHAs are already familiar with this format, as a

[8] CMS assigned each home health episode to the state and county code of the beneficiary's mailing address.
[9] Section 50208(a)(2) of the BBA of 2018 amended section 1895(c) of the Act by adding this requirement.

number of states already required HHAs to use FIPS state and county codes for State-mandated reporting programs.

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. In addition, CMS posted the data used to categorize each county or county equivalent. These can be found at the downloads section associated with this proposed rule 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

CMS seeks comments regarding its application of the methodology specified by section 50208 of the BBA of 2018

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 approach. CMS now converts the national per-visit rates into per 15-minute unit rates. CMS also limits the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes. CMS notes that it plans to publish the cost-per-unit amounts for 2019 in the rate update change request, which CMS issues after the publication of the 2019 HH PPS final rule.

2. Fixed Dollar Loss (FDL) Ratio

CMS notes that the FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by statute (section 1895(b)(5)(A) of the Act). CMS has historically used a value of 0.80 for the loss-sharing ratio, meaning that Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount. In 2017, CMS raised the FDL ratio to 0.55 (from 0.45 in 2016). The FDL ratio is used in the calculation to determine the outlier threshold amount.[10]

CMS indicates that its simulations show that the FDL ratio would need to be changed from 0.55 to 0.51 to better approximate the 2.5 percent statutory maximum. Thus, for 2019 CMS proposes 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. CMS states that it may update the FDL ratio in the final rule, based on the use of more complete claims data. **CMS invites comments on its proposed change to the FDL ratio for 2019.**

[10] 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.

CMS also provide a clinical example 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.[11] 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, as outlined in regulation at 42 CFR 409.42(c), CMS notes 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. See pages 109-115 in the display copy for illustrative examples.

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

1. Background and Legislation, Overview, Data and File Construction

a. Background and Legislation

In the 2018 HH PPS proposed rule, CMS proposed an alternative case-mix model, known as the Home Health Groupings Model (HHGM), to be implemented for home health periods of care beginning on or after January 1, 2019. The HHGM uses 30-day periods rather than the 60-day episode in the current payment system. In order to provide additional time for public comments, CMS did not finalize the HHGM.

Effective for home health services furnished on or after January 1, 2020, Section 51001 of the BBA of 2018 requires payment for home health services to be based on a 30-day unit of service. The Secretary must implement the transition from the 60-day to a 30-day unit of service in a budget neutral manner. The Secretary is required to calculate the standard prospective payment amount so that estimated expenditures for 2020 under a 30-day unit of service are equal to estimated expenditures for 2020 if the law had not changed the unit of service from 60 to 30 days. This calculation is done before the application of the update to the standard prospective payment amounts.

Additionally, the Secretary is directed to make certain assumptions about changes in behavior of home health agencies (e.g., patterns of service delivery) that might occur due to the shorter unit of service as well as changes in case-mix adjustment factors. The Secretary must describe its assumptions on these issues in the proposed and final rules to implement the changes to the home health PPS required by Section 51001.

Beginning in 2020 and ending in 2026, the Secretary must determine for each year the difference between the estimated impact of the behavior changes it assumed for 2020 (and included in the calculation of the standard prospective payment amount) and the actual impact of those behavior changes for that year. The Secretary is required to make one or more permanent prospective adjustments (increases or decreases) to the standard prospective payment amount to offset the difference between actual and estimated behavior changes for purposes of future payment. The Secretary must also make one or more temporary prospective adjustments (increases or

[11] 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

decreases) to the payment amount for a unit of home health services to offset the difference between actual and estimated behavior changes for a previous year. These temporary adjustments are not taken into account in computing the payment amount for future years.

The Secretary is also required to eliminate the use of therapy thresholds in case mix adjustment factors for 2020 and subsequent years. No later than December 31, 2019, the Secretary must pursue notice and comment rulemaking on a revised case-mix system for the HH PPS.

b. Overview

For home health periods of care beginning on or after January 1, 2020, CMS proposes to implement case-mix methodology refinements based on the Patient-Driven Groupings Model (PDGM). CMS states that implementation starting in 2020 would provide time for provider education and training, updating and revising relevant manuals, and change claims processing systems.

The proposed PDGM shares many features of the HHGM. The PDGM uses 30-day periods rather than the 60-day episode in the current payment system. In addition, the PDGM does not use the number of therapy visits in determining payment. 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 proposes shifting to a Cost-Per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from the Medicare Cost Reports.

Figure 4, reproduced below from the proposed rule, provides an overview of the structure of the PDGM model. Under the proposed PDGM model, each 30-day period of care would be placed into one of 216 home health resource groups (HHRGs). In the PDGM, CMS proposes refinements to the comorbidity case-mix adjustments; all other variables remain as proposed in the HHGM.

- 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 are 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.

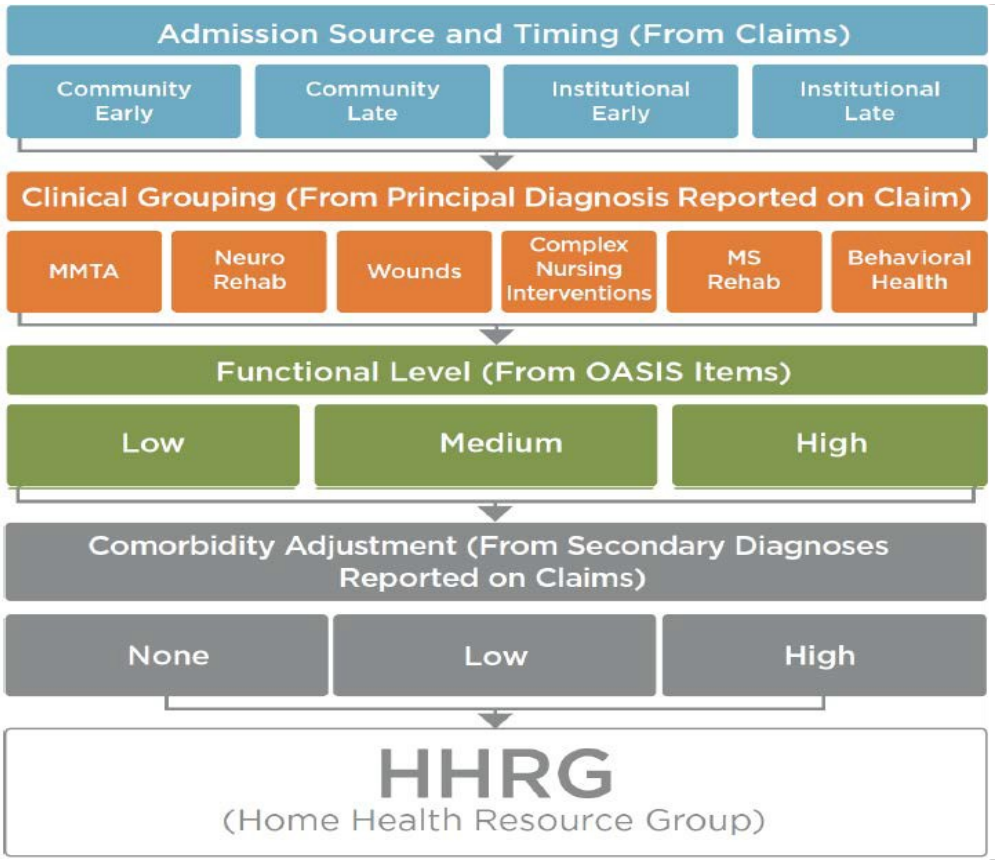
- Clinical Grouping. Based on the principal diagnosis reported on claims, the 30-day payment amount would include grouping periods into one of six clinical groups based on

the principal diagnosis listed on the home health claim. The proposed six clinical groups are 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 is predicted to have higher costs or lower costs. CMS proposes 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 proposes that 30-day periods would receive a comorbidity adjustment if any diagnosis codes listed on the home health claim are 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.

Figure 4: Structure of the Patient Driven Grouping Model



CMS also proposes changes in the Low-Utilization Payment Adjustment (LUPA) threshold. For each payment group, CMS proposes to use the 10th percentile value of visits to create a payment group specific LUPA threshold with a minimum threshold of at least 2 for each group. The LUPA add-on policy, the partial episode payment (PEP) adjustment policy, and the methodology used to calculate payments for high-cost outliers would remain unchanged except for occurring on a 30-day basis instead of a 60-day basis.

c. Data and File Construction

CMS discusses the methodology it used to create the PDGM. CMS developed a data file based on 100 percent of health episode claims with through dates in 2017, processed by March 2, 2018, and accessed via the Chronic Conditions Data Warehouse (CCW). Original or adjusted claims processed after March 2, 2018 would not be reflected in this core file. The claims data provides episode-level data, visit-level data, and whether non-routine supplies (NRS) were provided during the episode and total charges for NRS. CMS supplemented the data with additional variables that were obtained from the CCW, such as information regarding other Part A and Part B utilization.

CMS discusses how it cleaned the data including accounting for potential data entry errors. CMS also applied a set of data cleaning exclusions to the episode-level file which excluded episodes with no covered visits; episodes with any missing units or visit data; episodes with zero payments; episodes with no charges; and non-LUPA episodes missing an HHRG.

The analysis file also includes data on patient characteristics obtained from OASIS assessments. For constructing the core data file, CMS uploaded from the central CMS repository, 100 percent of the OASIS assessments submitted October 2016 through December 2017. Episodes that could not be linked with an OASIS assessment were excluded from the analysis file.

CMS discusses the variety of data sources it used to construct resource use. BLS data on average wages and fringe benefits were used to produce one version of the wage-weighted cost per minute for each home health discipline (see Table 30 in the proposed rule). Home Health Agency Medicare Cost Report data for FY 2016 were also used to construct a measure of resource use after trimming out HHAs whose costs were outliers. CMS used these data to provide a representation of the average costs of visits provided by HHAs in the six Medicare home health disciplines: skilled nursing; physical therapy (PT); occupational therapy (OT); speech-language pathology (SPL); medical social services; and home health aide services.

The 2017 analytic file included 6,771,059 episodes. After excluding 959,410 episodes (14.2 percent) the analytic file included 5,811,649 episodes. Episodes were excluded because they could not be linked to an OASIS assessment or because they met CMS' exclusion criteria. CMS converted these 60-day episodes into two 30-day periods that included 10,160,226 30-day periods. CMS excluded 30-day periods missing diagnosis codes; periods where the diagnosis code did not link to a clinical group; periods without nursing visit or therapy visit; and periods identified as LUPA. The final analytic sample included 8,624,776 30-day periods that were used for the analyses in the development of the PDGM.

In response to the 2018 HH PPS proposed rule, CMS received many comments raising concerns about limited industry participation in the development of the alternative case-mix methodology. CMS discusses the Technical Expert Panel (required by the BBA of 2018) convened on February 1, 2018 which discussed the proposed case-mix methodology as well as comments received from the 2018 HH PPS proposed rule. In addition, as required by the BBA of 2018, the Secretary issued a report on the recommendations from the TEP members to Congressional Committees.[12]

CMS also received comments about the inability of stakeholders to obtain the necessary data to replicate and model the effects on their business. In response to these concerns, to accompany the 2019 HH PPS proposed and final rules, CMS will provide upon request a Home Health Claims-OASIS LDS file. Instructions for requesting this information are on the CMS website at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html. In addition, CMS will provide a PDGM Grouper Tool to allow HHAs to replicate the PDGM methodology using their own internal data and estimated Home Health Agency-level impacts on the HHA Center web page.

2. Methodology Used to Calculate the Cost of Care

As discussed below, CMS proposes 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. The current payment system uses the wage-weighted minutes of care (WWMC) approach based on data from the BLS.

CMS used information from the HHA Medicare Cost Reports and Home Health Claims calculate the measures of home health resource use:

- Home Health Medicare Cost Report Data: All Medicare-certified HHAs must report costs through publically available home health cost reports maintained by the Health care Cost Report Information System (HCRIS). CMS notes these cost reports enable estimation of the cost per visit by provider and the estimated NRS cost to charge ratios. CMS used a trimming process to remove cost reports with missing or questionable data and extreme values.[13] CMS notes that it proxied opportunity costs by using hourly wage rates.
- Home Health Claims Data: Medicare home health claims are used in both the WWMC and CPM+NRS methods to obtain minutes of care by discipline of care.

Under the PDGM, CMS proposes to use a CPM+NRS methodology that is based on information from Medicare cost reports. CMS would group episodes into their case-mix group taking into account admission source, timing, clinical group, functional level, and comorbidity adjustment. The average resource use for each case-mix group would determine the group's case-mix weight. CMS determined resource use as the estimated cost of visits recorded on the home health claim

[12] This report is available on the CMS HHA Center web page at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/index.html.

[13] Discussion of the trimming methodology is described in the report "Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates" (Morefield, Christian, and Goldberg 2013) available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Analyses-in-Support-of-Rebasing-and-Updating-the-Medicare-Home-Health-Payment-Rates-Technical-Report.pdf.

plus the cost of NRS recorded on the claims. CMS calculated the cost of NRS by taking NRS charges on claims and converting them to costs using a NRS cost to charge ratio that is specific to each HHA. NRS costs are reflected in the average resource use that contributes to the case-mix weight. Under this methodology, CMS would return the NRS conversion factor to the base rate. Holding all else equal, if there is a high amount of NRS cost for all periods in a particular group, the resource use for those periods will be higher relative to the overall average and the case-mix weight will be correspondingly be higher.

Incorporating the NRS cost into the measure of overall resource use required adjusting the NRS charges submitted on claims based on the NRS cost-to-charge ratio from cost report data. In the proposed rule, CMS outlines the twelve steps used to generate the measure of resource use under the CPM+NRS approach. Under this approach the mean total 30-day period costs were $1,570.68; the distribution ranged from a 5th percentile value of $296.66 to a 95th percentile value of $3,839.91 (Table 31).

In response to the 2018 HH PPS proposed rule, several commenters supported the proposed changes and others objected to using Medicare cost report data to calculate resource use. Commenters' concerns included inaccuracy of HHA cost reports and that the use of cost report would favor facility-based agencies and inefficient HHAs with historically high costs. A few commenters stated that HHA's supply costs are approximately the same nationally and that including NRS in the base rate will penalize rural providers and overpay for NRS in high wage-index areas. With regards to the accuracy of the information, CMS notes that each HHA Medicare 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 for misrepresentation or falsification of information in the cost report. To address concerns about facility-based HHAs, CMS notes that facility-based HHAs are only 8 percent of HHAs and coincidentally the percentage of 30-day periods furnished by facility-based freestanding HHAs is also 8 percent. In addition, CMS notes that on average, each HHA provider contributed 823 30-day periods to the payment regression, which is only 0.010 percent of all 30-day periods. Including or excluding any single HHA, on average, would not dramatically impact the results of the payment regression.

CMS states that using cost report data instead of BLS average hourly rates for the entire home health care industry better reflects changes in utilization that impacts costs. CMS notes that because the cost estimates using the two approaches are measuring different items, they cannot be directly compared. The CPM+NRS method incorporates HHA-specific costs that represent the total costs during a 30-day period while the WWMC method provides an estimate of only the labor costs related to direct patient care from patient visits that are incurred during a 30-day period. The WWMC costs are not HHA-specific and do not account for any non-labor costs (such as transportation costs) or non-direct patient care labor costs (such as administration costs). CMS notes however, based on a high correlation coefficient between the two approaches for calculating resource use (correlation coefficient is equal to 0.8512), the relationship in relative costs is similar between the two methods.

CMS concludes that using cost report data to develop case-mix weights more evenly weights skilled nursing services and therapy services compared with using the BLS data. Table 32

(reproduced below) shows the ratios between the estimated costs per hour for each methodology for each of the home health disciplines.

Table 32: Relative Values in Costs per Hour by Disciplines (Skilled Nursing is Base)						
Estimated Cost per Hour	**Skilled Nursing**	**Physical Therapy**	**Occupational Therapy**	**Speech Therapy**	**Medical/ Social Service**	**Home Health Aide**
CPM+NRS	1.00	1.14	1.15	1.25	1.39	0.40
WWMC	1.00	1.36	1.38	1.56	0.94	0.35

CMS proposes to calculate the cost of a 30-day period of home care under the PDGM using the CPM+NRS approach. CMS believes that using cost report data to calculate the cost of home health care better aligns the case-mix weights with the total relative cost of treating various patients. CMS invites comments on this proposed methodology.

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 proposed rule with regards to payment under the HH PPS.

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 proposes 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.

Table 33 (reproduced below) includes estimates of 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. This includes the application of the proposed home health payment update percentage of 2.1 percent. CMS first calculated the total, aggregate amount of expenditures that would occur under the current case-mix adjustment methodology and the 60-day episode of payment using the proposed 2019 payment parameters; this resulted in a total aggregate expenditures target amount of $16.1 billion. CMS then calculated what the 30-day payment amount would need to be in 2019, with and without behavior assumptions, and take into account needed changes to the outlier fixed-dollar loss ratio under the PDGM in order to pay out no more than 2.5 percent of total HHP payments as outlier payments (discussed below in section F.12) in order to obtain $16.1 billion in total expenditures in 2019 with the application of a 30-day unit of payment. 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 and as required, it would calculate this amount before application of the proposed home health update percentage for 2020.

Table 33: 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	
LUPA Threshold (1/3 of LUPAs 1-2 visits away from threshold get extra visits and become case-mix adjusted)	$1,841.05	-1.75%
Clinical Group Coding (among available diagnoses, one leading to highest payment grouping classification designated as principal)	$1,793.69	-4.28%
Comorbidity Coding (assigns comorbidity level based on comorbidities appearing on HHA claims and not just OASIS)	$1,866.76	-0.38%
Clinical Group Coding + Comorbidity Coding	$1,786.54	-4.6%
Clinical Group Coding + Comorbidity Coding + LUPA Threshold	$1,753.68	-6.42%

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. For example, if expenditures are estimated to be $18 billion in 2020, but expenditures are actually $18.25 billion in 2020, CMS can temporarily reduce future payments to recover the $250 million.

For implementation purposes, CMS notes that for 60-day episodes of care that begin on or before December 31, 2019 and end on or after January 1, 2020 payment will be the 2020 national, standardized 60-day episode payment amount. For home health units of service that begin on or after January 1, 2020, the unit of service will be a 30-day period and payment will be made under the 2020 national, standardized 30-day payment amount. For home health units of service that begin on or after December 2, 2020 through December 31, 2020 and end on or after January 1, 2021, the HHA will be paid the 2021 national, standardized 30-day payment amount.

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 discusses how 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 makes 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 would allow newly enrolled HHAs to structure their operations without becoming dependent on a partial, advanced payment.

    - These HHAs would 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. CMS notes that without such notification, there would be an increase in denials of claims subject to the home health consolidated billing edits that are prevented when an episode is established in the common working file (CWF) but the RAP.

- 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 states it did not propose this alternative because it wanted to clearly signal its intent to potentially eliminate the split percentage payment approach over time. Given that existing HHAs (certified with effective dates prior to January 1, 2019) would need to adapt to changes in cash flow with the elimination of the split percentage payment approach, CMS hopes to receive additional feedback on the timeframes for a phase-out of the split percentage approach.

CMS seeks comments on the change in the unit of payment form a 60-day to a 30-day unit of payment:

- The proposed calculation of the 30-day payment amount in a budget-neutral manner and behavior change assumptions for 2020;
- The proposed interpretation of the statutory language regarding actual behavior change;
- The proposal not to allow newly-enrolled HHAs to receive RAP payments in 2020 and still require the submission of a "no pay" RAP at the beginning of care;
- The proposal to maintain the split percentage payment approach for existing HHAs and applying this policy to 30-day periods of care;
- Ways to phase-out the split percentage payment approach in the future; and
- Whether to implement a NOA process if the split percentage payment approach is eliminated in the future.

4. Episode of Timing Categories

Similar to the 30-day periods proposed in the 2018 HH PPS proposed rule, under the PDGM model, CMS proposes to classify the 30-day periods as "early" or "late" depending on when they occur within a sequence of 30-day periods. CMS proposes the first 30-day period is classified as early. All subsequent 30-day periods in the sequence (second or later) are classified as late. Similar to the current definition of a "home health sequence", CMS proposes that a 30-day period could not be considered early unless there was a gap of more than 60 days between the end of one period and the start of another.

CMS discusses the evidence demonstrating that beneficiaries in their first 30-day period of care have different needs and patterns of resource use than those in the later 30-day periods. CMS' evaluation of resource utilization from home health data demonstrated that HHAs provide more resources in the first 30-day period of home health (early) than in later periods of care (Table

34). Specifically, the median value of resource use for early episodes (the first 30-day period) was $1,866.79 while the median resource use for late episodes (subsequent 30-day periods) was $987.94.

In response to the 2018 HH PPS proposed rule, several commenters stated that HHA costs are typically highest during the first 30 days of care. Other commenters, however, stated that HHAs might modify the way they provide care due to financial incentives which could cause a decrease in overall payments to HHAs and an increase in hospital admissions. Some commenters suggested that CMS modify the definition of an "early" 30-day period to either the first two 30-day periods or the first four 30-days of care to more closely mirror the current payment system's definition of "early".

CMS acknowledges that the public comments received in response to the 2018 HH PPS proposed rule and comments made by the TEP participants presented conflicting predictions regarding anticipated provider behavior in response to the alternative case-mix adjustment methodology. In response to comments, CMS notes that the data do not support defining the first two 30-day periods as early because only the first 30-day period demonstrates marked increase in resource use. CMS believes the PDGM's definition of "early" as the first 30-day period most accurately reflects agencies' average cost for patients with characteristics measured on the OASIS and used in defining payment groups. CMS notes that since it proposes to recalibrate the PDGM case-mix weights on an annual basis to reflect the most recent utilization data available, future recalibrations of the PDGM case-mix weights may result in changes to the case-mix weights for early versus late 30-day periods of care.

CMS disagrees with comments suggesting that a readmission to home health within the 60-day gap period results in an "early" instead of a "late" 30-day period. Because the PDGM also includes a category determined specifically by the source of admission, the PDGM accounts for whether the patient was admitted to home health care from the community or following an institutional stay, including inpatient stays that occur after the commencement of home health care (discussed below in section F.5). CMS does not believe that the timing element of the PDGM would create a financial incentive to inappropriately encourage the admission of home health patients to an acute care setting in order to receive a subsequent home health referral in the higher-paid "early" category.

To identify the first 30-day period within a sequence, the Medicare claims processing system will verify that the claim "From date" and "Admission date" match. If this condition is met, the claims processing systems will send the "early" indicator to the HH Grouper for the 30-day period of care. When the CWF receives the claim, the system will look back 60 days to ensure there is not a prior, related episode. If another related episode is identified, the claim will be returned to the shared systems for subsequent regrouping and re-pricing. Those periods that are not identified as the first 30-day period in a sequence of adjacent periods and separated by no more than a 60-day gap, will be categorized as "late" periods.

The 60-day period to determine a gap that will begin a new sequence of 30-day periods will be counted, in most instances, from the calculated end date of the 30-day period. In most cases, CWF will count from "day 30" of a 30-day period without regard to an earlier discharge date.

The exception is for 30-day periods subject to partial episode payment (PEP) adjustments; CWF will count 60 days from the date of the last billable home health visit provided. Because PEPs are paid based upon the last billable service date, CMS considers the end of the PEP HH episode as the last billable home health visit provided and begins the count of gap days from the date of the last billable home health visits. CMS provides examples in the proposed rule.

For inpatient stays occurring within a period, the inpatient stay would not be part of the gap because counting would still begin at "day 60" which would be later than the inpatient discharge date. If an inpatient stay occurred within the time after the HH period and before the beginning of the next HH period, the inpatient days would be counted as any other day wound and be counted as part of the gap.

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 acknowledges commenters expressing concerns about the operational aspects of the proposed timing elements of the 2018 HH PPS proposed rule. 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.

CMS agrees with commenters about the potential for problematic provider behavior due to financial incentives and intends to monitor provider behavior in response to the PDGM. Additionally, it will share any concerning behavior or patterns with the Medicare Administrative Contractors (MACs) and CMS' Center for Program Integrity.

CMS invites public comments on the timing categories for the proposed PDGM.

5. Admission Source Category

In the 2018 HH PPS proposed rule, CMS proposed that each period of care would be classified into one of two admission source categories depending on what healthcare setting was utilized in the 14 days prior to home health: institutional or community. Several commenters supported this proposal. Commenters also expressed a wide variety of concerns regarding admission source, including concerns that the categories would discourage admission of community entrants due to lower reimbursement; HHAs may encourage hospitalization during an episode of home health care; and the complex operational aspects of the admission source. Discussions at the TEP were similar to comments received.

CMS discusses how its analytic findings demonstrate that institutional admissions have higher average resource use when compared to community admissions. Table 35 (reproduced below) shows that institutional admissions have $807.89 higher resource use as compared to community

admissions. This pattern of higher resource use for institutional admissions remains consistent for the 25th and 75th percentiles.

Table 35: Average Resource Use by Admission Source (14 Day Look-Back; 30-Day Periods) Admission Source, Community and Institutional Only*							
	Average Resource Use	**Frequency of Periods**	**Percent of Periods**	**Standard Deviation of Resource Use**	**25th Percentile of Resource Use**	**Median Resource Use**	**75th Percentile of Resource Use**
Community	$1,363.11	6,408,805	74.3%	$1,119.20	$570.26	$1062.05	$1,817.75
Institutional	$2,171.00	2,215,971	25.7%	$1,303.24	$1,246.05	$1,920.06	$2,791.91
Total	$1,570.68	8,624,776	100.0%	$1,221.38	$679.12	$1,272.18	$2,117.47
* Source: 2017 Medicare claims data for episodes ending on or before December 31,2017 (as of March 2, 2018)							

CMS reiterates the discussion in the 2018 HH PPS proposed rule about research demonstrating that patients who are discharged from acute and PAC settings are sicker upon admission, are being discharged rapidly back to the community, and are more likely to be re-hospitalized after discharge due to the acute nature of their illness. CMS concludes these findings suggest that beneficiaries admitted to home health from the community typically require less resources but for longer periods of time. CMS notes that the goal of the admission source variable is to align payment with the costs of providing home health care. Other CMS initiatives such as HH QRP and the HH VBP demonstration, take readmission into account as a measure of quality.

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.

In response to commenters recommendations that CMS consider incorporating other clinical settings into the definition of the institutional category, including hospices and outpatient facilities, CMS explored the option of creating a third admission source category for observational stays/ED visits. CMS found that home health periods with preceding observational stays and ED visits show resource use that falls between that of the institutional and community categories. For beneficiaries with a preceding ED visit the average resource use was $1,660.64 per home health period and for beneficiaries with preceding observational stays the average resource use was $1,820.06 as compared to $2,171.00 for institutional admits and $1,337.73 for community admits (Tables 36 and 37). CMS acknowledges the increased resource use of HH stays with a preceding observation stay/ED visit but it is concerned that a third admission source category could create an incentive for providers to encourage outpatient encounters both prior to a 30-day period of care or within a 30-day period of care within 14 days of the start of the next 30-day period. CMS discusses how the clinical threshold for an observational stay or an ED visit is not as high as that required for an institutional admission. CMS also notes that the proportion of home health periods with admissions from ED visits and observational stays is low relative to community and institutional stays, approximately 5.8 percent and 2 percent respectively, of total home health periods. CMS is also concerned that creating a third community admission source category would potentially introduce added

complexity into the payment system for a small portion of home health visits. CMS concludes that incorporating HH stays with preceding observational stays and ED visits into the community admission category is most appropriate at this time. It will continue to assess this issue over time.

In response to concerns about the operational aspects of the admission source category, CMS discusses the automated claims processing procedures designed to reduce provider's administrative burden. 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 proposes to 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).

CMS proposes that if an occurrence code were submitted on the home health claim, the claim would be categorized as an institutional admission. The Medicare systems would 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 would 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.

For the PDGM, CMS proposes to establish two admission sources for grouping 30-day periods of care: institutional and community. The admission category would be determined by the health care setting utilized in the 14 days prior to the home health admission. The institutional category would include patients admitted from either acute care or PAC settings. CMS proposes this would include beneficiaries with any inpatient acute care hospitalizations, skilled nursing facility stays, inpatient rehabilitation facility stays, or long term care hospital stays within 14 days prior to home health admission.

- The institutional category would 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 would not categorize PAC 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 in a different setting and then readmit the patient, if necessary, after discharge from the PAC.
- All other 30-day periods would be considered community admissions.

For purposes of a RAP, CMS proposes to 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 would not adjust the RAP but it would adjust the final home health claim to an institutional admission. In addition, admission source occurrence codes will only be included on the final claim and not on any RAPs submitted.

CMS invites public comment.

6. Proposed Clinical Grouping

In the 2018 HH PPS proposed rule, 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. CMS believed the proposed groups reflect how clinicians differentiate between patients and the types of care they need to receive.

After reviewing comments submitted in response to the 2018 proposed rule and discussion at the TEP, CMS proposes the use of the same six clinical groups for the PDGM. Table 40 (reproduced below) lists the six proposed clinical groups. The principal diagnosis is the basis for the clinical grouping; secondary diagnosis codes and patient characteristics will 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 reflect the reported principal diagnosis, clinical relevance, and coding guidelines.[14] A complete list of ICD-10-CM codes and their assign clinical groupings is posted on the CMS HHA Center Webpage.

[14] 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.

Table 40: Proposed 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 a variety of medical & surgical conditions not classified in one of the above listed groups.

Many commenters and TEP members supported CMS' proposal to group patients by clinical characteristics. Commenters did raise concerns about the clinical groups including concern about reduced therapy use in the clinical groups that aren't specific for musculoskeletal or neurologic rehabilitation; concern that the groups do not capture clinical complex patients requiring multiple home health disciplines; and concern that the MMTA clinical group included too many diagnosis codes. Several commenters expressed concerns about the assignment of certain ICD-10 CM diagnosis codes.

CMS discusses the many reasons a diagnosis code was not assigned to one of the six 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. CMS did review 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 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 six 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 would have further case-mix adjustments. CMS does agree that diagnosis alone does not provide the entire clinical picture of the home health patient but notes that the clinical group is one aspect of the PDGM.

In response to commenters and TEP participants concern that the MMTA clinical group is too broad, CMS performed additional analysis on the division of MMTA into subgroups to estimate the payment regression if the groups were separated from the MMTA. Table 38 (reproduced

below) displays the additional subgroups that were identified based on data that showed above-average resource use for the diagnosis codes in those groups; certain groups were combined because they had a minimal number of codes. CMS evaluated the impact each MMTA variable had on case-mix weight and found that the change in case-mix weight was minimal for the 30-day periods assigned to these subgroups compared to the case-mix weights without the subgroups (Table 39). CMS notes the impact of other variables in the model (admission source, timing, comorbidity adjustment) on the final case-mix weights were similar whether or not MMTA subgroups were used.

Table 38: Distribution of Resource Use by 30-Day Periods (MMTA Subgroups)			
Subgroup	**N**	**Mean**	**Median**
Aftercare	304,871	$1,605.43	$1,326.03
Cardiac/Circulatory	1,594,149	$1,433.02	$1,121.27
Endocrine	425,077	$1,524.45	$1,062.41
GI/GU	402,322	$1,414.44	$1,115.29
Infectious Disease/Neoplasms/Blood-forming Diseases	347,755	$1,400.65	$1,077.58
Respiratory	724,722	$1,411.61	$1,133.23
Other	1,266,750	$1,366.56	$1,035.76
Total	5,025,646	$1,428.17	$1,105.20

CMS concludes that using the MMTA subgroup model would result in more payment groups with minimal differences in case-mix weights and does not propose to divide the MMTA clinical subgroup. CMS plans to continue to examine this issue to determine if future changes to the clinical groupings are needed after the implementation of the PDGM.

CMS solicits comments on whether there may be other reasons why MMTA should be broken into the subgroups shown in Table 38, even if the additional subgroups do not result in significant differences in case-mix weights across these subgroups.

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.[15] 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 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. The OASIS items included in the

[15] 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.

functional level adjustment under the HHGM are consistent with the OASIS items proposed for the PDGM (Table 41, reproduced below).

CMS also proposed that each of the six clinical groups would be further classified into roughly three functional impairment levels of low, medium, and high. Approximately one third of home health period from each of the clinical groups would be within each functional impairment level.

CMS notes that the majority of comments received were from physical therapists, physical therapy assistants, occupational therapists, and national physical, occupational, and speech-language pathology associations. Comments were similar between those received in response to the 2018 HHS proposed rule and TEP participants. Most commenters agreed that the level of functional impairment should be included in the model and were generally supportive of the OASIS items selected for determining the functional level payment adjustment. Other commenters were concerned about the effect of the IMPACT Act; adequacy of the functional impairment thresholds and payment adjustments; and potential HHA behavioral changes.

In response to concerns about the IMPACT Act, CMS notes that the analysis presented in the 2018 HH PPS proposed rule was based on 2016 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. After consideration of comments received, CMS continues to believe that the three PDGM functional impairment levels in each of the six clinical groups appropriately capture the level of functional impairment.

CMS proposes that the functional impairment level payment adjustment under the PDGM includes the OASIS items identified in the 2018 HH PPS. CMS proposes to assign points for each of the responses to the proposed OASIS functional items (Table 41, reproduced below) to sum up the points to create a functional score for the period of care. CMS proposes to use the three functional levels of low, medium and high based on the 2017 data for each of the clinical groups. Table 42 (reproduced below) shows the functional thresholds for each functional level by clinical group. Table 38 in the proposed rule shows the average resource use by clinical group and functional level for 2016.

TABLE 41: 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	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 42: 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 expects to make annual recalibration of the PDGM case-mix weights. If the PDGM is finalized, CMS plans to continue to analyze all of the components of the case-mix adjustment, including adjustment for functional status, and would make refinements as necessary to ensure that payment for home health periods are in alignment with costs. **CMS invites comments on the proposed OASIS items and the associated points and thresholds to group patients into three functional impairment levels.**

8. Comorbidity Adjustments

In the 2018 HH PPS proposed rule, CMS proposes to include a comorbidity adjustment category based on the presence of secondary diagnoses. Specifically, CMS proposes that 30-day periods would receive a comorbidity adjustment if any diagnosis codes listed on the home health claim are included on a list of comorbidities that occurred in at least 0.1 percent of 30-day periods and was associated with increased average resource use.

On the basis of its analysis, CMS proposed that if a period had at least one secondary diagnosis reported on the home health claim that is in one of the 15 subcategories listed below, that period would receive a comorbidity adjustment to account for the higher costs associated with the comorbidity.

- Heart Disease 1: includes hypertensive heart disease.
- Cerebral Vascular Disease 4: includes sequelae of cerebrovascular disease.
- Circulatory Disease and Blood Disorders 9: includes venous embolisms and thrombosis.
- Circulatory Disease and Blood Disorders 10: includes varicose veins of lower extremities with ulcers and inflammation, and esophageal varices.
- Circulatory Disease and Blood Disorders 11: includes lymphedema.
- Endocrine Disease 2: includes diabetes with complications due to an underlying condition.
- Neoplasm 18: includes secondary malignant neoplasms.
- Neurological Disease and Associated Conditions 5: includes secondary Parkinsonism.
- Neurological Disease and Associated Conditions 7: includes encephalitis, myelitis, encephalomyelitis, and hemiplegia, paraplegia, and quadriplegia.
- Neurological Disease and Associated Conditions 10: includes diabetes with neurological complications.
- Respiratory Disease 7: includes pneumonia, pneumonitis, and pulmonary edema.
- Skin Disease 1: includes cutaneous, abscesses, and cellulitis.
- Skin Disease 2: includes stage one-pressure ulcers.
- Skin Disease 3: includes atherosclerosis with gangrene.
- Skin Disease 4: includes unstageable and stages two through four pressure ulcers.

Comments on the comorbidity adjustment and suggestions for refinement were very similar between those in response to the 2018 HH PPS proposed rule and those made by TEP participants. The majority of commenters thought that the presence of multiple comorbidities has more effect on home health resource use than a single comorbidity and that any case-mix adjustment should account for multiple comorbidities.

In response to these comments, CMS updated its analysis and found compelling evidence that patients with certain comorbidities and interactions of certain comorbidities have home health episodes with higher resource use than home health episodes without these comorbidities or interactions. The specific details about the methodology CMS used are summarized in the proposed rule. Table 44 (summarized below) identifies the 11 individual comorbidity subgroups that are statistically and clinically significant for potential inclusion in the comorbidity case-mix adjustment.

Table 44: Individual Subgroups for Comorbidity Adjustment		
Comorbidity Subgroup	**Description**	**Coefficient**
Neuro 11	Includes diabetic retinopathy and other blindness	$61.23
Neuro 10	Includes diabetic neuropathies	$67.98
Circulatory 9	Includes acute and chronic embolisms and thrombosis	$86.62
Heart 11	Includes heart failure	$101.57
Cerebral 4	Includes sequelae of cerebrovascular diseases	$128.78
Neuro 5	Includes Parkinson's Disease	$144.99
Skin 1	Includes cutaneous abscess, cellulitis, and lymphangitis	$174.93
Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia	$204.42
Circulatory 10	Includes varicose veins with ulceration	$215.67
Skin 3	Includes diseases of arterioles and capillaries with ulceration and non-pressure chronic ulcers	$365.78
Skin 4	Includes stages Two-Four and unstageable pressure ulcers by site	$484.83

CMS examined the impact of interactions between the various comorbidity subgroups on resource use and identified 27 comorbidity subgroup interactions that are statistically and clinically significant (Table 45). In order to be considered a comorbidity subgroup interaction, CMS required two-reported diagnosis in the corresponding combinations. Specifically, comorbidity subgroups are not interchangeable between the interaction groups. CMS provides several examples including the following: If a 30-day period of care had the secondary diagnosis reported I50.22, chronic systolic (congestive) heart failure and G20, Parkinson's Disease, (these diagnoses fall under comorbidity subgroups Heart 11 and Neuro 5 respectively and are in the same comorbidity subgroup interaction), this interaction of comorbid conditions would result in a higher level of resource use than just having a comorbid diagnosis classified in Heart 11 and Neuro 5. CMS will have an updated PDGM Grouper Tool on the HHA Center webpage to allow providers to determine whether a home health period of care would receive a comorbidity adjustment under the PDGM.

CMS proposes three levels in the PDGM comorbidity case-mix adjustment: 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. Changing to three comorbidity levels results in 216 possible case-mix groups for adjusting payments in the PDGM.

CMS proposes 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 44) associated with higher resource use, or
- High comorbidity adjustment: There are two or more secondary diagnoses reported within the same comorbidity subgroup interaction (Table 45) that are associated with higher resource use.

CMS proposes 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 all 11 individual comorbidity subgroups; the high comorbidity adjustment amount would be the same across all 27 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 would be no comorbidity adjustment applied.

Using 2017 Medicare claims data, CMS found for a 30-day period, the mean resource use without a comorbidity adjustment was $1,539.92, the mean resource use with the low comorbidity adjustment was $1,575.12 and the mean resource use with the high comorbidity adjustment was $1,878.84. Table 48 includes the coefficient amounts associated with both the low and high comorbidity adjustment and the case-mix variables in the PDGM.

CMS invites comments on the change to the comorbidity case-mix adjustments in the PDGM, including comments associated with the low comorbidity and high comorbidity payment adjustment.

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).

In the 2018 HH PPS proposed rule, CMS proposed to set the LUPA threshold at the 10^{th} percentile value of visits with a minimum threshold of at least 2 visits, whichever is higher for each payment group. In response to this proposal, some commenters recommended maintaining the use of a single LUPA threshold instead of varying the threshold at the subgroup level and raise concerns about the administrative burden associated with this proposal.

After consideration of comments and analyzing the data, CMS believes that proposed LUPA thresholds based on the case-mix assignment for the 30-day period of care in the proposed PDGM is an improvement over the current 5 visit threshold that does not vary by case-mix assignment. CMS does not believe that this proposal would result in administrative burden since LUPA visits are billed the same as non-LUPA periods. Given the PDGM will not be implemented until January 1, 2010, CMS notes there should be sufficient time for providers .to make any necessary system changes

Under the PDGM, consistent with the 2018 PPS proposed rule, CMS proposes to set the LUPA threshold at the 10^{th} percentile value of visits with a minimum threshold of at least 2 visits, whichever is higher for each payment group. Assuming no behavior change, approximately 7.1 percent of 30-day periods would be LUPA; under the current payment system approximately 8 percent of episodes are LUPA. Table 47 in the proposed rule lists the LUPA thresholds based on

2017 utilization data (available on March 2, 2018) for each proposed PDGM payment group. CMS proposes to update LUPA thresholds every year based on the most current utilization data available. CMS invites comments on the LUPA threshold proposal.

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. In the 2018 HH PPS proposed rule, CMS proposed the HHGM case-mix adjustment methodology, which sorted 30-day periods into different payment groups based on five categories: admission source, timing, clinical group, functional level, and comorbidity group. CMS did not finalize the HHGM and is proposing an alternative case-mix adjustment methodology, the PDGM. For the PDGM, CMS proposes refinements to the comorbidity case-mix adjustment and all other variables remain as proposed in the HHGM. The PDGM results in a total of 216 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. It determined the case-mix weight for each of the different PDGM payment groups by regressing resource use on a series of indicator variables for each of the five categories using a fixed effects model. CMS normalized the results from the fixed effects regression model to calculate the case-mix weight of all 30-day periods within a particular payment group. CMS used the case-mix weight to adjust the 30-day payment rate to determine each 30-day period payment. Table 48 in the proposed rule shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use for PDGM payment groups.

In response to comments on the proposed alternative case-mix adjustment methodology in the 2018 HH PPS proposed rule, CMS states annual recalibration will be made to the PDGM case-mix weights. The actual PDGM case-mix weights for 2020 will be updated in the 2020 HHS proposed rule. MedPAC raised concerns about the development of alternative case-mix adjustment using the regression approach. In response, CMS states it has used this approach since the inception of the HHS PPS in 2000 and it continues to believe that using a regression approach for the calculation of the HH PPS case-mix weights is appropriate.

The case-mix weight for each HHRG payment group (216 different HHRG payment groups under the PDGM) is provided in Table 49. The case-mix weight excludes LUPA episodes, outlier episodes, and episodes with partial episode payment (PEP) adjustments. CMS notes that 15 HHRG payment groups represent approximately 50.2 percent of the total episodes and 61 HHRG payment groups represent approximately 1.0 percent of the total episodes. The HHRG payment group with the smallest weight (0.5075) includes the 5 categories for community admitted, late, behavioral health, low functional level, and with no comorbidity adjustment. The HHRG payment group with the largest weight (1.9168) includes the five categories for institutional admitted, early, wound, high functional impairment level, and with interactive comorbidity adjustment.

CMS invites comments on the proposed PDGM case-mix weights, case-mix weight methodology and proposed annual recalibration of the case-mix weights.

In conjunction with the implementation of the PDGM, CMS proposes 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. Currently, CMS provides an updated version of the software effective October 1 to address ICD coding revisions, which are effective October 1. CMS also provides an update on October 1 to capture HH PPS policies that become effective on January 1. CMS proposes to discontinue the October release and provide a single HH PPS Grouper software release effective January 1 of each calendar year. Under this proposal, HHAs would use the ICD-10-CM codes and reporting guidelines during the entire calendar year. HHAs would begin using the most recent ICD-10-CM codes and reporting guidelines on home health claims beginning January 1 of each calendar year. CMS invites comments on this proposal.

11. Low-Utilization Payment Adjustment (LUPA) Add-On Payments and Partial 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 proposes that under the PDGM, the LUPA add-on factors will remain the same as the current payment system.

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 proposes to 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-dayepisode, CMS proposes the original 30-day period would 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 proposes to maintain the current methodology for payment of high-cost outliers under the PDGM except that outlier payments would be determined on a 30-day basis to align with the 30-day unit of payment under the proposed 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.

In response to a similar proposal in the 2018 HH PPS proposed rule, 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 permitted to be 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 that 8 hours each day. CMS concludes that maintaining the 8-hour cap is appropriate under the proposed PDGM.

Using 2017 claims data and 2019 payment rates, CMS estimates that outlier payments under the proposed 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.

CMS invites public comment.

G. Changes Regarding Certifying and Recertifying Patient Eligibility

1. & 2. Background and Current Documentation Requirements

CMS reviews 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.[16] 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 notes 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

[16]Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act as amended by section 6407 of the Affordable Care Act

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.

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

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.[17] CMS notes that it 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).[18]

CMS proposes to amend the regulations text at 42 CFR 424.22(c) to align the regulations text with current sub-regulatory guidance to allow 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).

- 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 on 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.

CMS welcome comments on this assumption and its overall proposal.

[17]Section 51002 of the BBA of 2018 amended sections 1814(a) and 1835(a) of the Act

[18] 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

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

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 an estimate of how much longer skilled services will be required at each home health recertification, 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 agrees with the commenters and this estimate required at each recertification is not currently used for quality, payment, and or program integrity purposes. Thus, CMS proposes 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) would remain unchanged.

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

CMS invites comments regarding the proposed elimination of this requirement as well as the corresponding regulations text changes at §424.22(b)(2).

H. Role of 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, that the use of this technology results in lower mortality, improved quality of life, and reductions in hospital admissions.[19] CMS notes that it does not have 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 propose 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 proposes 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 and/or caregiver to the HHA."

[19] 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).

CMS states that 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.[20] CMS proposes 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. CMS states that these costs would 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.

CMS seeks comments on the proposed definition of remote patient monitoring under the HH PPS, and the proposed changes to its regulations to include the costs of remote patient monitoring as allowable administrative costs (that is, operating expenses). CMS also states that it welcomes comments regarding additional utilization of telecommunications technologies for consideration in future rulemaking.

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[21] 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.[22] 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)

[20] 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.

[21] 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.

[22] 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.

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).

In this rule, CMS proposes to remove two measures from the HHVBP measure set and replace three others beginning with PY 4 (2019 data for 2021 payment). The measures proposed for removal are:

- "Influenza Immunization Received for Current Flu Season" would be removed based on input from stakeholders and a Technical Expert Panel because of concerns about the measure specifications. Specifically, the measure does not exclude patients who were offered but refused a flu vaccine or patients for whom a vaccine is contraindicated. CMS therefore concludes that the measure does not fully capture HHA performance in administering flu vaccines.
- "Pneumococcal Polysaccharide Vaccine Ever Received" would be removed because the Advisory Committee on Immunization Practices clinical guidelines for this vaccine have changed.[23]
- Three OASIS-based measures would be replaced with two related composite measures, based on the recommendation of a technical expert panel (TEP) convened in November 2017. Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing would be removed, and the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, described below would be added. CMS believes that the composites would create a more comprehensive assessment of HHA performance across a broader range of Activities of Daily Living (ADL) outcomes. In addition, while the measures to be removed assess improvement, the composites assess the magnitude of patient changes, including both improvement and decline.

The proposed new composite measures combine several existing and endorsed HH QRP outcome measures. The composites would be included within the Patient and Family Engagement domain because CMS says that functional status and functional decline are important areas to assess in home health settings.

"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)

[23] 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.

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

- Improvement in Toilet Transferring (M1840)
- 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. The change from start (or resumption) of care to discharge for each component is calculated, and the scores are normalized so that the maximum possible change for an item equals 1. The normalization step results in a range of possible scores for the change in self-care composite from -6 to +6 and for the change in mobility composite from -3 to +3. A risk-adjusted score is calculated using models that predict values for episodes which are averaged both nationally and for the individual HHA. Specifically, the risk-adjusted score for a composite measure for an HHA equals the HHA's observed score plus the national predicted value minus the HHA-predicted value. Table 50 in the proposed 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 proposed composite measures. CMS proposes to use data for episodes ending in 2017 for the prediction model if these measures are finalized. Missing values for an item would 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.

Under the proposed rule, the composite measures would each have a maximum score of 15 points. The three ADL improvement measures that would be replaced currently have a maximum cumulative score of 30 points. Thus, the proposal would maintain a 30-point maximum for ADL-related measures in the HHVBP Model.

Table 51 in the proposed rule describes the 16 measures proposed 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 proposed composites, the measure computation and risk adjustment). The following table below provides a summary of the measures previously adopted for PY 3 and the proposed changes.

Measure Set for the HHVBP Model PY 3 with *Proposed Changes for PY 4*			
NQS Domains	**Measure Title**	**Measure Type**	**Data Source**
Clinical Quality of Care	*Improvement in Ambulation-Locomotion- Remove*	Outcome	OASIS
	Improvement in Bed Transferring- Remove	Outcome	OASIS
	Improvement in Bathing-Remove	Outcome	OASIS
	Improvement in Dyspnea	Outcome	OASIS
Communication & Care Coordination	Discharged to Community	Outcome	OASIS
	Advance Care Plan	Process	Web portal
	Acute Care Hospitalization: Unplanned hospitalization during first 60 days of Home Health	Outcome	Claims

Measure Set for the HHVBP Model PY 3 with *Proposed Changes for PY 4*			
NQS Domains	**Measure Title**	**Measure Type**	**Data Source**
Efficiency & Cost Reduction	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 Immunization Received for Current Flu Season - Remove*	Process	OASIS
	Pneumococcal Polysaccharide Vaccine Ever Received – Remove	Process	OASIS
	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 -- Add*	*Composite Outcome*	*OASIS*
	Total Normalized Composite Change in Mobility -- Add	*Composite Outcome*	*OASIS*

C. Reweighting of HHVBP Model Measures

CMS proposes to change the weighting of the HHVBP Model measures when calculating a Total Performance Score (TPS). 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 proposed rule would create 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 would each be weighted at 35 percent, while the HHCAHPS category would be weighted at 30 percent. Points awarded for data reporting for each new measure would continue to receive equal weight and account for the remaining 10 percent of the TPS. Corresponding changes are proposed to the regulatory text at 42 CFR 484.320(c).

CMS believes that the proposed reweighting would better support improvement in the claims-based measures. Figures 5 and 6 of the proposed 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.

In addition to weighting by measure category, CMS proposes the following policies for calculating weights:

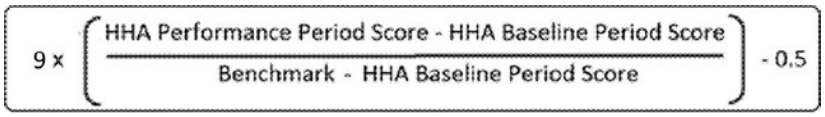
- If scores are missing for individual measures within a category, the weights of the remaining measures would be adjusted proportionately so that the category total weight remains the same.
- If an HHA is missing all the measures for one of the three categories, the weights of the other categories would be adjusted. Table 65 in the proposed rule, reproduced as an Attachment to this summary, shows the current and proposed weights for each measure under all scenarios (i.e., scores for 1, 2, or all 3 categories).
- The claims-based measure "Acute care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health" would 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 would have a greater impact on Medicare expenditures.

Table 53 of the proposed rule offers a numerical example of calculating the TPS under the current and proposed weights.

D. Performance Scoring Methodology

CMS proposes 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. This proposal responds to 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 proposal, a unique improvement range would be measured for each HHS 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 was equal to or higher than the benchmark score, the HHA would receive the maximum improvement score of 9 points (the HHA could still receive 10 points for achievement). If the score was below the baseline period, zero points would be awarded for improvement. If the score was greater than the baseline level but below the benchmark, the following formula would be used to determine the improvement score:



CMS notes that for the two proposed new composite measures, the maximum score would be 15 points. The proposed rule includes numerical examples of calculating achievement and improvement scores.

E. Update on Public Display of Total Performance Scores

CMS continues to say that it is considering 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 is offered at this time, but **CMS seeks comment on what information should be made publicly available.** It notes that HHAs can review and appeal the TPS and payment adjustment provided in the Annual Total Performance Score and Payment Adjustment Report. The information included that might be considered for public reporting includes the agency name, address, TPS, payment adjustment percentage, performance information for each measure, state and cohort information, and percentile ranking.

F. Impact Analysis of HHVBP Model

CMS does not believe the proposed changes in this 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 proposed rule includes estimates of the distribution of payment adjustments under the model using performance year data for 2016, the first year of HHVBP, and taking into account the changes proposed 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 62 in the proposed rule, summarized below, displays the estimated distribution of possible payment adjustments being used in PYs 4 and 5 of the HHVBP model.

Payment Adjustment Distribution by Percentile of Quality TPS (from Proposed Rule Table 62)			
	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 63 in the proposed rule shows the estimated distribution of payment adjustments by state and stratified by small/large volume HHAs. Among other impacts the table shows that under the proposed 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 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 proposed 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 65, which is reproduced as an Attachment to this summary, shows the current and proposed weights for measures in the HHVBP Model. As noted above, the table includes the weightings for HHAs that have scores for all measures and those for which the claims measures or HHCAHPS measures are missing and the remaining classifications are re-weighted. Under the proposed rule the number of HHAs without claims or HHCAHPS measures that do not have enough measures to receive a payment adjustment would drop from 99 to 73, and the majority of these would be smaller HHAs (16 of the 26 HHAs). This table also displays the weights that would result if in the final rule the proposed reweighting is adopted but the proposed changes to HHVBP measures changes are not.

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 comments it sought and received during the 2018 rulemaking regarding 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. 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, CMS 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.

C. Removal Factors for Previously Adopted HH QRP Measures

Elsewhere in the proposed rule, CMS discusses the Meaningful Measures Initiative[24], 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 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.

As part of this review, CMS evaluated the current six criteria that it uses to consider removing measures from the HH QRP and is proposing to replace these with the seven factors adopted by the various other Medicare provider quality reporting programs.[25] The proposed seven 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; and 7) collection or public reporting of the measure leads to negative unintended consequences other than patient harm.

The proposed Factor 8 would be that the costs associated with a measure outweigh the benefit of its continued use in the program. CMS notes that there are different types of costs associated with measures. These include the direct cost of information collection and submission of quality measures to CMS; the provider and clinician cost associated with complying with quality program requirements; the provider and clinical cost associated with participating in multiple quality programs and tracking similar or duplicative measures across programs; the CMS cost associated with program oversight of the measure; and the provider/clinician cost associated with compliance with other federal or state regulations (if applicable).

In considering the case-by-case application of the proposed Factor 8, CMS says it 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. CMS notes that none of the factors results in automatic removal; these are considerations that are taken into account on a case-by-case basis. Further, readers are reminded that measure removal is subject to notice and comment rulemaking unless a measure is determined to cause patient safety concern.

[24] See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-instruments/QualityInitiavevGenInfo/MMF/General-info-Sub-Page.html.

[25] The current six removal criteria adopted for the HH QRP are not listed in the proposed rule, but they are identical to the first six of the seven proposed removal factors listed above. The six criteria can be found in the FY 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 proposes to remove seven measures beginning with the 2021 QRP out of the 31 currently adopted measures. The proposed measure removals are summarized in the following table. The proposed measure set is displayed below.

Measure	**Rationale for Removal**	**Data Submission and Public Reporting Changes (if finalized)**
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 would continue as a risk adjustor for other measures.[26] Public reporting until January 2021.
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. Public reporting until January 2021.
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 percentile scores were both 100%.	OASIS Item M1910 (falls risk assessment) no longer submitted beginning 1/1/20. Public reporting until January 2021.
4. Pneumococcal Polysaccharide Vaccine 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. Public reporting until January 2021.
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	OASIS Items M1340, (Does patient have a Surgical Wound?) and M1342, (Status of Most Problematic

[26] 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 (if finalized)
	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.	Surgical Wound) no longer required beginning 1/1/20 but reporting would continue as a risk adjustor for other measures.[27] Public reporting until January 2021.
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 January 2020.
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.

Summary Table: Measure Set Proposed for the 2021 HH QRP
(2020 Measures Proposed for Removal in Italics)

Short Name	Measure Name & Data Source
OASIS-based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167)
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674)
Application of Functional Assessment	Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631)
Bathing	Improvement in Bathing (NQF #0174)
Bed Transferring	Improvement in Bed Transferring (NQF #0175)
Depression Assessment	*Depression Assessment Conducted*
Diabetic Foot Care	*Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care (NQF #0519)*
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
Falls Risk	*Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate*

[27] 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.

Short Name	Measure Name & Data Source
	(NQF #0537)
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)
PPV	*Pneumococcal Polysaccharide Vaccine Ever Received (NQF #0525)*
Pressure Ulcers*	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Surgical Wounds	*Improvement in Status of Surgical Wounds (NQF #0178)*
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)
ED Use without Readmission	*Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF #2505)*
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
Rehospitalization	*Rehospitalization During the First 30 Days of Home Health (NQF #2380)*
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 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, 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 proposes to revise 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 HH VBP 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 proposed rule, CMS does 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 proposes to modify the 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.

Measures 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	1 years of claims data: 2017 *Proposed 2 years: 2016 and 2017*

H. Impact Analysis of HH QRP

The proposed removal of seven measures from the HH QRP is estimated to reduce the burden associated with OASIS data collection for a net $60 million in annualized cost savings to HHAs. This estimate uses a 7 percent discount relative to 2016 over a perpetual time horizon 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

1. Current Home Infusion Therapy Coverage within Fee-for-Service (FFS) Medicare

Currently, FFS Medicare covers home infusion services under one or more benefits: home health, Part D, or durable medical equipment under Part B (Part B-DME); beneficiary costs, therefore, are variable. CMS states that home infusion therapy requires several components including the drug itself, drug delivery equipment and supplies (e.g., infusion pump, tubing), and professional services (e.g., patient education, catheter site care).[28] Coverage limitations may vary with benefit category; for example, the Part B-DME benefit covers only certain diseases and drugs and requires very limited professional service provision by the DME supplier. Suppliers are Medicare-enrolled pharmacies that provide external infusion pumps and supplies and that maintain licensure in the states where they deliver infusions. Suppliers are expected to provide training in equipment use; some also choose to provide additional professional services (e.g., catheter care, patient assessment) for which there is no added reimbursement. Some Medicare Advantage (MA) plans provide more generous home infusion benefits than FFS Medicare.

2. Legislative Changes Related to Home Infusion Therapy

The 21st Century Cures Act (Pub. L. 114-255) adds a separate Part B benefit category for "home infusion therapy services", effective January 1, 2021. Such services must be delivered under a physician-ordered plan of care to an eligible beneficiary under the care of an applicable provider (physician, nurse practitioner, physician assistant) and must be furnished in the patient's home by a qualified home infusion therapy supplier. The benefit covers professional services (including nursing) consistent with the care plan; training and education (other than basic DME equipment instruction); remote monitoring; and other monitoring services. The Part B-DME benefit will continue to provide home infusion drug, equipment, and supply coverage. Additional Cures Act provisions address practitioner involvement, professional service details, standards for accrediting suppliers, designation of accrediting organizations, and payment parameters.

The Bipartisan Budget Act of 2018 (Pub. L, 115-123, BBA 2018) establishes a "temporary transitional payment" for home infusion therapy services for CY 2019 and 2020 (ending with the January 1, 2021 effective date of home infusion therapy services benefit. In the rule, CMS proposes regulations (definitions, eligibility, and payment parameters) for transitional payment implementation.

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

B. Standards for Home Infusion Therapy Services

1. Approach to Standard Setting

The Cures Act directs the Secretary to designate organizations to accredit home infusion therapy services suppliers no later than January 1, 2021. The designated accrediting organizations (AOs) will assess supplier compliance with AO standards. Currently, six AOs offer accreditation to home infusion therapy suppliers; accreditation is typically required by commercial payers.[29] To develop standards specific to Part B home infusion therapy services, CMS staff reviewed existing standards from the six AOs as well as publications from government and industry sources. CMS concluded that all six AOs had very similar standards in core content areas and that those standards would be adequate to protect Medicare beneficiaries. CMS, therefore, proposes to limit development of new AO standards to those content areas specified in statute. **CMS seeks comments on this approach to standard-setting, if additional standards are needed, and if more burden would be imposed by additional standards.**

2. Requirements for Suppliers of Home Infusion Therapy Services

CMS proposes to add requirements for suppliers of the new Part B home infusion therapy services benefit., at 42 CFR part 486, Subpart I. A qualified home infusion therapy supplier would be accredited by an AO designated by the Secretary and furnishes infusion therapy services to individuals with acute or chronic conditions on a 7-day-a-week, 24-hour-a-day basis (§486.505). CMS also proposes that the supplier will ensure that each patient is under the care of an applicable provider and has a plan of care established by a physician prescribing the home infusion therapy services to be furnished. The care plan is to be periodically reviewed by the physician, though CMS does not propose care plan review timelines (§486.520). CMS further proposes that, consistent with the care plan, a qualified home infusion therapy supplier will provide professional services (including nursing); patient training and education; and remote monitoring and monitoring services (§486.525). Ongoing monitoring allows evaluation of response to treatment, detection of adverse drug reactions or other complications, and determination of patient compliance. CMS discusses the types of ongoing monitoring that could be included. Direct monitoring occurs during home visits for professional services. Remote monitoring can be performed via multiple communication methods guided by patient preferences (e.g., telephone, electronic mail, videoconferencing), provided privacy and security are properly protected.

CMS invites comments on the proposed care plan requirements and asks if review timeframes should be specified. CMS seeks comments regarding the required supplier services as proposed.

[29] The six existing 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.

C. Accrediting Organization Approval and Oversight

1. Background

As previously noted, six AOs already accredit home infusion suppliers as part of their deeming accreditation of home health agencies but have not been separately approved by Medicare to accredit suppliers for the new home infusion therapy services benefit category. CMS proposes to invite national AOs to apply for designation by the Secretary as approved infusion supplier accreditors. CMS plans a Federal Register solicitation notice for this purpose, to be published after the 2019 HH PPS final rule is released. Each AO's application would be required to describe an accreditation program that is separate from that AO's home health accreditation program, has distinct (infusion-supplier-specific) accreditation survey processes and standards, meets all requirements for application to CMS as proposed in §488.1010, and include supplier requirements that are at least as stringent as Medicare's requirements (proposed 42 CFR Subpart I). The application would contain a crosswalk table linking the AO's exact standards language to the corresponding Medicare requirements. CMS also proposes that continued infusion therapy payments (e.g., Part B-DME) to existing suppliers who are accredited currently by the six active AOs would be contingent upon their AOs submitting applications to be Medicare-approved home infusion therapy AOs. 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 invites comments on its proposals regarding applications from existing national AOs.**

CMS also reviews two statutory special rules. The first is applicable if the Secretary were to remove a home infusion therapy AO from the designated AO list. Any supplier accredited by that AO while the AO is designated, shall be considered as accredited by a designated AO for the remainder of the supplier's accreditation period. The second applies if a supplier is accredited before January 1, 2021 by an AO designated by the Secretary as of January 1, 2019. That supplier shall be considered to have been accredited by a designated AO as of January 1, 2023, for the remaining period such accreditation is in effect. CMS does not propose any regulations related to the special rules.

2. Proposed Processes and Standards for AOs with CMS-Approved Accreditation Programs

a. Considerations for Establishing Regulatory Requirements

CMS intends to implement a comprehensive, consistent, and standardized set of regulations specific to home infusion therapy supplier AOs. To that end, CMS proposes to add 42 CFR 488 Subpart L to guide the agency's oversight and approval of those AOs. CMS considered applying existing regulations at §488.1- 488.13 to AO oversight, but upon review found that multiple sections were not applicable to home infusion therapy AOs and suppliers. **CMS seeks comment on the decision not to use the existing regulations.**

b. Validation Process Considerations

CMS is choosing not to propose a formal validation process for CMS-approved home infusion therapy AOs for several reasons. Validation surveys typically are conducted by state survey agencies within 60 days of an AO's on-site survey in response to CMS Regional Office requests. However, home infusion therapy is not included in the Secretary's agreement with state agencies for validation surveys, so contractor usage would be required to implement a validation program. CMS also notes that small sample size, given the limited number of home infusion therapy suppliers, could impair the validity and generalizability of the survey data collected. CMS believes that the proposed Subpart L regulations will facilitate performance, comparability, and program standards reviews of home infusion therapy AOs. Finally, CMS asserts that data submission by AOs required under Subpart L will support ongoing AO performance monitoring.[30] **CMS seeks comment on the decision not to propose a validation process.**

c. Subpart L Regulations

CMS provides an extensive and detailed discussion of the proposed regulations, from which highlights are provided below. (Readers interested in specific regulations should consult the preamble and regulatory text directly for full details.) CMS' statutory authority for these regulations is reprised at §488.1000 and definitions are provided at §488.1005.

AO Application and Reapplication Procedures (§488.1010)
Major activities or characteristics required of AOs under the proposed regulations during application and reapplication processes include the following:

- Be a "national accrediting organization" (the accreditation program is active, fully implemented, operational, and widely dispersed geographically) (§488.1010)(a)(1)).
- Demonstrate ability to take into account the capacities of rural home infusion suppliers, including supplier numbers and their service limitations (§488.1010)(a)(3)).
- Crosswalk the Medicare requirements (see summary section VI.B.2) to the corresponding AO standards to demonstrate that the latter meet or exceed Medicare stringency (§488.1010)(a)(5)).
- Provide a detailed description of the AO's survey processes (§488.1010)(a)(6)); establish procedures for all types of survey activities, ensure the activities are unannounced, and follow-up off-site audits with periodic onsite visits (§488.1010)(a)(7)).
- Acknowledge that the AO agrees to routinely provide CMS with information extracted from each evaluation activity and to provide upon request any other evaluation-related information including corrective action plans; acknowledge that the AO agrees to notify CMS within two business days upon identifying an "immediate jeopardy situation" (a provider's or supplier's non-compliance with one or more Medicare accreditation requirements has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient) (§488.1010)(a)(6)).

[30] 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.

- Set criteria for determining the size and composition of all accreditation evaluation teams (§488.1010)(a)(8)); demonstrate sufficient staffing to perform all survey activities and describe how trained staff numbers would be maintained or increased as needed (§488.1010)(a)(9)).
- Provide education and past experience requirements for surveyors (§488.1010)(a)(10)); describe the orientation program (§488.1010)(a)(10)) and in-service training plan for surveyors and auditors (§488.1010)(a)(11)).
- Describe evaluation processes for surveyors, survey teams, and audit staff (§488.1010)(a)(12)).
- Establish policies and procedures to avoid and manage conflicts of interest involving personnel who conduct surveys and audits or who participate in accreditation decision-making (§488.1010)(a)(13)).
- Describe processes for handling a supplier's dispute of the AO's survey or audit findings or adverse decision (§488.1010)(a)(14)).
- Describe policies and procedures for investigating and responding to complaints and grievances against the AO's accredited suppliers(§488.1010)(a)(16)).
- Furnish descriptions of the AO's accreditation status decision-making process, of all types and categories of accreditation decisions and their respective durations, and of procedures for granting, withholding, or removing accreditation when suppliers fail to meet AO standards or requirements (§488.1010)(a)(17)).
- Agree that the AO will notify CMS within 3 business days of any decision to revoke, terminate, withdraw, or revise a supplier's accreditation status (§488.1010)(a)(17)).
- Provide a list of suppliers currently accredited by the AO and a list of survey activities scheduled by the AO within six months after application submission (§488.1010)(a)(18-19)); provide a list of the AO's proposed accreditation fees (§488.1010)(a)(24)).
- Describe the AO's data management and analysis system for its surveys and accreditation decisions and how the data are used to assure the AO's compliance with Medicare requirements (§488.1010)(a)(21)).
- Agree in writing to submit timely, accurate, and complete data as CMS determines necessary to evaluate the AO's performance (§488.1010)(a)(21); furnish the AO's three most recent annual audited financial statements to CMS (§488.1010)(a)(22)).
- Agree in writing to procedures specified by CMS for notifying its accredited suppliers upon voluntary or involuntary termination of the AO from the designated AO list, including the implications for payments to the suppliers; agree to work with CMS to redirect its suppliers to other designated AOs (§488.1010)(a)(23)).
- Submit AO-initiated changes to standards or survey processes in writing to CMS at least 60 days in advance and agree not to implement changes without prior approval from CMS; respond within 30 days to CMS notices of regulatory changes including any related AO standards or process changes to ensure the AO meets or exceeds Medicare's requirements (§488.1010)(a)(23)).
- Respond to notices from CMS requesting more information to facilitate the agency's decision to approve or deny the AO's application for designation as a Medicare-approved AO for home infusion therapy services (§488.1010)(b)).

Proposed steps in processing AO applications by CMS include the following:

- Upon receipt, the AO's application is assigned to a CMS technical review team to assess completeness; the team will notify the AO of any missing elements (§488.1010).
- Upon receipt of a complete application package, CMS will trigger a 30-day public comment period on the application by publishing a Federal Register notice (§488.1020).
- CMS will finish reviewing the AO's application within 210 days of receiving a complete application package, during which time the AO may voluntarily withdraw its application (§488.1010); CMS will publish a final decision in the Federal Register that will specify reasons for application denial when the decision is negative, after which publication the AO can no longer voluntarily withdraw its application (§488.1020).
- After voluntary application withdrawal or a CMS denial, an AO can resubmit the application after addressing the issues leading to withdrawal or denial unless a request for reconsideration of a CMS denial is pending (§488.1015).

CMS seeks comment on the proposed AO application and reapplication requirements and their associated burden; the application resubmission requirements; on the public notice process; and on the appropriate term of approval for an AO.

Subpart L regulations also address release and use of accreditation surveys in §488.1025. CMS proposes to require each AO's accreditation agreement with each of its suppliers include supplier consent for release to CMS of the supplier's most current accreditation survey and any associated information CMS specifies (e.g., corrective action plan). CMS also proposes that a decision to deny supplier accreditation may be made based on the agency's review of the survey materials, independent of the AO's accreditation decision. Finally, CMS proposes that disclosing survey information would be prohibited except when requested during a CMS enforcement action. **CMS invites comments on release of supplier accreditation survey information as proposed.**

Ongoing CMS Oversight of Approved AOs (§488.1030)

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

- Performance review: targets AO survey activity and Subpart L requirements and part of routine, ongoing CMS oversight of AOs.
- Comparability review: targets comparison of AO standards with Medicare requirements to assure AO standards meet or exceed Medicare requirements, triggered by changes in AO standards or Medicare requirements.
- Accreditation program review: opened when substantial noncompliance is suspected or demonstrated by a performance or comparability review.

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.[31] When revised AO standards are received by CMS, comparability would be determined within 60 days of revision receipt and conveyed to the AO.[32] 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.

CMS proposes 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 must be stated.[33] AO implementation of standards determined not to be comparable by CMS could trigger an accreditation program review.

When evidence is found of substantial noncompliance by an AO with Medicare requirements, CMS proposes to initiate an accreditation program review and 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 correction action plan review within 30 days of receipt. CMS proposes 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 proposes to immediately revoke approval if continued approval places beneficiaries in immediate jeopardy or is hazardous to public health.
CMS seeks comments on the ongoing review process as proposed and any associated burden.

CMS proposes 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 (§488.1035). CMS proposes that the agency be permitted to conduct an onsite inspection of AO offices and operations at any time. Reasons for such visits are limited (e.g., during a probationary period, for assuring the accreditation program is fully implemented), and the AOs must be notified of the planned visit. **CMS invites comments on its proposals about onsite visits and any related burden.**

Termination and Appeal (§488.1045)

CMS proposes 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

[31] 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.
[32] 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.
[33] No response by CMS within 60 days would trigger deemed approval of the AO's proposed revisions.

therapy suppliers at least 90 days in advance of the termination date. A second notice to suppliers is required ten 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 proposes that the AO must notify all of its suppliers within 30 days of publication of the termination notice in the Federal Register. The AO must inform the suppliers about implications for supplier payments if the supplier's accreditation were to lapse. For both voluntary and involuntary AO terminations, CMS proposes 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 must 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.

CMS proposes that an approved AO must complete three steps before an accredited supplier's request for withdrawal of accreditation would become effective.

(1) The AO must directly contact the supplier for written confirmation of the supplier's request to withdraw from the AO's accreditation program.

(2) The AO must 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 must submit a final notice of supplier withdrawal from accreditation to CMS within five days after the withdrawal becomes effective.

CMS proposes 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. 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 office could not issue subpoenas and would produce a written report of findings and recommendations within 45 days after the hearing ends. The hearing officer's decision is final.

3. Impact Analysis

In the regulatory impact analysis section of the proposed rule, CMS estimates a cost burden of $23,258 for each existing home infusion therapy AO to comply with the proposed AO approval and oversight regulations (§§488.1010 through 488.1050). CMS does not calculate a total burden as not all activities would have to be performed by all six existing AOs each year.

CMS states it cannot accurately estimate AO burden related to AO accreditation of home infusion drug therapy suppliers as no AOs have yet been approved and no suppliers yet accredited. **CMS seeks comments on how to estimate this burden.**

CMS estimates little new burden to home infusion therapy suppliers as they are already accredited by AOs in order to provide services for other payers. There would be a new accreditation fee which has not yet been set by any AO since no AO is yet Medicare-approved for this service. Existing AO accreditation fees are approximately $6,000 - $12,000.

D. Payment for Home Infusion Therapy Services

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

a. Payment Description and Duration

Section 50401 of the BBA of 2018 established a home infusion therapy services "temporary transitional payment". Payment is made for professional services (including skilled nursing), training and education, remote monitoring, and monitoring services furnished in coordination with transitional home infusion drug administration. These items and services parallel those that will be provided under the new home infusion therapy services benefit established by the Cures Act (described previously in the rule and in this summary). The temporary transitional payment becomes effective on January 1, 2019 and remains in effect until succeeded by the Cures Act home infusion therapy services payment on January 1, 2021. The temporary transitional payment is made to an "eligible home infusion supplier" separately from payment made for under the Part B-DME benefit for an external infusion pump and its associated transitional home infusion drug.

b. Definitions to Operationalize the Temporary Transitional Payment

As defined in the statute, a transitional home infusion drug is a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME. The statute also provides that:

- 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.

CMS proposes 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 builds on 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, when services begin on one calendar day continue into to the next, the drug administration calendar day is 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 is not an infusion drug administration calendar day.

c. Temporary Transitional Payment Categories

The statute requires the Secretary to establish three categories of payment and specifies the Healthcare Common Procedure Coding System (HCPCS) codes to include in each category. Payment categories for subsequent drug additions to the LCDs and compounded infusion drugs not otherwise classified (J codes J7799 and J7999) will be determined by the Medicare administrative contractor (MACs). The transitional home infusion drugs and their payment categories are shown in the table below.

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
J0895	deferoxamine mesylate
J1170	hydromorphone
J1250	dobutamine hydrochloride
J1265	dopamine
J1325	epoprostenol
1455	foscarnet sodium
J1457	gallium nitrate
J1570	ganciclovir sodium
J2175	meperidine hydrochloride
J2260	miltinone lactate
J2270, J2274	morphine sulfate
J2278	ziconotide
J3010	fentanyl citrate
J3285	treprostinil
J code	**Category 2****
J1555 JB	cuvitru
J1559 JB	hizentra
J1561 JB	gamunex-c/gammaked
J1562 JB	vivaglobin
J1569 JB	gammagard
J1575 JB	hyqvia
J code	**Category 3*****
J9000	doxorubicin hydrochloride
J9039	blinatumomab
J9040	bleomycin sulfate
J9065	cladribine
J9100	cytarabine
J9190	fluorouracil
J9200	floxuridine
J9360	vinoblastine sulfate
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 drugs

d. Payment Amounts

The statute specifies that the payment amounts for each infusion drug administration calendar will equal the Physician Fee Schedule (PFS) payment without any geographic adjustments as of January 1, 2018 (or as subsequently modified by the Secretary) using certain HCPCS codes as shown in the table below. Also specified by statute, when drugs in more than one payment category are furnished on the same infusion drug administration calendar day, Medicare will make a single payment at the rate of the payment category with the highest payment.

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 hours, single or initial substance/drug	1
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	3

e. Billing

For temporary transitional payment billing, CMS proposes to create three HCPCS G-codes, one for each payment category. The eligible home infusion supplier would submit a claim with a single G-code for home therapy infusion services furnished on each infusion drug administration calendar day along with reporting the time spent delivering those services. The same supplier also would submit a claim for the DME equipment, supplies, and drug utilized on that date. The G-code could be billed on the same or a separate claim form as the DME, but in either case all claims will be processed by the DME MAC.

f. Impact Analysis

In the regulatory impact analysis section of the proposed rule, CMS estimates a net increase of approximately $60 million in Medicare payments to home infusion suppliers in 2019, reflecting services provided under the temporary transitional payment for home health infusion therapy. CMS does not expect an increase in beneficiaries receiving home infusion therapy services since referral patterns are likely to remain unchanged. The temporary transitional payment applies only to existing Medicare home infusion suppliers. Existing suppliers already are enrolled as DME suppliers of external infusion pumps and supplies (including infused drugs) but have not been separately reimbursed previously for providing these services under the DME benefit.

CMS presents an analysis using data extracted from 2017 beneficiary DME infusion therapy claims. The analysis reflects that anticipated patient costs are variable across the proposed payment categories; the categories serve as cost proxies for the volume and intensity of professional services that would be required. Table 66 from the rule is duplicated below and shows the estimated increased costs by payment category.

TABLE 66: ESTIMATED INCREASED COSTS OF EXISTING DME HOME INFUSION PATIENTS NOW RECEIVING COVERED HOME INFUSION THERAPY SERVICES, CY 2019

Payment Category	Number of Beneficiaries	Total Weeks of Care	Estimated Total Visits	2018 Payment Rate	Estimated Cost
1	5,885	130,896	136,781	$141.12	$19,302,535
2	6,315	236,470	75,780	$224.28	$16,995,938
3	5,774	87,260	93,034	$239.76	$22,305,832
Total	17,974				$58,604,305

2. Payment Considerations for CY 2021 and Subsequent Years (Cures Act benefit)

a. Required Payment Parameters

The home infusion therapy services benefit category created by the Cures Act becomes effective January 1, 2021, superseding the temporary transitional payment established by BBA 2018. Previously in the rule, CMS has offered many proposals related to the Cures Act benefit, particularly about the supplier accreditation mechanism. Payment proposals are comparatively few and generally address Cures Act benefit payment parameters that are shared with the temporary transitional payment. CMS anticipates addressing payment for the Cures Act benefit more fully through future rulemaking and uses the current rule to pose questions and to solicit comments related to future payments.

CMS reprises the services covered by the Cures Act benefit and notes the applicability to that benefit of the infusion drug administration calendar day definition proposed for the transitional payment; CMS anticipates retaining the definition. **CMS seeks comment on the proposed definition.** The Cures Act sets several payment parameters for the new benefit category: a single daily payment; payment does not exceed that for five hours of infusion drug therapy provided in

a physician's office under the Physician Fee Schedule (PFS); must be adjusted for patient acuity, drug administration complexity and costs that vary by region; and may be adjusted for outliers or other factors identified by the Secretary. CMS notes that the payment categories as defined for the transitional payment reflect therapy type and drug administration complexity, but **CMS invites comments on other ways to account for these factors and on ways to capture patient acuity.** CMS observes that the PFS geographic practice cost indices (GPCIs) incorporate regional wage variation and so will consider using GPCIs to adjust the home infusion therapy services payment. **CMS solicits feedback on possible home infusion therapy outlier scenarios and potential outlier benefit payment designs.**

b. Billing

Billing for the Cures Act benefit could involve a DME claim with or without a Part B practitioner claim depending upon the types of infusion therapy suppliers and providers for each patient (e.g., physicians, HHAs, pharmacists). The qualified home infusion therapy services supplier must be enrolled in Medicare as a Part B Home Infusion Therapy supplier, while furnishing the DME equipment, supplies, and drug will still require DME supplier enrollment. Part B practitioner claims are processed by A/B MACs that are capable of geographic wage adjustments. **CMS seeks comment on whether requiring two separate claim forms be submitted is reasonable. CMS more generally seeks comment on the unit of single payment, payment limitations, and payment adjustments, as well as mechanisms for home infusion therapy supplier billing.**

3. Professional (Nursing) and Monitoring Services

Determination of the reasonable and necessary number of infusion therapy visits needed to support safe infusion drug self-administration is guided by the physician-ordered plan of care. CMS expects that suppliers will consider the extent of patient (and caregiver) training and education needed given the administration complexity of the prescribed drug and as the care plan evolves. CMS believes that most patients will have central venous access devices and will need training and education about device usage (e.g., accessing, site care, flushing). CMS also anticipates suppliers will deliver training and education about their medications (including specifics of their self-administration such as handling and storage) and management of their diseases, including self-monitoring. **CMS invites comments about what constitutes a reasonable and necessary amount of training and education.**

CMS expects that patient monitoring also will be part of the home infusion therapy professional services. The supplier will need to evaluate and assess the patient in person periodically; blood draws for diagnostic testing may be indicated. The supplier may also monitor the patient remotely (e.g., telephone, electronic mail, videoconferencing). In some cases, patients will upload clinical data (e.g., weight, blood pressure) for transmission to a remote monitoring service center; if abnormalities are detected, the home infusion therapy supplier would be contacted. **CMS solicits comments on additional interpretations of professional, nursing, training and education, and monitoring services for consideration under the home infusion therapy benefit, especially on the use of remote monitoring.**

4. The Role of Prior Authorization

The statute awards discretion to the Secretary to apply prior authorization for home infusion drug therapy services. CMS does not make a specific proposal but would maintain the discretion to decide if and how extensively to require prior authorization; considerations might involve the type of drug or home visit frequency. **CMS seeks comments as to whether and how prior authorization could potentially be utilized for home infusion therapy.**

5. Interactions Between Home Infusion Therapy and Home Health

Home infusion drug therapy does not require the patient to be homebound; conversely, homebound patients receiving home health services also may require home infusion drug therapy. A single HHA might provide home health and home infusion therapy services to a patient, in which circumstance the HHA would submit claims for both types of services. **CMS solicits feedback on the relationship between the Medicare home health benefit and the home infusion therapy benefit, including how payment would be made when an eligible beneficiary requires both home health and home infusion therapy services.**

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

CMS proposes two changes to the regulations regarding the organizations that it approves to accredit HHAs as well as other Medicare-certified providers and suppliers, including hospitals, skilled nursing facilities, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, and ambulatory surgical centers. If an accrediting organization (AO) applies to CMS and is recognized as having standards that meet or exceed Medicare requirements, any provider or supplier accredited by the AO's CMS-approved accreditation program may be deemed by CMS to meet the Medicare conditions or requirements. CMS approval of accreditation programs is made for up to six years.

Under the first proposed change, AOs for Medicare-certified providers and suppliers would be required to include a written statement in their application which states 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. CMS says it makes this proposal because it has received numerous complaints from facilities that have notified an AO of their intent to withdraw their accreditation and the AO terminates their accreditation immediately without regard to their current accreditation status, up to date payment of fees, contract status, or the facility's requested effective date of withdrawal. CMS believes it is not reasonable for AOs to penalize facilities this way. Medicare certified providers and suppliers may freely choose to demonstrate compliance with the Medicare conditions by receiving surveys from any CMS-approved AO of their choice, or the state survey agency.

Second, new requirements for training for AO surveyors would be added to the AO oversight regulations. Specifically, all AO surveyors would be required to complete the relevant program-specific CMS online trainings consistent with requirements established by CMS for state surveyors. This training is available to the public on the CMS website at any time. AOs would be required to document to CMS that each of their surveyors has completed the CMS online surveyor training. Failing to provide this documentation could result in CMS placing the AO on an accreditation program review (See 42 CFR 488.8(c)).

CMS makes this proposal because there is a historically high "disparity rate" between survey results by AOs and the state survey agencies conducting validation surveys of the AOs. AOs have consistently failed to find the same condition level deficiencies in the care provided by the hospital or other provider surveyed that were found by the state survey agency. CMS believes this discrepancy can largely be attributed the difference in the training and education provided to the AO surveyors, which varies among AOs and is not consistent. It expects that completion of the same surveyor training by both SA and AO surveyors would increase consistency between the surveys.

In the impact analysis section of the rule, CMS reports that there are currently nine AOs that accredit Medicare-certified providers and suppliers, and it estimates that the cost across all of them to comply with the proposed training requirement would total between $143,208 and $238,680. This assumes 30 to 50 hours of training for 15 surveyors for each affected AO. Only minimal costs are estimated for the proposed requirement that AOs include a written statement in the application that accreditation would be extended until the effective date of any elective withdrawal by the provider or supplier. The estimate totals $158 across all nine AOs; CMS notes that these costs would not all be incurred at the same time as AO renewals occur at different times.

VIII. Requests for Information

CMS makes two requests for information as part of this proposed rule. The usual procedures and disclaimers associated with RFIs are included.

A. Request for Information on Promoting Electronic Interoperability

CMS discusses the status of adoption of health IT among Medicare and Medicaid participating providers. It says that as of 2015, 96 percent of hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care, yet significant obstacles to electronic exchange of health information remain. It reviews CMS and Office of National Coordinator (ONC) initiatives and regulatory activities aimed at advancing health information exchange. The January 2018 ONC draft Trusted Exchange Framework and Common Agreement (TEFCA)[34] is highlighted.

[34] The draft is available at https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

CMS is interested in feedback from stakeholders on how it should use the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities to advance electronic exchange of health information in support of care transitions between hospitals and community providers. As an example, CMS says it might consider revising the hospital CoPs to require that hospitals electronically transfer medically necessary patient information to the other facility when a patient is transferred. Similarly, it might require that hospitals electronically send discharge information to a patient's community provider when possible, and to provide discharge instructions electronically to patients or a third-party application, if requested.

Relevant provisions of proposed CoP regulations are discussed including the November 3, 2015 proposed rule to implement provisions of the IMPACT Act (80 FR 68126), June 16, 2016 proposed changes to CoPs for hospitals and CAHs (81 FR 39448), and an October 4, 2016 final rule on requirements for LTC facilities (81 FR 68688).

In this rule, CMS requests stakeholder feedback on the following questions:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?

- Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

In addition, CMS discusses the MyHealthEData initiative to promote patient access to their medical records and the Blue Button 2.0 initiative for beneficiary access to Medicare claims information through API technology.

CMS seeks ideas from the public on how best to accomplish the goal of fully interoperable health IT and EHR systems for providers and suppliers and how to advance the MyHealthEData initiative for patients. In particular, it would like to identify fundamental barriers to interoperability and patient access and how they might be reduced through revisions to the CoPs, CfCs, and RfPs for hospitals and other Medicare providers and suppliers. CMS has a particular interest in hearing about issues for providers and suppliers who are ineligible for the Medicare and Medicaid EHR Incentives program, such as long-term care and post-acute care providers, behavioral health providers, clinical laboratories and social service providers.

B. Request for Information on Price Transparency: Improving Beneficiary Access to HHA Charge Information

The Affordable Care Act established section 2718(e) of the Public Health Service Act. This provision requires each hospital operating within the United States to make public a list of its standard charges for items and services including for diagnosis-related groups according to guidelines established by the Secretary. In the FY 2015 IPPS/LTCH rule (79 FR 50146), CMS reminded hospitals of their obligation to comply with this provision by making public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH proposed rule, CMS updated its guidelines effective January 1, 2019 to require hospitals to make available a list of their current standard charges via the internet in a machine-readable format and to update this information at least annually. All providers are encouraged to engage in consumer-friendly communication of their charges to help patients understand their potential financial liability for services and to enable comparison of charges across providers, and to update this information at least annually.

The proposed rule describes CMS' concern that challenges continue to exist for patients due to insufficient price transparency. Such challenges include surprise billing for out-of-network physicians and chargemaster data that are not helpful in estimating what a patient is likely to pay for a service.

CMS is considering ways to improve the accessibility and usability of current charge information, and seeks comments from HHAs and all other providers and suppliers on the following:

- How should "standard charges" be defined in the home health setting? Should it be defined as average or median rates for the items on the chargemaster; average or median rates for groups of services commonly billed together, as determined by the HHA based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each item on the chargemaster or for groups of services commonly billed together? Should "standard charges" be defined and reported for both some measure of the average contracted rate and the chargemaster? Or is the best measure of an HHA's standard charges its chargemaster?

- What types of information would be most beneficial to patients, how can HHAs best enable patients to use charge and cost information in their decision-making, and how can CMS and HHAs help third parties create patient-friendly interfaces with these data?

- Should HHAs be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service? How can information on out-of-pocket costs be provided to better support patients' choice and decision making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how co-pays and co-insurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should HHAs play any role in helping to inform patients of what their out-of-pocket obligations will be?

- If HHAs were required to provide patients with information on what Medicare pays for services, what changes would be needed to be made by HHAs? What burden would such a requirement add?

In addition, CMS seeks comment on the following questions involving how to improve a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care?
- What challenges do providers face in providing information about out-of-pocket costs to patients with Medigap?
- What changes would be needed to support providers sharing out-of-pocket cost information with patients that reflects the patient's Medigap coverage?
- Who is best situated to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care?
- What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

IX. Regulatory Impact Analysis

CMS provides a regulatory impact analysis (RIA) because the proposed 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	+ 2.1%	+$400 million
Decrease of FDL ratio	+0.1%	+$20 million
New rural add-on provision	-0.1%	- $20 million
Net impact	+2.1%	+$400 million

CMS estimates that the net impact of the HH PPS policies in this rule is an increase of 2.1 percent, or $400 million, in Medicare payments to HHAs for 2019. This estimate does not take into account the approximately $60 million in additional Medicare payments 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 59 on pages 521-523 of the display copy 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 HH facilities (almost 80 percent of all facilities) would experience an average increase of payments of 2.2 percent. Government-based facilities would experience a 2.6 percent increase. HHAs located in the New England region would experience the smallest increase in payments of 1.4 percent compared with a 2.7 percent increase for HHAs located in the Pacific region.

Table 60 on pages 524-526 in the display copy 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 facility size. The PDGM is implemented in a budget neutral manner, but the effect of the proposed PDGM varies by specific types of providers and location. Proprietary free-standing HHAs would experience a reduction in payments of -1.2 percent. Voluntary/nonprofit free-standing HHAs are expected to average a 2.6 percent increase and government-based HHAs are expected to experience a 1.1 percent increase. Rural HHAs are expected to receive 4.0 percent increase compared with a -0.6 decrease in payment for urban HHAs. Smaller HHAs (<100 episodes) are expected to fare better, a 1.9 percent increase, compared with a reduction in payments for larger agencies (1,000 or more) of 0.2 percent.

Table 61 on pages 526-528 in the display copy 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 27 percent more (ratio of 1.27) under the PGPM model, on average, compared with what they currently receive.

CMS provides at Tables 69 thru 73 on pages 548-549 of the display copy the required accounting statements. Table 69 presents the accounting statement for HH PPS for 2019, setting out the $400 million in government payments to HHAs. Table 70 provides the accounting statement for 2019 due to the implementation of the PDGM – no savings as this will be implemented in a budget neutral manner. Table 71 shows the $60 million net burden for HHAs submission of the OASIS data. Table 72 shows the $60 million in temporary transitional payment and Table 73 shows the net burden to each home infusion therapy accreditation organization—estimated at $23,258.