account for the resource costs associated with providing home health care to those patients with functional impairments. Research has shown a relationship exists between functional status, rates of hospital readmission, and the overall costs of health care services.42 Functional status is defined in a number of ways, but generally, functional status reflects an individual's ability to carry out activities of daily living (ADLs) and to participate in various life situations and in society.43 CMS currently requires the collection of data on functional status in home health through a standardized assessment instrument: the Outcome and Assessment Information Set (OASIS). Under the current HH PPS, a functional status score is derived from the responses to those items and this score contributes to the overall case-mix adjustment for a home health episode payment.

Including functional status in the case-mix adjustment methodology allows for higher payment for those patients with higher service needs. As functional status is commonly used for risk adjustment in various payment systems, including in the current HH PPS, we proposed that the alternative case-mix adjustment methodology would also adjust payments based on responses to selected functional OASIS items that have demonstrated higher resource use. Therefore, we examined every OASIS item for potential inclusion in the alternative case-mix adjustment methodology including those items associated with functional status.

Generally, worsening functional status is associated with higher resource use, indicating that the responses to functional OASIS items may be useful as adjustors to

---

42 Burke, R. MD, MS, Whitfield, E. PhD, Hittle, D. PhD, Min, S. PhD , Levy,C. MD, PhD, Prochazka, A. MD, MS, Coleman, E. MD, MPH, Schwartz, R.MD, Ginde, A. (2016). "Hospital Readmission From Post-Acute Care Facilities: Risk Factors, Timing, and Outcomes". The Journal of Post-Acute Care and Long Term Care Medicine. (17), 249-255.

43 Clauser, S. Ph.D., 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.

construct case-mix weights for an alternative case-mix adjustment methodology. However, due to the lack of variation in resource use across certain responses and because certain responses were infrequently chosen, we combined some responses into larger response categories to better capture the relationship between worsening functional status and resource use. The resulting combinations of responses for these OASIS items are found at Exhibit 7-2 in the HHGM technical report, "Overview of the Home Health Groupings Model," on the HHA Center webpage.44

Each OASIS item included in the final model has a positive relationship with resource use, meaning as functional status declines (as measured by a higher response category), periods have more resource use, on average. As such, in the CY 2018 HH PPS proposed rule, we proposed that the following OASIS items would be included as part of the functional level adjustment under an alternative case-mix adjustment methodology:

- M1800: Grooming.
- M1810: Current Ability to Dress Upper Body.
- M1820: Current Ability to Dress Lower Body.
- M1830: Bathing.
- M1840: Toilet Transferring.
- M1850: Transferring.
- M1860: Ambulation/Locomotion.
- M1033 Risk of Hospitalization (at least four responses checked, excluding responses #8, #9, and #10).45

44 https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf
45 Exclusions of the OASIS C-1 Item M1033 include, response #8: "currently reports exhaustion"; response #9: "other risk(s) not listed in 1-8; response #10: None of the above.

In the CY 2018 HH PPS proposed rule, we discussed how under the HHGM a home health period of care receives points based on each of the responses associated with the proposed functional OASIS items which are then converted into a table of points corresponding to increased resource use. That is, the higher the points, the higher the functional impairment. The sum of all of these points' results in a functional impairment score which is used to group home health periods into a functional level with similar resource use. We proposed three functional impairment levels of low, medium, and high with approximately one third of home health periods from each of the clinical groups within each level. This means home health periods in the low impairment level have responses for the proposed functional OASIS items that are associated with the lowest resource use on average. Home health periods in the high impairment level have responses for the proposed functional OASIS items that are associated with the highest resource use on average. We also proposed that the functional impairment level thresholds would vary between the clinical groups to account for the patient characteristics within each clinical group associated with increased resource costs affected by functional impairment. We provided a detailed analysis of the development of the functional points and the functional impairment level thresholds by clinical group in the HHGM technical report 46 and in Tables 36 and 37 in the CY 2018 HH PPS proposed rule (82 FR 35321).

In the CY 2018 HH PPS proposed rule, we solicited comments on the proposed functional OASIS items, the associated points, and the thresholds by clinical group used

46 "Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements Overview of the Home Health Groupings Model" located at https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf

to group patients into three functional impairment levels under the HHGM, as outlined above. The majority of comments received were from physical therapists, physical therapy assistants, occupational therapists, and national physical, occupational, and speech-language pathology associations. Likewise, a Technical Expert Panel (TEP) was convened in February 2018 to collect perspectives, feedback, and identify and prioritize recommendations from a wide variety of industry experts and patient representatives regarding the public comments received on the proposed HHGM. Comments were very similar between those received on the CY 2018 HH PPS proposed rule and those made by the TEP participants.

Most commenters agreed that the level of functional impairment should be included as part of the overall case-mix adjustment in a revised case-mix model. Likewise, commenters were generally supportive of the OASIS items selected to be used in the functional level payment adjustment. Commenters noted that the role of patient characteristics and functional status as an indicator of resource use is a well-established principle in rehabilitation care. Some commenters stated that adopting a similar component in the home health payment system will help to remove the incentive to provide unnecessary therapy services to reach higher classifications for payment but will also move the HH PPS toward greater consistency with other post-acute care prospective payment systems. Other comments received on the functional impairment level adjustment encompassed several common themes: the effect of the IMPACT Act provisions on the HHGM; adequacy of the functional impairment thresholds and corresponding payment adjustments; potential HHA behavioral changes to the provision of home health services; the impact of the removal of therapy thresholds on HHAs; and

recommendations for the inclusion of other OASIS items into the functional impairment level adjustment.

We note that the analysis presented in the CY 2018 HH PPS proposed rule was based on CY 2016 home health episodes using version OASIS-C1/ICD-10 data set, which did not include the aforementioned IMPACT Act functional items. To accommodate new data being collected for the Home Health Quality Reporting Program 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. Because these GG functional items are not required to be collected on the OASIS until January 1, 2019, we do not have the data to determine the effect, if any, of these newly added items on resource costs during a home health period of care. However, if the alternative case-mix adjustment methodology, is implemented in CY 2020, we would continue to examine the effects of all OASIS items, including the "GG" functional items, on resource use to determine if any refinements are warranted.

Addressing those comments regarding the use and adequacy of the functional impairment thresholds to adjust payment, we remind commenters that the structure of categorizing functional impairment into Low, Medium, and High levels has been part of the home health payment structure since the implementation of the HH PPS. The current HH PPS groups' scores are based on functional OASIS items with similar average resource use within the same functional level, with approximately a third of episodes classified as low functional score, a third of episodes are classified as medium functional score, and a third of episodes are classified as high functional score. Likewise, the PDGM groups' scores would be based on functional OASIS items with similar resource

use and would have three levels of functional impairment severity: low, medium and high. However, the three functional impairment thresholds vary between the clinical groups to account for the patient characteristics within that clinical group associated with increased resource costs affected by functional impairment. This is to further ensure that payment is more accurately aligned with actual patient resource needs. As such, we believe the more granular structure of these functional levels provides the information needed on functional impairment and allows greater flexibility for clinicians to tailor a more patient-centered home health plan of care to meet the individualized needs of their patients. As HHA-reported OASIS information determines the functional impairment levels, accurate reporting on the OASIS will help to ensure that the case-mix adjustment is in alignment with the actual level of functional impairment.

Concerns regarding HHAs changing the way they provide services to eligible beneficiaries, specifically therapy services, should be mitigated by the more granular functional impairment level adjustment (for example, functional thresholds which vary between each of the clinical groups). The functional impairment level case-mix payment adjustment is reflective of the resource costs associated with these reported OASIS items and therefore ensures greater payment accuracy based on patient characteristics. We believe that this approach will help to maintain and could potentially increase access to needed therapy services. We remind HHAs that the provision of home health services should be based on patient characteristics and identified care needs. This could include those patients with complex and/or chronic care needs, or those patients requiring home health services over a longer period of time or for which there is no measureable or expected improvement.

While the majority of commenters agreed that the elimination of therapy thresholds is appropriate because of the financial incentive to overprovide therapy services, some commenters indicated that the reductions in payment for therapy visits could result in a decrease in HHA viability and could force some HHAs to go out of business, such as those HHAs that provide more therapy services than nursing. We note that section 51001(a)(3) of the BBA of 2018 amended section 1894(b)(4)(B) of the Act to prohibit the use of therapy thresholds as part of the overall case-mix adjustment for CY 2020 and subsequent years. Consequently, we have no regulatory discretion in this matter.

Several commenters provided recommendations for additional OASIS items for inclusion to account for functional impairment. Most notably, commenters suggested adding OASIS items associated with cognition, instrumental activities of daily living (IADLs), and caregiver support. The current HH PPS does not use OASIS items associated with cognition, IADLs, or caregiver support to case-mix adjust for payment. Nonetheless, the relationship between cognition and functional status is important and well-documented in health care literature so we included them in our analysis because they generally have clinical significance based on research and standards of practice. As described in the CY 2018 HH PPS proposed rule and the technical report, we examined every single OASIS item and its effect on costs. These included those OASIS items associated with cognition, IADLs, and caregiver support. Only those OASIS items associated with higher resource costs were considered for inclusion in the functional level adjustment in the HHGM. Despite commenters' recommendations, the variables suggested were only minimally helpful in explaining or predicting resource use and most

reduced the amount of actual payment. As such, we excluded variables associated with cognition, IADLs, and caregiver support because they would decrease payment for a home health period of care which is counter to the purpose of a case-mix adjustment under the HHGM. The complete analysis of all of the OASIS items can be found in the HHGM technical report on the HHA Center webpage.47

After careful consideration of all comments received on the functional level adjustment as part of an alternative case-mix adjustment methodology, we believe that the three PDGM functional impairment levels in each of the six clinical groups are designed to capture the level of functional impairment. We believe that the more granular nature of the levels of functional impairment by clinical group would encourage therapists to determine the appropriate services for their patients in accordance with identified needs rather than an arbitrary threshold of visits. While the functional level adjustment is not meant to be a direct proxy for the therapy thresholds, the PDGM has other case-mix variables to adjust payment for those patients requiring multiple therapy disciplines or those chronically ill patients with significant functional impairment. We believe that also accounting for timing, source of admission, clinical group (meaning the primary reason the patient requires home health services), and the presence of comorbidities will provide the necessary adjustments to payment to ensure that care needs are met based on actual patient characteristics. Therefore, we continue to uphold that the functional impairment level adjustment is sufficient and along with the other case-mix adjustments, payment will better align with the costs of providing services.

In summary, we are proposing that the OASIS items identified in the CY 2018

47 https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf

HH PPS proposed rule would be included as part of the functional impairment level payment adjustment under the proposed PDGM. These items are:

- M1800: Grooming.
- M1810: Current Ability to Dress Upper Body.
- M1820: Current Ability to Dress Lower Body.
- M1830: Bathing.
- M1840: Toilet Transferring.
- M1850: Transferring.
- M1860: Ambulation/Locomotion.
- M1033: Risk of Hospitalization.[48]

We are proposing that a home health period of care receives points based on each of the responses associated with the proposed functional OASIS items which are then converted into a table of points corresponding to increased resource use (See Table 41). The sum of all of these points results in a functional score which is used to group home health periods into a functional level with similar resource use. We are proposing three functional levels of low impairment, medium impairment, and high impairment with approximately one third of home health periods from each of the clinical groups within each functional impairment level (See Table 42). The CY 2018 HH PPS Proposed rule (82 FR 35320) and the technical report posted on the HHA Center webpage provide a more detailed explanation as to the construction of these functional impairment levels using the proposed OASIS items.

TABLE 41: OASIS POINTS TABLE FOR THOSE ITEMS ASSOCIATED

48 In Version OASIS C-2 (effective 1/1/2018), three responses are excluded: #8:"currently reports exhaustion", #9: "other risks not listed in 1-8", and #10: "None of the above".

WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS, CY 2017

	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%**
M1033: Risk of Hospitalization	4 or more items checked	**11**	**17.8%**

Source: CY 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, CY 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: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017(as of March 2, 2018).

Table 43 shows the average resource use by clinical group and functional level for CY 2017:

TABLE 43: AVERAGE RESOURCE USE BY CLINICAL GROUP AND FUNCTIONAL LEVEL, CY 2017

	Mean 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
MMTA - Low	$1,236.05	1,650,146	19.1%	$1,076.20	$511.06	$907.38	$1,632.74
MMTA - Medium	$1,487.24	1,709,484	19.8%	$1,162.37	$628.29	$1,202.12	$2,020.73
MMTA - High	$1,667.38	1,402,299	16.3%	$1,274.53	$719.29	$1,371.99	$2,265.39
Behavioral Health - Low	$971.26	98,193	1.1%	$845.25	$397.45	$686.39	$1,285.36
Behavioral Health - Medium	$1,309.40	93,145	1.1%	$990.34	$557.57	$1,064.55	$1,784.48
Behavioral Health - High	$1,485.06	96,899	1.1%	$1,092.42	$653.44	$1,233.97	$2,027.14
Complex - Low	$1,313.78	104,504	1.2%	$1,194.16	$553.50	$953.84	$1,669.45
Complex - Medium	$1,668.06	104,717	1.2%	$1,415.99	$694.35	$1,275.32	$2,202.65
Complex - High	$1,771.05	97,779	1.1%	$1,527.71	$704.28	$1,336.79	$2,361.61
MS Rehab - Low	$1,545.07	587,873	6.8%	$1,048.07	$779.96	$1,323.12	$2,055.60
MS Rehab - Medium	$1,731.15	536,444	6.2%	$1,111.26	$931.97	$1,527.46	$2,293.96
MS Rehab - High	$1,900.89	469,117	5.4%	$1,243.84	$1,009.66	$1,672.76	$2,520.57
Neuro - Low	$1,591.74	308,011	3.6%	$1,163.69	$744.21	$1,323.86	$2,127.18
Neuro - Medium	$1,833.25	287,788	3.3%	$1,271.31	$900.27	$1,568.22	$2,467.92
Neuro - High	$1,945.49	303,787	3.5%	$1,420.56	$899.47	$1,618.16	$2,629.54
Wound - Low	$1,663.25	275,383	3.2%	$1,271.45	$790.83	$1,328.52	$2,152.26
Wound - Medium	$1,893.35	238,063	2.8%	$1,370.79	$927.26	$1,550.78	$2,475.29
Wound - High	$2,044.09	261,144	3.0%	$1,520.35	$975.19	$1,644.10	$2,669.06
Total	$1,570.68	8,624,776	100.0%	$1,221.38	$679.12	$1,272.18	$2,117.47

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

Like the annual recalibration of the case-mix weights under the current HH PPS,

we expect that annual recalibrations would also be made to the PDGM case-mix weights. If the PDGM is finalized for CY 2020, we will update the functional points and thresholds using the most current claims data available. Likewise, we would 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 the costs of providing care. We invite comments on the proposed OASIS items and the associated points and thresholds used to group patients into three functional impairment levels under the PDGM, as outlined above.

8. Comorbidity Adjustment

The alternative case-mix adjustment methodology proposed in the CY 2018 HH PPS proposed rule, groups home health periods based on the primary reason for home health care (principal diagnosis), functional level, admission source, and timing. To further account for differences in resource use based on patient characteristics, in the CY 2018 HH PPS proposed rule, we proposed to use the presence of comorbidities as part of the overall case-mix adjustment under the alternative case-mix adjustment methodology. Specifically, we proposed a home health specific list of comorbidities further refined into broader, body system-based categories and more granular subcategories to capture those conditions that affect resource costs during a home health period of care. The proposed comorbidities included those conditions that represent more than 0.1 percent of periods and had at least as high as the median resource use as they indicate a direct relationship between the comorbidity and resource utilization.

Specifically, we proposed a list based on the principles of patient assessment by

body systems and their associated diseases, conditions, and injuries to develop larger categories of conditions that identified clinically relevant relationships associated with increased resource use. The broad, body system-based categories we proposed to use to group comorbidities within the HHGM included the following:

- Heart Disease
- Respiratory Disease
- Circulatory Disease and Blood Disorders
- Cerebral Vascular Disease
- Gastrointestinal Disease
- Neurological Disease and Associated Conditions
- Endocrine Disease
- Neoplasms
- Genitourinary and Renal Disease
- Skin Disease
- Musculoskeletal Disease or Injury
- Behavioral Health (including Substance Use Disorders)
- Infectious Disease

These broad categories used to group comorbidities within the alternative case-mix adjustment methodology were further refined by grouping similar diagnoses within the broad categories into statistically and clinically significant subcategories which would receive the comorbidity adjustment in the alternative case-mix adjustment methodology (for example, Heart Disease 1; Cerebral Vascular Disease 4). All of the comorbidity diagnoses grouped into the aforementioned categories and subcategories are posted on

the Home Health Agency Webpage and listed in the HHGM technical report at the following link: https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html

We originally proposed that if a 30-day period of care had at least one secondary diagnosis reported on the home health claim that fell into one of the subcategories, that 30-day period of care would receive a comorbidity adjustment to account for higher costs associated with the comorbidity. Therefore, the payment adjustment for comorbidities would be predicated on the presence of one of the identified diagnoses within the subcategories associated with increased resource use at or above the median. The comorbidity adjustment amount would be the same across all of the subcategories. A 30-day period of care would receive only one comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the subcategories associated with higher resource use. If there is no reported diagnosis that meets the comorbidity adjustment criteria, the 30-day period of care would not qualify for the payment adjustment.

We solicited comments on the proposed comorbidity adjustment in the CY 2018 HH PPS proposed rule, including the proposed comorbidity diagnoses and their associated subcategories, as part of the overall alternative case-mix adjustment methodology. While all commenters supported the inclusion of a comorbidity adjustment, most commenters said that a single comorbidity payment amount as part of the overall case-mix adjustment is insufficient to fully capture the home health needs and resource costs associated with the presence of comorbidities. Meeting the requirement of section 51001 of the BBA of 2018, a Technical Expert Panel (TEP) was convened in

February 2018 to collect perspectives, feedback, and identify and prioritize recommendations from a wide variety of industry experts and patient representatives regarding the public comments received on the proposed alternative case-mix adjustment methodology. Comments on the comorbidity adjustment and suggestions for refinement to this adjustment were very similar between those received on the CY 2018 HH PPS proposed rule and those made by the TEP participants. Specifically, the majority of commenters stated that the presence of multiple comorbidities has more of an effect on home health resource use than a single comorbidity and that any case-mix adjustment should account for multiple comorbidities. There was general agreement that most home health patients have multiple conditions which increase the complexity of their care and affects the ability to care for one's self at home. Several suggested that CMS should let the data help determine how many comorbidity adjustment levels there should be and what percentage of 30-day periods should be in each level. Some commenters stated they preferred specificity and complexity over simplicity if the complexity improved accuracy. Others suggested including interactions between comorbidities in the model, specifically interactions of comorbid conditions with the principal diagnosis and with other comorbidities. Commenters and TEP members alike focused on those conditions they saw as most impactful on the provision of care to home health beneficiaries. These conditions included chronic respiratory and cardiac conditions, as well as psychological and diabetes-related conditions. Most encouraged CMS to continue to develop a system to allow for appropriate changes to be made over time to the list of comorbidity subcategories that would assign a comorbidity adjustment to a 30-day period of care.

We agree with commenters that the relationship between comorbidities and

resource use can be complex and that a single adjustment, regardless of the type or number of comorbidities, may be insufficient to fully capture the resource use of a varied population of home health beneficiaries. However, we also recognize that adjusting payment based on the number of reported comorbidities may encourage HHAs to inappropriately report comorbid conditions in order to increase payment, regardless of any true impact on the home health plan of care. Currently, OASIS instructions state that clinicians must list each diagnosis for which the patient is receiving home care and to enter the level of highest specificity as required by ICD-10 CM coding guidelines. These instructions state that clinicians should list diagnoses in the order that best reflects the seriousness of each condition and supports the disciplines and services provided.49 We also note that CMS currently uses interaction items as part of the HH PPS case-mix adjustments. In the CY 2008 HH PPS final rule (72 FR 49772), we added secondary diagnoses and their interactions with the principal diagnosis as part of the clinical dimension in the overall case-mix adjustment. However, analysis since then has shown that nominal case-mix growth became an ongoing issue resulting from the incentive in the current HH PPS to code only those conditions associated with clinical points even though the data did not show an associated increase in resource utilization. Likewise, when we looked at a multi-morbidity approach to the overall case-mix adjustment to a home health period of care, for the CY 2018 HH PPS proposed rule our analysis showed that the reporting of secondary diagnoses on home health claims was not robust enough to support a payment adjustment based on the presence of multiple comorbidities. This

49 "Outcome and Assessment Information Set OASIS-C2 Guidance Manual Effective January 1, 2018 accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-C2-Guidance-Manual-Effective_1_1_18.pdf

means that the data did not show significant variations in resource use with an increase in reported comorbidities.

In spite of concerns of potential manipulation of coding patterns to increase payment due to the comorbidity adjustment, the results of our most recent analyses for this proposed rule show compelling evidence that patients with certain comorbidities and interactions of certain comorbid conditions (as described later in this section) have home health episodes with higher resource use than home health episodes without those comorbidities or interactions. The goal of our analyses was to identify those clinically and statistically significant comorbidities and interactions that could be used to further case-mix adjust a 30-day home health period of care. As a result of these analyses, we identified that there were certain individual comorbidity subgroups and interactions of the comorbidity subgroups (for example, having diagnoses associated with two of the comorbidity subgroups) which could be used as part of the comorbidity case-mix adjustment in the PDGM.

To identify these relationships with resource utilization, we looked at all diagnoses reported on the OASIS (M1021, M1023, and M1025) for each 30-day period of care. These fields represent 18 different diagnoses which could be reported on the OASIS. In the PDGM, the principal diagnosis assigns each 30-day period of care into a clinical group which identifies the primary reason the patient requires home health services. During our analysis, this usually was the reported principal diagnosis, but in cases where the diagnosis did not link to a clinical group (for example, the diagnosis could not be reported as a principal diagnosis in accordance with ICD-10 CM coding guidelines), we used a secondary diagnosis to assign the 30-day period of care into a

clinical group. Any other diagnoses, except the one used to link the 30-day period of care into a clinical group, were considered comorbidities. However, if one of those comorbid diagnoses was in the same ICD-10 CM block of codes as the diagnosis used to place the 30-day period of care into a clinical group, then that comorbid diagnosis was excluded (for example, if the reported principal diagnosis was I63.432, Cerebral infarction due to embolism of left post cerebral artery, and the reported secondary diagnosis was I65.01, Occlusion and stenosis of right vertebral artery., I65.01 would be excluded as a comorbidity as both codes are in the same block of ICD-10 diagnosis codes, Cerebrovascular Diseases, and both would group into the Neuro clinical group if reported as the principal diagnosis). Then, we checked those reported comorbid diagnoses against the home health-specific comorbidity subgroup list to see if any reported secondary diagnoses are listed in a subgroup (for example, if a reported secondary diagnosis was I50.9, Heart Failure, unspecified, this diagnosis is found in the Heart 11 subgroup).

We went through the following steps to determine which individual comorbidity subgroups would be used as part of the comorbidity adjustment:

- After dropping the comorbidity subgroups with a small number of 30-day periods of care (for example, those that made up fewer than 0.1 percent of 30-day periods of care), this left 59 different comorbidity subgroups.
- Of those, there are 56 comorbidity subgroups with a p-value less than or equal to 0.05.
- Of those 56 subgroups, there are 22 comorbidity subgroups that have a positive coefficient when regressing resource use on the comorbidity subgroups (and the interactions as described below) and indicators for the clinical group, functional level,

admission source, and timing. We determine the median coefficient of those 22 comorbidity subgroups to be $60.67.

- There are 11 comorbidity subgroups with coefficients that are at or above the median

(for example, $60.67 or above). This is a decrease from the 15 subgroups presented in the CY 2018 HH PPS proposed rule. Potential reasons for this decrease include the use of CY 2017 data in this analysis, whereas the 2018 HH PPS proposed rule used CY 2016 data; the combination and/or addition of comorbidity groups; and the inclusion of the interactions between the comorbidities.

Those 11 individual comorbidity subgroups that are statistically and clinically significant for potential inclusion in the comorbidity case-mix adjustment are listed below in Table 44:

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	Include diseases of arteries,	$365.78

	arterioles and capillaries with ulceration and non-pressure chronic ulcers	
Skin 4	Includes stages Two-Four and unstageable pressure ulcers by site	$484.83

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

Next, we examined the impact of interactions between the various comorbidity subgroups on resource use. The following steps show how we identified which interactions (for example, diagnoses from two different comorbidity subgroups) had a clinically and statistically significant relationship with increased resource utilization and could be used for the comorbidity adjustment:

- After dropping the combinations of comorbidity subgroups and interactions with a small number of 30-day periods of care (that is, those that made up fewer than 0.1 percent of 30-day periods of care), there are 343 different comorbidity subgroup interactions (for example, comorbidity subgroup interaction Skin 1 plus Skin 3). As mentioned previously, we regressed resource use on the comorbidity subgroups, the interactions, and indicators for the clinical group, functional level, admission source, and timing.

- From that regression, we found 187 comorbidity subgroup interactions with a p-value less than or equal to 0.05.

- Of those 187 comorbidity subgroup interactions, there are 27 comorbidity subgroup interactions where the coefficient on the comorbidity subgroup interaction term plus the coefficients on both single comorbidity variables equals a value that exceeds $150. We used $150 as the inclusion threshold as this amount is approximately three times that of the median value for the individual comorbidity subgroups and we believe is

appropriate to reflect the increased resource use associated with comorbidity interactions. The 27 comorbidity subgroup interactions that are statistically and clinically significant for potential inclusion in the comorbidity adjustment are listed in Table 45.

TABLE 45: COMORBIDITY SUBGROUP INTERACTIONS FOR COMORBIDITY ADJUSTMENT

Comorbidity Subgroup Interaction	Comorbidity Subgroup	Description	Comorbidity Subgroup	Description	Sum of Interaction Term Plus Single Comorbidity Coefficients
1	Circulatory 4	Hypertensive Chronic Kidney Disease	Neuro 11	Includes diabetic retinopathy and other blindness	$151.98
2	Endocrine 3	Diabetes with Complications	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia	$162.35
3	Neuro 3	Dementia in diseases classified elsewhere	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	$190.30
4	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 1	Cutaneous abscess, cellulitis, and lymphangitis	$193.33

Comorbidity Subgroup Interaction	Comorbidity Subgroup	Description	Comorbidity Subgroup	Description	Sum of Interaction Term Plus Single Comorbidity Coefficients
5	Cerebral 4	Sequelae of Cerebrovascular Diseases	Heart 11	Heart Failure	$195.55
6	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia	Renal 3	Nephrogenic Diabetes Insipidus	$202.44
7	Circulatory 10	Includes varicose veins with ulceration	Endocrine 3	Diabetes with Complications	$205.52
8	Heart 11	Heart Failure	Neuro 5	Parkinson's Disease	$212.88
9	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	$260.83
10	Neuro 3	Dementia in diseases classified elsewhere	Skin 4	Stages Two-Four and unstageable pressure ulcers by site	$274.16

Comorbidity Subgroup Interaction	Comorbidity Subgroup	Description	Comorbidity Subgroup	Description	Sum of Interaction Term Plus Single Comorbidity Coefficients
11	Behavioral 2	Mood Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	$287.42
12	Circulatory 10	Includes varicose veins with ulceration	Heart 11	Heart Failure	$292.39
13	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	$296.70
14	Renal 1	Chronic kidney disease and ESRD	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	$300.31
15	Respiratory 5	COPD and Asthma	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic	$306.63

Comorbidity Subgroup Interaction	Comorbidity Subgroup	Description	Comorbidity Subgroup	Description	Sum of Interaction Term Plus Single Comorbidity Coefficients
				ulcers	
16	Skin 1	Cutaneous abscess, cellulitis, and lymphangitis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	$390.47
17	Renal 3	Nephrogenic Diabetes Insipidus	Skin 4	Stages Two-Four and unstageable pressure ulcers by site	$422.34
18	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	$422.20
19	Heart 12	Other Heart Diseases	Skin 4	Stages Two-Four and unstageable pressure ulcers by site	$423.08

Comorbidity Subgroup Interaction	Comorbidity Subgroup	Description	Comorbidity Subgroup	Description	Sum of Interaction Term Plus Single Comorbidity Coefficients
20	Respiratory 5	COPD and Asthma	Skin 4	Stages Two-Four and unstageable pressure ulcers by site	$428.02
21	Circulatory 7	Atherosclerosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	$432.46
22	Renal 1	Chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site	$436.39
23	Endocrine 3	Diabetes with Complications	Skin 4	Stages Two-Four and unstageable pressure ulcers by site	$487.96
24	Endocrine 3	Diabetes with Complications	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	$504.54

Comorbidity Subgroup Interaction	Comorbidity Subgroup	Description	Comorbidity Subgroup	Description	Sum of Interaction Term Plus Single Comorbidity Coefficients
25	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 4	Stages Two-Four and unstageable pressure ulcers by site	$509.63
26	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site	$529.47
27	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	Skin 4	Stages Two-Four and unstageable pressure ulcers by site	$750.85

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017(as of March 2, 2018).

In order to be considered a comorbidity subgroup interaction, at least two reported diagnoses, must occur in the above corresponding combinations, as shown in Table 45. For example, one diagnosis from Heart 11 must be reported along with at least one diagnosis from Neuro 5 in order to qualify for comorbidity subgroup interaction 8. In other words, the comorbidity subgroups are not interchangeable between the interaction groups (for example, reported conditions from the Renal 1 and Respiratory 5 subgroups would not be considered an interaction for purposes of the comorbidity adjustment) .

For illustrative purposes, this would mean that if a 30-day period of care had the following secondary diagnoses 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 results in a higher level of resource use than just having a comorbid diagnosis classified in Heart 11 or in Neuro 5. There will be an updated PDGM Grouper Tool posted on the HHA Center webpage that HHAs can access to simulate the HIPPS code and case-mix weight under the PDGM.50 This Grouper Tool allows providers to fill in information, including the comorbidities, to determine whether a home health period of care would receive a comorbidity adjustment under the PDGM.

The comorbidity interactions identify subgroup combinations of comorbidities that are associated with higher levels of resource use. As such, we believe that the comorbidity adjustment payment should be dependent on whether the 30-day period of care has an individual comorbidity subgroup associated with higher resource use or there

50 https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html

is a comorbidity subgroup interaction resulting in higher resource use. Therefore, we propose to have three levels in the PDGM comorbidity case-mix adjustment: No Comorbidity Adjustment, Low Comorbidity Adjustment, and High Comorbidity Adjustment. This means that depending on if and which secondary diagnoses are reported, a 30-day period of care may receive no comorbidity adjustment (meaning, no secondary diagnoses exist or do not meet the criteria for a comorbidity adjustment), a "low" comorbidity adjustment, or a "high" comorbidity adjustment. We propose 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, as listed in Table 44, (for example, Heart Disease 11, Cerebral Vascular Disease 4, etc.) associated with higher resource use, or;
- **High comorbidity adjustment:** There are two or more secondary diagnoses reported that fall within the same comorbidity subgroup interaction, as listed in Table 45, (for example, Heart 11 plus Neuro 5) that are associated with higher resource use.

Under the PDGM, a 30-day period of care can receive payment for a low comorbidity adjustment or a high comorbidity adjustment, but not both. A 30-day period of care can receive only one low comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the individual comorbidity subgroups or one high comorbidity adjustment regardless of the number of comorbidity group interactions, as applicable. The low comorbidity adjustment amount would be the same across all 11 individual comorbidity subgroups. Similarly, the high

comorbidity adjustment amount would be the same across all 27 comorbidity subgroup interactions. See Table 48 in section III.F.10 of this proposed rule for the coefficient amounts associated with both the low and high comorbidity adjustment, as well as for all of the case-mix variables in the PDGM. If a 30-day home health period of care does not have any reported comorbidities that fall into one of the payment adjustments described above, there would be no comorbidity adjustment applied. Table 46 illustrates the average resource use for each of the comorbidity levels as described in this section.

TABLE 46: AVERAGE RESOURCE USE BY COMORBIDITY ADJUSTMENT, CY 2017

	Mean 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
No Comorbidity Adjustment	$1,539.92	5,402,694	62.6%	$1,183.86	$673.27	$1,253.95	$2,078.68
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$1,575.12	2,721,969	31.6%	$1,248.71	$658.77	$1,262.47	$2,131.92
Comorbidity Adjustment - Has at least one interaction from interaction list	$1,878.84	500,113	5.8%	$1,412.06	$880.07	$1,523.87	$2,469.93
Total	$1,570.68	8,624,776	100.0%	$1,221.38	$679.12	$1,272.18	$2,117.47

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

Changing to three comorbidity levels results in 216 possible case-mix groups for the purposes of adjusting payment in the PDGM. While this is more case-mix groups than the 144 case-mix groups proposed in the CY 2018 HH PPS proposed rule, this change is responsive to the comments received regarding refinements to the comorbidity adjustment without being unduly complex. We believe that this method for adjusting payment for the presence of comorbidities is more robust, reflective of patient characteristics, better aligns payment with actual resource use, and addresses comments

received from the CY 2018 HH PPS proposed rule and recommendations from TEP members. The comorbidity payment adjustment takes into account the presence of individual comorbid conditions, as well as the interactions between multiple comorbid conditions, and reflects the types of conditions most commonly seen in home health patients. Similar to monitoring of nominal case-mix growth under the current HH PPS, upon implementation of the PDGM, CMS will monitor the reporting of secondary diagnoses to determine whether adjustments to payment based on the number of reported comorbidities is resulting in HHAs inappropriately reporting comorbid conditions solely for the purpose of increased payment and appropriate program integrity actions will be taken.

As mentioned previously in this section, there will be an updated PDGM Grouper Tool posted on the HHA Center webpage which will be key to understanding whether a 30-day home health period of care would receive a no, low, or high comorbidity adjustment under the PDGM. If implemented, we would continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements to help ensure that payment is in alignment with the actual costs of providing care. We invite comments on the change to the comorbidity case-mix adjustment in the PDGM including the three comorbidity levels: No Comorbidity, Low Comorbidity, and High Comorbidity Adjustment. We also invite comments on the payment associated with the Low Comorbidity and High Comorbidity Adjustment to account for increased resource utilization resulting from the presence of certain comorbidities and comorbidity interactions.

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

Currently, a 60-day episode with four or fewer visits is paid the national per visit amount by discipline, adjusted by the appropriate wage index based on the site of service of the beneficiary, instead of the full 60-day episode payment amount. Such payment adjustments are called Low Utilization Payment Adjustments (LUPAs). While the alternative case-mix model proposed in the CY 2018 HH PPS proposed rule still included LUPAs, the approach to calculating the LUPA thresholds needed to change due to the proposed change in the unit of payment to 30-day periods of care from 60-day episodes. The 30-day periods of care have substantially more episodes with four or fewer visits than 60-day episodes. To create LUPA thresholds we proposed in the CY 2018 HH PPS proposed rule to set the LUPA threshold at the 10th percentile value of visits or 2, whichever is higher, for each payment group, (82 FR 35324).

We received comments in response to the CY 2018 HH PPS proposed rule on maintaining the use of a single LUPA threshold instead of varying the thresholds at the subgroup level. Other commenters expressed concern that the variable LUPA thresholds will add additional administrative burden and create additional opportunity for error. After analyzing the data to evaluate the potential impact, we believe that the change to a 30-day period of care under the proposed PDGM from the current 60-day episode warrants variable LUPA thresholds depending on the payment group to which it is assigned. We believe that the proposed LUPA thresholds that vary 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. This is the same approach proposed in the CY 2018 proposed rule where LUPA thresholds would vary by case-mix group. LUPA thresholds that vary by case-mix group take into account

different resource use patterns based on beneficiaries' clinical characteristics. Additionally, we do not believe that the case-mix-specific LUPA thresholds would result in additional administrative burden as LUPA visits are billed the same as non-LUPA periods. Likewise, the PDGM will not be implemented until January 1, 2020, giving HHAs and vendors sufficient time to make necessary changes to their systems and to ensure that appropriate quality checks are in place to minimize any claims errors. Therefore, we propose to vary the LUPA threshold for a 30-day period of care under the PDGM depending on the PDGM payment group to which it is assigned.

We note that in the current payment system, approximately 8 percent of episodes are LUPAs. Under the PDGM, consistent with the CY 2018 HH PPS proposed rule, we propose the 10th percentile value of visits or 2 visits, whichever is higher, in order to target approximately the same percentage of LUPAs (approximately 7.1 percent of 30-day periods would be LUPAs (assuming no behavior change)). For example, for episodes in the payment group corresponding to "MMTA – Functional Level Medium – Early Timing – Institutional Admission – No Comorbidity" (HIPPS code 2AB1 in Table 47), the threshold is four visits. If a home health 30-day period of care is assigned to that particular payment group had three or fewer visits the HHA would be paid using the national per-visit rates in section III.C.4 of this proposed rule instead of the case-mix adjusted 30-day period of care payment amount. The LUPA thresholds for the PDGM payment group with the corresponding HIPPS code is listed in Table 47.

TABLE 47: PROPOSED LUPA THRESHOLDS FOR THE PROPOSED PDGM PAYMENT GROUPS

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
1AA11	MMTA – Low	Early - Community	0	4
1AA21	MMTA – Low	Early - Community	1	4
1AA31	MMTA – Low	Early - Community	2	4
1AB11	MMTA – Medium	Early - Community	0	4
1AB21	MMTA – Medium	Early - Community	1	4
1AB31	MMTA – Medium	Early - Community	2	5
1AC11	MMTA – High	Early - Community	0	4
1AC21	MMTA – High	Early - Community	1	4
1AC31	MMTA – High	Early - Community	2	4
1BA11	Neuro – Low	Early - Community	0	4
1BA21	Neuro – Low	Early - Community	1	5
1BA31	Neuro – Low	Early - Community	2	5
1BB11	Neuro - Medium	Early - Community	0	5
1BB21	Neuro - Medium	Early - Community	1	5
1BB31	Neuro - Medium	Early - Community	2	5
1BC11	Neuro - High	Early - Community	0	4
1BC21	Neuro - High	Early - Community	1	5
1BC31	Neuro - High	Early - Community	2	5
1CA11	Wound - Low	Early - Community	0	4
1CA21	Wound - Low	Early - Community	1	4
1CA31	Wound - Low	Early - Community	2	4
1CB11	Wound - Medium	Early - Community	0	5
1CB21	Wound - Medium	Early - Community	1	5
1CB31	Wound - Medium	Early - Community	2	5
1CC11	Wound - High	Early - Community	0	4
1CC21	Wound - High	Early - Community	1	5
1CC31	Wound - High	Early - Community	2	4
1DA11	Complex - Low	Early - Community	0	3
1DA21	Complex - Low	Early - Community	1	2
1DA31	Complex - Low	Early - Community	2	4
1DB11	Complex - Medium	Early - Community	0	3
1DB21	Complex - Medium	Early - Community	1	3
1DB31	Complex - Medium	Early - Community	2	4
1DC11	Complex - High	Early - Community	0	3
1DC21	Complex - High	Early - Community	1	3
1DC31	Complex - High	Early - Community	2	3
1EA11	MS Rehab - Low	Early - Community	0	5
1EA21	MS Rehab - Low	Early - Community	1	5
1EA31	MS Rehab - Low	Early - Community	2	5
1EB11	MS Rehab - Medium	Early - Community	0	5
1EB21	MS Rehab - Medium	Early - Community	1	5
1EB31	MS Rehab - Medium	Early - Community	2	5
1EC11	MS Rehab - High	Early - Community	0	5
1EC21	MS Rehab - High	Early - Community	1	5
1EC31	MS Rehab - High	Early - Community	2	5
1FA11	Behavioral Health - Low	Early - Community	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
1FA21	Behavioral Health - Low	Early - Community	1	3
1FA31	Behavioral Health - Low	Early - Community	2	3
1FB11	Behavioral Health - Medium	Early - Community	0	4
1FB21	Behavioral Health - Medium	Early - Community	1	4
1FB31	Behavioral Health - Medium	Early - Community	2	4
1FC11	Behavioral Health - High	Early - Community	0	4
1FC21	Behavioral Health - High	Early - Community	1	4
1FC31	Behavioral Health - High	Early - Community	2	4
2AA11	MMTA - Low	Early - Institutional	0	3
2AA21	MMTA - Low	Early - Institutional	1	4
2AA31	MMTA - Low	Early - Institutional	2	4
2AB11	MMTA - Medium	Early - Institutional	0	4
2AB21	MMTA - Medium	Early - Institutional	1	5
2AB31	MMTA - Medium	Early - Institutional	2	5
2AC11	MMTA - High	Early - Institutional	0	4
2AC21	MMTA - High	Early - Institutional	1	4
2AC31	MMTA - High	Early - Institutional	2	4
2BA11	Neuro - Low	Early - Institutional	0	5
2BA21	Neuro - Low	Early - Institutional	1	5
2BA31	Neuro - Low	Early - Institutional	2	5
2BB11	Neuro - Medium	Early - Institutional	0	6
2BB21	Neuro - Medium	Early - Institutional	1	6
2BB31	Neuro - Medium	Early - Institutional	2	6
2BC11	Neuro - High	Early - Institutional	0	5
2BC21	Neuro - High	Early - Institutional	1	5
2BC31	Neuro - High	Early - Institutional	2	5
2CA11	Wound - Low	Early - Institutional	0	4
2CA21	Wound - Low	Early - Institutional	1	4
2CA31	Wound - Low	Early - Institutional	2	4
2CB11	Wound - Medium	Early - Institutional	0	5
2CB21	Wound - Medium	Early - Institutional	1	5
2CB31	Wound - Medium	Early - Institutional	2	5
2CC11	Wound - High	Early - Institutional	0	4
2CC21	Wound - High	Early - Institutional	1	5
2CC31	Wound - High	Early - Institutional	2	4
2DA11	Complex - Low	Early - Institutional	0	3
2DA21	Complex - Low	Early - Institutional	1	3
2DA31	Complex - Low	Early - Institutional	2	4
2DB11	Complex - Medium	Early - Institutional	0	4
2DB21	Complex - Medium	Early - Institutional	1	4
2DB31	Complex - Medium	Early - Institutional	2	5
2DC11	Complex - High	Early - Institutional	0	4
2DC21	Complex - High	Early - Institutional	1	4
2DC31	Complex - High	Early - Institutional	2	4
2EA11	MS Rehab - Low	Early - Institutional	0	5
2EA21	MS Rehab - Low	Early - Institutional	1	5
2EA31	MS Rehab - Low	Early - Institutional	2	5
2EB11	MS Rehab - Medium	Early - Institutional	0	6
2EB21	MS Rehab - Medium	Early - Institutional	1	6

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
2EB31	MS Rehab - Medium	Early - Institutional	2	6
2EC11	MS Rehab - High	Early - Institutional	0	6
2EC21	MS Rehab - High	Early - Institutional	1	6
2EC31	MS Rehab - High	Early - Institutional	2	6
2FA11	Behavioral Health - Low	Early - Institutional	0	3
2FA21	Behavioral Health - Low	Early - Institutional	1	3
2FA31	Behavioral Health - Low	Early - Institutional	2	4
2FB11	Behavioral Health - Medium	Early - Institutional	0	4
2FB21	Behavioral Health - Medium	Early - Institutional	1	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	5
2FC11	Behavioral Health - High	Early - Institutional	0	4
2FC21	Behavioral Health - High	Early - Institutional	1	4
2FC31	Behavioral Health - High	Early - Institutional	2	5
3AA11	MMTA - Low	Late - Community	0	2
3AA21	MMTA - Low	Late - Community	1	2
3AA31	MMTA - Low	Late - Community	2	3
3AB11	MMTA - Medium	Late - Community	0	2
3AB21	MMTA - Medium	Late - Community	1	2
3AB31	MMTA - Medium	Late - Community	2	3
3AC11	MMTA - High	Late - Community	0	2
3AC21	MMTA - High	Late - Community	1	2
3AC31	MMTA - High	Late - Community	2	3
3BA11	Neuro - Low	Late - Community	0	2
3BA21	Neuro - Low	Late - Community	1	2
3BA31	Neuro - Low	Late - Community	2	2
3BB11	Neuro - Medium	Late - Community	0	2
3BB21	Neuro - Medium	Late - Community	1	2
3BB31	Neuro - Medium	Late - Community	2	3
3BC11	Neuro - High	Late - Community	0	2
3BC21	Neuro - High	Late - Community	1	2
3BC31	Neuro - High	Late - Community	2	2
3CA11	Wound - Low	Late - Community	0	2
3CA21	Wound - Low	Late - Community	1	3
3CA31	Wound - Low	Late - Community	2	3
3CB11	Wound - Medium	Late - Community	0	3
3CB21	Wound - Medium	Late - Community	1	3
3CB31	Wound - Medium	Late - Community	2	3
3CC11	Wound - High	Late - Community	0	3
3CC21	Wound - High	Late - Community	1	3
3CC31	Wound - High	Late - Community	2	3
3DA11	Complex - Low	Late - Community	0	2
3DA21	Complex - Low	Late - Community	1	2
3DA31	Complex - Low	Late - Community	2	2
3DB11	Complex - Medium	Late - Community	0	2
3DB21	Complex - Medium	Late - Community	1	2
3DB31	Complex - Medium	Late - Community	2	2
3DC11	Complex - High	Late - Community	0	2
3DC21	Complex - High	Late - Community	1	2
3DC31	Complex - High	Late - Community	2	2

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
3EA11	MS Rehab - Low	Late - Community	0	2
3EA21	MS Rehab - Low	Late - Community	1	2
3EA31	MS Rehab - Low	Late - Community	2	2
3EB11	MS Rehab - Medium	Late - Community	0	2
3EB21	MS Rehab - Medium	Late - Community	1	2
3EB31	MS Rehab - Medium	Late - Community	2	3
3EC11	MS Rehab - High	Late - Community	0	2
3EC21	MS Rehab - High	Late - Community	1	2
3EC31	MS Rehab - High	Late - Community	2	3
3FA11	Behavioral Health - Low	Late - Community	0	2
3FA21	Behavioral Health - Low	Late - Community	1	2
3FA31	Behavioral Health - Low	Late - Community	2	2
3FB11	Behavioral Health - Medium	Late - Community	0	2
3FB21	Behavioral Health - Medium	Late - Community	1	2
3FB31	Behavioral Health - Medium	Late - Community	2	2
3FC11	Behavioral Health - High	Late - Community	0	2
3FC21	Behavioral Health - High	Late - Community	1	2
3FC31	Behavioral Health - High	Late - Community	2	2
4AA11	MMTA - Low	Late - Institutional	0	3
4AA21	MMTA - Low	Late - Institutional	1	3
4AA31	MMTA - Low	Late - Institutional	2	3
4AB11	MMTA - Medium	Late - Institutional	0	3
4AB21	MMTA - Medium	Late - Institutional	1	3
4AB31	MMTA - Medium	Late - Institutional	2	4
4AC11	MMTA - High	Late - Institutional	0	3
4AC21	MMTA - High	Late - Institutional	1	3
4AC31	MMTA - High	Late - Institutional	2	4
4BA11	Neuro - Low	Late - Institutional	0	3
4BA21	Neuro - Low	Late - Institutional	1	4
4BA31	Neuro - Low	Late - Institutional	2	3
4BB11	Neuro - Medium	Late - Institutional	0	4
4BB21	Neuro - Medium	Late - Institutional	1	4
4BB31	Neuro - Medium	Late - Institutional	2	5
4BC11	Neuro - High	Late - Institutional	0	4
4BC21	Neuro - High	Late - Institutional	1	4
4BC31	Neuro - High	Late - Institutional	2	4
4CA11	Wound - Low	Late - Institutional	0	3
4CA21	Wound - Low	Late - Institutional	1	3
4CA31	Wound - Low	Late - Institutional	2	3
4CB11	Wound - Medium	Late - Institutional	0	4
4CB21	Wound - Medium	Late - Institutional	1	4
4CB31	Wound - Medium	Late - Institutional	2	4
4CC11	Wound - High	Late - Institutional	0	3
4CC21	Wound - High	Late - Institutional	1	4
4CC31	Wound - High	Late - Institutional	2	4
4DA11	Complex - Low	Late - Institutional	0	2
4DA21	Complex - Low	Late - Institutional	1	3
4DA31	Complex - Low	Late - Institutional	2	3
4DB11	Complex - Medium	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4DB21	Complex - Medium	Late - Institutional	1	3
4DB31	Complex - Medium	Late - Institutional	2	4
4DC11	Complex - High	Late - Institutional	0	3
4DC21	Complex - High	Late - Institutional	1	3
4DC31	Complex - High	Late - Institutional	2	3
4EA11	MS Rehab - Low	Late - Institutional	0	3
4EA21	MS Rehab - Low	Late - Institutional	1	3
4EA31	MS Rehab - Low	Late - Institutional	2	3
4EB11	MS Rehab - Medium	Late - Institutional	0	4
4EB21	MS Rehab - Medium	Late - Institutional	1	4
4EB31	MS Rehab - Medium	Late - Institutional	2	4
4EC11	MS Rehab - High	Late - Institutional	0	4
4EC21	MS Rehab - High	Late - Institutional	1	4
4EC31	MS Rehab - High	Late - Institutional	2	4
4FA11	Behavioral Health - Low	Late - Institutional	0	2
4FA21	Behavioral Health - Low	Late - Institutional	1	2
4FA31	Behavioral Health - Low	Late - Institutional	2	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	3
4FB31	Behavioral Health - Medium	Late - Institutional	2	3
4FC11	Behavioral Health - High	Late - Institutional	0	3
4FC21	Behavioral Health - High	Late - Institutional	1	3
4FC31	Behavioral Health - High	Late - Institutional	2	4

In summary, we propose to vary the LUPA threshold for a 30-day period of care under the PDGM depending on the PDGM payment group to which it is assigned. We also propose that the LUPA thresholds for each PDGM payment group would be re-evaluated every year based on the most current utilization data available. We invite public comments on the LUPA threshold methodology proposed for the PDGM and the associated regulations text changes in section III.F.13 of this proposed rule.

10. HH PPS Case-Mix Weights under the PDGM

Section 1895(b)(4)(B) 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 CY 2018 HH PPS proposed rule (82 FR 35270), we proposed an alternative case-mix adjustment

methodology to better align payment with patient care needs. The proposed alternative case-mix adjustment methodology places patients into meaningful payment categories based on patient characteristics (principal diagnosis, functional level, comorbid conditions, referral source and timing). We did not finalize the alternative case-mix adjustment methodology in the CY 2018 final rule in order to consider comments and feedback for any potential refinements to the model. Refinements were made to the comorbidity case-mix adjustment while all other variables remain as proposed in the CY 2018 HH PPS proposed rule (for example, clinical group, functional level, admission source, and episode timing). As outlined in previous sections of this proposed rule, we are again proposing an alternative case-mix adjustment methodology, called the PDGM, but this methodology now results in 216 unique case-mix groups. These 216 unique case-mix payment groups are called Home Health Resource Groups (HHRGs). In accordance with the BBA of 2018, the proposed PDGM will be implemented in a budget neutral manner.

To generate PDGM case-mix weights, we utilized a data file based on home health episodes of care, as reported in Medicare home health claims. The claims data provide episode-level data as well as visit-level data. The claims also provide data on whether non-routine supplies (NRS) was provided during the episode and the total charges for NRS. We used CY 2017 home health claims data with linked OASIS assessment data to obtain patient characteristics. We 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 categories using a fixed effects model. The regression measures resource use with the Cost per Minute (CPM) + NRS approach outlined in

section III.F.2 of this proposed rule. The model used in the PDGM payment regression generates outcomes that are statistically significant and consistent with findings.

We received comments in response to the proposed alternative case-mix adjustment methodology in the CY 2018 HH PPS proposed rule on the standards for subsequent case-mix weight recalibration (nature and timing). Similar to the annual recalibration of the case-mix weights under the current HH PPS, annual recalibration will be made to the PDGM case-mix weights. We will make refinements as necessary to ensure that payment for home health periods are in alignment with costs. We note that this includes a re-calculation of the proposed PDGM case-mix weights for CY 2020 in the CY 2020 HH PPS proposed rule using CY 2018 home health claims data linked with OASIS assessment data. In other words, the table below represents the PDGM case-mix weights if we were to implement the PDGM in CY 2019. However, since we are proposing to implement the PDGM on January 1, 2020, the actual PDGM case-mix weights for CY 2020 will be updated in the CY 2020 HH PPS proposed rule. We also received a comment from MedPAC about the development of alternative case-mix adjustment methodology using the regression approach, which is a statistical estimate of the cost associated with a payment group instead of the actual cost. MedPAC stated that this approach results in estimated payments that may not equal the actual costs experienced by HHAs. As noted, CMS has used a regression approach since the inception of the HH PPS in 2000. The regression smoothens weights compared to a system where each payment group receives a weight that is based solely on the average resource use of all 30-day periods in a payment group compared to the overall average resource use across all 30 day periods. Smoothing the weights helps to see relationships

between variables and foresee trends. In addition, using a regression approach to calculate case-mix weights allows CMS to use a fixed effects model, which will estimate the variation observed within individual HHAs and opposed to estimating the variation across HHAs. With the fixed effects, the coefficients should better estimate the relationship the regression variables have with resource use compared to not accounting for fixed effects. We continue to believe that using a regression approach for the calculation of the HH PPS case-mix weights is most appropriate.

After best fitting the model on home health episodes from 2017 data, we used the estimated coefficients of the model to predict the expected average resource use of each episode based on the five PDGM categories. In order to normalize the results, we have divided the regression predicted resource use of each episode by the overall average resource use of all episodes used to estimate the model in order to calculate the case mix weight of all episodes within a particular payment group, where each payment group is defined as the unique combination of the subgroups within the five PDGM categories (admission source, timing of the 30-day period, clinical grouping, functional level, and comorbidity adjustment). The case-mix weight is then used to adjust the base payment rate to determine each period's payment. Table 48 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use. Information can be found in section III.F.6 of this rule for the clinical groups, section III.F.7 of this rule for the functional levels, section III.F.5 for admission source, section III.F.4 for timing, and section III.F.8 for the comorbidity adjustment.

TABLE 48: COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR PDGM PAYMENT GROUP

Variable	Coefficient	Coefficient Divided by Average Resource Use
Clinical Group and Functional Level (MMTA - Low is excluded)		
MMTA - Medium Functional	$237.83	0.1514
MMTA - High Functional	$416.75	0.2653
Behavioral Health - Low Functional	-$116.39	-0.0741
Behavioral Health - Medium Functional	$169.86	0.1081
Behavioral Health - High Functional	$309.97	0.1974
Complex - Low Functional	-$27.39	-0.0174
Complex - Medium Functional	$331.88	0.2113
Complex - High Functional	$476.69	0.3035
MS Rehab - Low Functional	$141.37	0.0900
MS Rehab - Medium Functional	$338.96	0.2158
MS Rehab - High Functional	$558.95	0.3559
Neuro - Low Functional	$329.19	0.2096
Neuro - Medium Functional	$593.98	0.3782
Neuro - High Functional	$711.48	0.4530
Wound - Low Functional	$368.43	0.2346
Wound - Medium Functional	$628.37	0.4001
Wound - High Functional	$822.84	0.5239
Referral Source With Timing (Community Early excluded)		
Community - Late	-$646.84	-0.4118
Institutional - Early	$278.85	0.1775
Institutional - Late	$45.71	0.0291
Comorbidity Adjustment (No Comorbidity Adjustment Group is excluded)		
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$92.44	0.0589
Comorbidity Adjustment - Has at least one interaction from interaction list	$345.20	0.2198
Constant	$1,560.37	0.9934
Average Resource Use	$1,570.68	
N	8,624,776	
Adj. R-Squared	0.2925	

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Table 49 presents the case-mix weight for each HHRG in the regression model (Table 48). LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded. Please find LUPA information in section III.F.9 of this rule. Weights are

determined by first calculating the predicted resource use for episodes with a particular combination of admission source, episode timing, clinical grouping, functional level, and comorbidity adjustment. This combination specific calculation is then divided by the average resource use of all the episodes that were used to estimate the standard 30-day payment rate, which is $1,570.68. The resulting ratio represents the case-mix weight for that particular combination of a HHRG payment group. The adjusted R-squared value for this model is 0.2925 which is slightly higher than the adjusted R-squared value of 0.2704 that we proposed in CY 2018 by using the CY 2016 claims data. The adjusted R-squared value provides a measure of how well observed outcomes are replicated by the model, based on the proportion of total variation of outcomes explained by the model.

As noted above, there are 216 different HHRG payment groups under the PDGM. There are 15 HHRG payment groups that represent roughly 50.2 percent of the total episodes. There are 61 HHRG payment groups that represent roughly 1.0 percent of total episodes. The HHRG payment group with the smallest weight has a weight of 0.5075 (community admitted, late, behavioral health, low functional impairment level, with no comorbidity adjustment). The HHRG payment group with the largest weight has a weight of 1.9146 (institutional admitted, early, wound, high functional impairment level, with interactive comorbidity adjustment).

TABLE 49: CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment	Proposed CY 2019 Weight
1AA11	MMTA - Low	Early - Community	0	0.9934
1AA21	MMTA - Low	Early - Community	1	1.0523
1AA31	MMTA - Low	Early - Community	2	1.2132
1AB11	MMTA - Medium	Early - Community	0	1.1449
1AB21	MMTA - Medium	Early - Community	1	1.2037
1AB31	MMTA - Medium	Early - Community	2	1.3646
1AC11	MMTA - High	Early - Community	0	1.2588
1AC21	MMTA - High	Early - Community	1	1.3176
1AC31	MMTA - High	Early - Community	2	1.4785
1BA11	Neuro - Low	Early - Community	0	1.2030
1BA21	Neuro - Low	Early - Community	1	1.2619
1BA31	Neuro - Low	Early - Community	2	1.4228
1BB11	Neuro - Medium	Early - Community	0	1.3716
1BB21	Neuro - Medium	Early - Community	1	1.4305
1BB31	Neuro - Medium	Early - Community	2	1.5914
1BC11	Neuro - High	Early - Community	0	1.4464
1BC21	Neuro - High	Early - Community	1	1.5053
1BC31	Neuro - High	Early - Community	2	1.6662
1CA11	Wound - Low	Early - Community	0	1.2280
1CA21	Wound - Low	Early - Community	1	1.2869
1CA31	Wound - Low	Early - Community	2	1.4478
1CB11	Wound - Medium	Early - Community	0	1.3935
1CB21	Wound - Medium	Early - Community	1	1.4523
1CB31	Wound - Medium	Early - Community	2	1.6133
1CC11	Wound - High	Early - Community	0	1.5173
1CC21	Wound - High	Early - Community	1	1.5762
1CC31	Wound - High	Early - Community	2	1.7371
1DA11	Complex - Low	Early - Community	0	0.9760
1DA21	Complex - Low	Early - Community	1	1.0348
1DA31	Complex - Low	Early - Community	2	1.1958
1DB11	Complex - Medium	Early - Community	0	1.2047
1DB21	Complex - Medium	Early - Community	1	1.2636
1DB31	Complex - Medium	Early - Community	2	1.4245
1DC11	Complex - High	Early - Community	0	1.2969
1DC21	Complex - High	Early - Community	1	1.3558
1DC31	Complex - High	Early - Community	2	1.5167
1EA11	MS Rehab - Low	Early - Community	0	1.0834
1EA21	MS Rehab - Low	Early - Community	1	1.1423
1EA31	MS Rehab - Low	Early - Community	2	1.3032
1EB11	MS Rehab - Medium	Early - Community	0	1.2092
1EB21	MS Rehab - Medium	Early - Community	1	1.2681
1EB31	MS Rehab - Medium	Early - Community	2	1.4290
1EC11	MS Rehab - High	Early - Community	0	1.3493
1EC21	MS Rehab - High	Early - Community	1	1.4082
1EC31	MS Rehab - High	Early - Community	2	1.5691
1FA11	Behavioral Health - Low	Early - Community	0	0.9193
1FA21	Behavioral Health - Low	Early - Community	1	0.9782
1FA31	Behavioral Health - Low	Early - Community	2	1.1391

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment	Proposed CY 2019 Weight
1FB11	Behavioral Health - Medium	Early - Community	0	1.1016
1FB21	Behavioral Health - Medium	Early - Community	1	1.1604
1FB31	Behavioral Health - Medium	Early - Community	2	1.3214
1FC11	Behavioral Health - High	Early - Community	0	1.1908
1FC21	Behavioral Health - High	Early - Community	1	1.2496
1FC31	Behavioral Health - High	Early - Community	2	1.4106
2AA11	MMTA - Low	Early - Institutional	0	1.1710
2AA21	MMTA - Low	Early - Institutional	1	1.2298
2AA31	MMTA - Low	Early - Institutional	2	1.3907
2AB11	MMTA - Medium	Early - Institutional	0	1.3224
2AB21	MMTA - Medium	Early - Institutional	1	1.3812
2AB31	MMTA - Medium	Early - Institutional	2	1.5422
2AC11	MMTA - High	Early - Institutional	0	1.4363
2AC21	MMTA - High	Early - Institutional	1	1.4951
2AC31	MMTA - High	Early - Institutional	2	1.6561
2BA11	Neuro - Low	Early - Institutional	0	1.3805
2BA21	Neuro - Low	Early - Institutional	1	1.4394
2BA31	Neuro - Low	Early - Institutional	2	1.6003
2BB11	Neuro - Medium	Early - Institutional	0	1.5491
2BB21	Neuro - Medium	Early - Institutional	1	1.6080
2BB31	Neuro - Medium	Early - Institutional	2	1.7689
2BC11	Neuro - High	Early - Institutional	0	1.6239
2BC21	Neuro - High	Early - Institutional	1	1.6828
2BC31	Neuro - High	Early - Institutional	2	1.8437
2CA11	Wound - Low	Early - Institutional	0	1.4055
2CA21	Wound - Low	Early - Institutional	1	1.4644
2CA31	Wound - Low	Early - Institutional	2	1.6253
2CB11	Wound - Medium	Early - Institutional	0	1.5710
2CB21	Wound - Medium	Early - Institutional	1	1.6299
2CB31	Wound - Medium	Early - Institutional	2	1.7908
2CC11	Wound - High	Early - Institutional	0	1.6948
2CC21	Wound - High	Early - Institutional	1	1.7537
2CC31	Wound - High	Early - Institutional	2	1.9146
2DA11	Complex - Low	Early - Institutional	0	1.1535
2DA21	Complex - Low	Early - Institutional	1	1.2124
2DA31	Complex - Low	Early - Institutional	2	1.3733
2DB11	Complex - Medium	Early - Institutional	0	1.3823
2DB21	Complex - Medium	Early - Institutional	1	1.4411
2DB31	Complex - Medium	Early - Institutional	2	1.6020
2DC11	Complex - High	Early - Institutional	0	1.4745
2DC21	Complex - High	Early - Institutional	1	1.5333
2DC31	Complex - High	Early - Institutional	2	1.6942
2EA11	MS Rehab - Low	Early - Institutional	0	1.2610
2EA21	MS Rehab - Low	Early - Institutional	1	1.3198
2EA31	MS Rehab - Low	Early - Institutional	2	1.4807
2EB11	MS Rehab - Medium	Early - Institutional	0	1.3868
2EB21	MS Rehab - Medium	Early - Institutional	1	1.4456
2EB31	MS Rehab - Medium	Early - Institutional	2	1.6065
2EC11	MS Rehab - High	Early - Institutional	0	1.5268
2EC21	MS Rehab - High	Early - Institutional	1	1.5857
2EC31	MS Rehab - High	Early - Institutional	2	1.7466
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0969

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment	Proposed CY 2019 Weight
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1557
2FA31	Behavioral Health - Low	Early - Institutional	2	1.3166
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.2791
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.3380
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4989
2FC11	Behavioral Health - High	Early - Institutional	0	1.3683
2FC21	Behavioral Health - High	Early - Institutional	1	1.4272
2FC31	Behavioral Health - High	Early - Institutional	2	1.5881
3AA11	MMTA - Low	Late - Community	0	0.5816
3AA21	MMTA - Low	Late - Community	1	0.6405
3AA31	MMTA - Low	Late - Community	2	0.8014
3AB11	MMTA - Medium	Late - Community	0	0.7330
3AB21	MMTA - Medium	Late - Community	1	0.7919
3AB31	MMTA - Medium	Late - Community	2	0.9528
3AC11	MMTA - High	Late - Community	0	0.8469
3AC21	MMTA - High	Late - Community	1	0.9058
3AC31	MMTA - High	Late - Community	2	1.0667
3BA11	Neuro - Low	Late - Community	0	0.7912
3BA21	Neuro - Low	Late - Community	1	0.8500
3BA31	Neuro - Low	Late - Community	2	1.0110
3BB11	Neuro - Medium	Late - Community	0	0.9598
3BB21	Neuro - Medium	Late - Community	1	1.0186
3BB31	Neuro - Medium	Late - Community	2	1.1796
3BC11	Neuro - High	Late - Community	0	1.0346
3BC21	Neuro - High	Late - Community	1	1.0934
3BC31	Neuro - High	Late - Community	2	1.2544
3CA11	Wound - Low	Late - Community	0	0.8162
3CA21	Wound - Low	Late - Community	1	0.8750
3CA31	Wound - Low	Late - Community	2	1.0360
3CB11	Wound - Medium	Late - Community	0	0.9817
3CB21	Wound - Medium	Late - Community	1	1.0405
3CB31	Wound - Medium	Late - Community	2	1.2015
3CC11	Wound - High	Late - Community	0	1.1055
3CC21	Wound - High	Late - Community	1	1.1643
3CC31	Wound - High	Late - Community	2	1.3253
3DA11	Complex - Low	Late - Community	0	0.5642
3DA21	Complex - Low	Late - Community	1	0.6230
3DA31	Complex - Low	Late - Community	2	0.7840
3DB11	Complex - Medium	Late - Community	0	0.7929
3DB21	Complex - Medium	Late - Community	1	0.8518
3DB31	Complex - Medium	Late - Community	2	1.0127
3DC11	Complex - High	Late - Community	0	0.8851
3DC21	Complex - High	Late - Community	1	0.9440
3DC31	Complex - High	Late - Community	2	1.1049
3EA11	MS Rehab - Low	Late - Community	0	0.6716
3EA21	MS Rehab - Low	Late - Community	1	0.7305
3EA31	MS Rehab - Low	Late - Community	2	0.8914
3EB11	MS Rehab - Medium	Late - Community	0	0.7974
3EB21	MS Rehab - Medium	Late - Community	1	0.8563
3EB31	MS Rehab - Medium	Late - Community	2	1.0172
3EC11	MS Rehab - High	Late - Community	0	0.9375
3EC21	MS Rehab - High	Late - Community	1	0.9963

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment	Proposed CY 2019 Weight
3EC31	MS Rehab - High	Late - Community	2	1.1573
3FA11	Behavioral Health - Low	Late - Community	0	0.5075
3FA21	Behavioral Health - Low	Late - Community	1	0.5664
3FA31	Behavioral Health - Low	Late - Community	2	0.7273
3FB11	Behavioral Health - Medium	Late - Community	0	0.6898
3FB21	Behavioral Health - Medium	Late - Community	1	0.7486
3FB31	Behavioral Health - Medium	Late - Community	2	0.9095
3FC11	Behavioral Health - High	Late - Community	0	0.7790
3FC21	Behavioral Health - High	Late - Community	1	0.8378
3FC31	Behavioral Health - High	Late - Community	2	0.9987
4AA11	MMTA - Low	Late - Institutional	0	1.0225
4AA21	MMTA - Low	Late - Institutional	1	1.0814
4AA31	MMTA - Low	Late - Institutional	2	1.2423
4AB11	MMTA - Medium	Late - Institutional	0	1.1740
4AB21	MMTA - Medium	Late - Institutional	1	1.2328
4AB31	MMTA - Medium	Late - Institutional	2	1.3937
4AC11	MMTA - High	Late - Institutional	0	1.2879
4AC21	MMTA - High	Late - Institutional	1	1.3467
4AC31	MMTA - High	Late - Institutional	2	1.5076
4BA11	Neuro - Low	Late - Institutional	0	1.2321
4BA21	Neuro - Low	Late - Institutional	1	1.2910
4BA31	Neuro - Low	Late - Institutional	2	1.4519
4BB11	Neuro - Medium	Late - Institutional	0	1.4007
4BB21	Neuro - Medium	Late - Institutional	1	1.4595
4BB31	Neuro - Medium	Late - Institutional	2	1.6205
4BC11	Neuro - High	Late - Institutional	0	1.4755
4BC21	Neuro - High	Late - Institutional	1	1.5344
4BC31	Neuro - High	Late - Institutional	2	1.6953
4CA11	Wound - Low	Late - Institutional	0	1.2571
4CA21	Wound - Low	Late - Institutional	1	1.3160
4CA31	Wound - Low	Late - Institutional	2	1.4769
4CB11	Wound - Medium	Late - Institutional	0	1.4226
4CB21	Wound - Medium	Late - Institutional	1	1.4814
4CB31	Wound - Medium	Late - Institutional	2	1.6424
4CC11	Wound - High	Late - Institutional	0	1.5464
4CC21	Wound - High	Late - Institutional	1	1.6053
4CC31	Wound - High	Late - Institutional	2	1.7662
4DA11	Complex - Low	Late - Institutional	0	1.0051
4DA21	Complex - Low	Late - Institutional	1	1.0639
4DA31	Complex - Low	Late - Institutional	2	1.2249
4DB11	Complex - Medium	Late - Institutional	0	1.2338
4DB21	Complex - Medium	Late - Institutional	1	1.2927
4DB31	Complex - Medium	Late - Institutional	2	1.4536
4DC11	Complex - High	Late - Institutional	0	1.3260
4DC21	Complex - High	Late - Institutional	1	1.3849
4DC31	Complex - High	Late - Institutional	2	1.5458
4EA11	MS Rehab - Low	Late - Institutional	0	1.1125
4EA21	MS Rehab - Low	Late - Institutional	1	1.1714
4EA31	MS Rehab - Low	Late - Institutional	2	1.3323
4EB11	MS Rehab - Medium	Late - Institutional	0	1.2383
4EB21	MS Rehab - Medium	Late - Institutional	1	1.2972
4EB31	MS Rehab - Medium	Late - Institutional	2	1.4581

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment	Proposed CY 2019 Weight
4EC11	MS Rehab - High	Late - Institutional	0	1.3784
4EC21	MS Rehab - High	Late - Institutional	1	1.4373
4EC31	MS Rehab - High	Late - Institutional	2	1.5982
4FA11	Behavioral Health - Low	Late - Institutional	0	0.9484
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0073
4FA31	Behavioral Health - Low	Late - Institutional	2	1.1682
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1307
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.1895
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3505
4FC11	Behavioral Health - High	Late - Institutional	0	1.2199
4FC21	Behavioral Health - High	Late - Institutional	1	1.2787
4FC31	Behavioral Health - High	Late - Institutional	2	1.4397

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

In conjunction with the implementation of the PDGM, we are proposing to revise the frequency with which we update the HH PPS Grouper software used to assign the appropriate HIPPS code used for case-mix adjustment onto the claim. Since CY 2004 when the HH PPS moved from a fiscal year to a calendar year basis, we have updated the Grouper software twice a year. We provide an updated version of the Grouper software effective every October 1 in order to address ICD coding revisions, which are effective on October 1. We also provide an updated version of the HH PPS Grouper software effective on January 1 in order to capture the new or revised HH PPS policies that become effective on January 1. In an effort to reduce provider burden associated with testing and installing two software releases, we propose to discontinue the October release of the HH PPS Grouper software and provide a single HH PPS Grouper software release effective January 1 of each calendar year. We propose that the January release of the HH PPS Grouper software would include the most recent revisions to the ICD coding system as well as the payment policy updates contained in the HH PPS final rule. Therefore, under this proposal, during the last quarter of each calendar year, HHAs would continue to use the ICD-10-CM codes and reporting guidelines that they would have used

for the first three calendar quarters. HHAs would begin using the most recent ICD-10-CM codes and reporting guidelines on home health claims beginning on January 1 of each calendar year. We are soliciting comments on this proposal.

We invite comments on the proposed PDGM case-mix weights, case-mix weight methodology and proposed annual recalibration of the case-mix weights, updates to the HH PPS Grouper software, and the associated regulations text changes in section III.F.13 of this proposed rule.

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

LUPA episodes qualify for an add-on payment in the case that the established episode is the first or only episode in a sequence of adjacent episodes. As stated in the CY 2008 HH PPS final rule, LUPA add-on payments are made because the national per-visit payment rates do not adequately account for the front-loading of costs for the first episode of care as the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). 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. Under the PDGM, we propose that the LUPA add-on factors will remain the same as the current payment system, described in section III.C.4 of this proposed rule. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount.

The current partial episode payment (PEP) adjustment is a proportion of the episode payment and is based on the span of days including the start-of-care date (for example, the date of the first billable service) 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 defined as:

- A beneficiary elected transfer, or
- A discharge and return to home health that would warrant, for purposes of payment, a new OASIS assessment, physician certification of eligibility, and a new plan of care.

We received comments on eliminating PEPs in response to the CY 2018 HH PPS proposed rule. We note that the change in the unit of payment from 60 days to 30 days will reduce the number of instances where a PEP adjustment occurs. However, we believe maintaining a PEP adjustment policy is appropriate to ensure that Medicare is not paying twice for the same period of care, as the PEP is involved with patient transfers there is a risk of a duplicate payment error. For example, if a patient chooses to transfer to a different HHA during the course of a home health period of care, the payment is proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event and ensures that Medicare is not paying two HHAs for the same 30-day period of care.

In summary for 30-day periods of care, we propose that the process for partial payment adjustments would remain the same as the existing policies pertaining to partial episode payments. When a new 30-day period begins due to the intervening event of the beneficiary elected transfer or discharge and return to home health during the 30-day

episode, the original 30-day period would be proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event. The proportional payment is the partial payment adjustment. The partial payment adjustment is calculated by using the span of days (first billable service date through and including the last billable service date) under the original plan of care as a proportion of 30. The proportion is multiplied by the original case-mix and wage index 30-day payment.

12. Payments for High-Cost Outliers Under the PDGM

As described in section III.E of this proposed rule, section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount in the case of outliers because of unusual variations in the type or amount of medically necessary care. The history of and current methodology for payment of high-cost outliers under the HH PPS is described in detail in section III.E of this proposed rule. In the CY 2018 HH PPS proposed rule (82 FR 35270), we proposed that we would maintain the current methodology for payment of high-cost outliers upon implementation of a 30-day unit of payment and that we would calculate payment for high-cost outliers based upon 30-day periods of care.

Commenters expressed concerns regarding the outlier policy proposed in the CY 2018 HH PPS proposed rule and the potential for more providers to exceed the 10 percent outlier cap under a 30-day period of care. Commenters also 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 outlier calculation purposes.

While we appreciate commenters' feedback regarding the proposed outlier

payment policy described in the CY 2018 HH PPS proposed rule, we are proposing to maintain the existing outlier policy under the proposed 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. We believe that maintaining the existing outlier policy and applying such policy to 30-day periods of care would ensure a smooth transition within the framework of the proposed PDGM. We plan to closely evaluate and model projected outlier payments within the framework of the PDGM and consider modifications to the outlier policy as appropriate. The requirement that the total amount of outlier payments not exceed 2.5 percent of total home health payments as well as the 10 percent cap on outlier payments at the home health agency level are statutory requirements, as described in section 1895(b)(5) of the Act. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5 percent maximum outlier payment amount.

Regarding the 8-hour limit on the amount of time per day counted toward the estimation of an episode's costs, as noted in the CY 2017 HH PPS final rule (81 FR 76729), where a patient is eligible for coverage of home health services, Medicare statute limits the amount of part-time or intermittent home health aide services and skilled nursing services covered during a home health episode. Section 1861(m)(7)(B) of the Act states that the term "'part–time or intermittent services' means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week)." Therefore, the daily and weekly cap on the amount

of skilled nursing and home health aide services combined is a limit defined within the statute. As we further noted in the CY 2018 HH PPS final rule (81 FR 76729), because outlier payments are predominately driven by the provision of skilled nursing services, the 8-hour daily cap on services aligns with the statute, which requires that skilled nursing and home health aide services combined be furnished less than 8 hours each day. Therefore, we believe that maintaining the 8-hour per day cap is appropriate under the proposed PDGM.

Simulating payments using preliminary CY 2017 claims data and the CY 2019 payment rates, we estimate 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 CY 2019. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we currently estimate that the FDL ratio under the proposed PDGM would need to change from 0.55 to 0.71. However, given the proposed implementation of the PDGM for 30-day periods of care beginning on or after January 1, 2020, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete utilization data available at the time of CY 2020 rate-setting.

We invite public comments on maintaining the current outlier payment methodology outlined in section III.E of this proposed rule for the proposed PDGM and the associated changes in the regulations text as described in section III.F.13 of this proposed rule.

13. Conforming Regulations Text Revisions for the Implementation of the PDGM in CY 2020

We are proposing to make a number of revisions to the regulations to implement the PDGM for episodes beginning on or after January 1, 2020, as outlined in sections III.F.1 through III.F.12 of this proposed rule. We propose to make conforming changes in §409.43 and part 484 Subpart E to revise the unit of service from a 60-day episode to a 30-day period. In addition, we are proposing to restructure §484.205. These revisions would be effective on January 1, 2020. Specifically, we propose to:

- Revise § 409.43, which outlines plan of care requirements. We propose to revise several paragraphs to phase out the unit of service from a 60-day episode for claims beginning on or before December 31, 2019, and to implement a 30-day period as the new unit of service for claims beginning on or after January 1, 2020 under the PDGM. We propose to move and revise paragraph (c)(2) to §484.205 as paragraph (c)(2) aligns more closely with the regulations addressing the basis of payment.

- Revise the definitions of rural area and urban area in §484.202 to remove "with respect to home health episodes ending on or after January 1, 2006" from each definition as this verbiage is no longer necessary.

- Restructure §484.205 to provide more logical organization and revise to account for the change in the unit of payment under the HH PPS for CY 2020. The PDGM uses 30-day periods rather than the 60-day episode used in the current payment system. Therefore, we propose to revise §484.205 to remove references to "60-day episode" and to refer more generally to the "national, standardized prospective payment". We are also proposing revisions to §484.205 as follows:

++ Add paragraphs to paragraph (b) to define the unit of payment.

++ Move language which addresses the requirement for OASIS submission from

§484.210 and insert it into §484.205 as new paragraph (c).

++ Move paragraph (c)(2) from §409.43 to §484.205 as new paragraph (g) in order to better align with the regulations detailing the basis of payment.

++ Add paragraph (h) to discuss split percentage payments under the current model and the proposed PDGM.

We are not proposing to change the requirements or policies relating to durable medical equipment or furnishing negative pressure wound therapy using a disposable device.

- Remove §484.210 which discusses data used for the calculation of the national prospective 60-day episode payment as we believe that this information is duplicative and already incorporated in other sections of part 484, subpart E.

- Revise the section heading of §484.215 from "Initial establishment of the calculation of the national 60-day episode payment" to "Initial establishment of the calculation of the national, standardized prospective 60-day episode payment and 30-day payment rates." Also, we propose to add paragraph (f) to this section to describe how the national, standardized prospective 60-day episode payment rate is converted into a national, standardized prospective 30-day period payment and when it applies.

- Revise the section heading of §484.220 from "Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels" to "Calculation of the case-mix and wage area adjusted prospective payment rates." We propose to remove the reference to "national 60-day episode payment rate" and replace it with "national, standardized prospective payment".

- Revise the section heading in §484.225 from "Annual update of the unadjusted

national prospective 60-day episode payment rate" to "Annual update of the unadjusted national, standardized prospective 60-day episode and 30-day payment rates". Also, we propose to revise §484.225 to remove references to "60-day episode" and to refer more generally to the "national, standardized prospective payment". In addition, we propose to add paragraph (d) to describe the annual update for CY 2020 and subsequent calendar years.

- Revise the section heading of §484.230 from "Methodology used for the calculation of low-utilization payment adjustment" to "Low utilization payment adjustment". Also, we propose to designate the current text to paragraph (a) and insert language such that proposed paragraph (a) applies to claims beginning on or before December 31, 2019, using the current payment system. We propose to add paragraph (b) to describe how low utilization payment adjustments are determined for claims beginning on or after January 1, 2020, using the proposed PDGM.

- Revise the section heading of §484.235 from "Methodology used for the calculation of partial episode payment adjustments" to "Partial payment adjustments". We propose to remove paragraphs (a), (b), and (c). We propose to remove paragraphs (1), (2), and (3) which describe partial payment adjustments from paragraph (d) in §484.205 and incorporate them into §484.235. We propose to add paragraph (a) to describe partial payment adjustments under the current system, that is, for claims beginning on or before December 31, 2019, and paragraph (b) to describe partial payment adjustments under the proposed PDGM, that is, for claims beginning on or after January 1, 2020.

- Revise the section heading for §484.240 from "Methodology used for the

calculation of the outlier payment" to "Outlier payments." In addition, we propose to remove language at paragraph (b) and append it to paragraph (a). We propose to add language to proposed revised paragraph (a) such that paragraph (a) will apply to payments under the current system, that is, for claims beginning on or before December 31, 2019. We propose to revise paragraph (b) to describe payments under the proposed PDGM, that is, for claims beginning on or after January 1, 2020. In paragraph (c), we propose to replace the "estimated" cost with "imputed" cost. Lastly, we propose to revise paragraph (d) to reflect the per-15 minute unit approach to imputing the cost for each claim.

We are soliciting comments on the proposed PDGM as outlined in sections III.F.1 through III.F.12 and the associated regulations text changes described above and in section IX of this proposed rule.

G. Proposed Changes Regarding Certifying and Recertifying Patient Eligibility for Medicare Home Health Services

1. Background

Sections 1814(a) and 1835(a) of the Act require that a physician certify patient eligibility for home health services (and recertify, where such services are furnished over a period of time). The certifying physician is responsible for determining whether the patient meets the eligibility criteria (that is, homebound status and need for skilled services) and for understanding the current clinical needs of the patient such that the physician can establish an effective plan of care. In addition, as a condition for payment, section 6407 of the Affordable Care Act amended sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act requiring, as part of the certification for home health services, that prior to certifying a patient's eligibility for the Medicare home health benefit the certifying physician must document that the physician himself or herself or an allowed non-physician practitioner had a face-to-face encounter with the patient. The regulations at 42 CFR 424.22(a) and (b) set forth the requirements for certification and recertification of eligibility for home health services. The regulations at §424.22(c) provide the supporting documentation requirements used as the basis for determining patient eligibility for Medicare home health services.

2. Current Supporting Documentation Requirements

In determining whether the patient is or was eligible to receive services under the Medicare home health benefit at the start of care, as of January 1, 2015, we require documentation in the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) to be

used as the basis for certification of home health eligibility as described at §424.22(c). Specifically, the certifying physician and/or the acute/post-acute care facility medical record (if the patient was directly admitted to home health) for the patient must contain information that justifies the referral for Medicare home health services. This includes documentation that substantiates the patient's:

- Need for the skilled services; and
- Homebound status;

Likewise, the certifying physician and/or the acute/post-acute care facility medical record (if the patient was directly admitted to home health) for the patient must contain the actual clinical note for the face-to-face encounter visit that demonstrates that the encounter:

- Occurred within the required timeframe,
- Was related to the primary reason the patient requires home health services; and
- Was performed by an allowed provider type.

This information can be found most often in clinical and progress notes and discharge summaries. While the face-to-face encounter must be related to the primary reason for home health services, the patient's skilled need and homebound status can be substantiated through an examination of all submitted medical record documentation from the certifying physician, acute/post-acute care facility, and/or HHA (if certain requirements are met). The synthesis of progress notes, diagnostic findings, medications, and nursing notes, help to create a longitudinal clinical picture of the patient's health status to make the determination that the patient is eligible for home health services.

HHAs must obtain as much documentation from the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) as they deem necessary to assure themselves that the Medicare home health patient eligibility criteria have been met. HHAs must be able to provide it to CMS and its review entities upon request. If the documentation used as the basis for the certification of eligibility (that is, the certifying physician's and/or the acute/post-acute care facility's medical record documentation) is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided.

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

Section 51002 of the BBA of 2018 amended sections 1814(a) and 1835(a) of the Act to provide that, effective for physician certifications and recertifications made on or after January 1, 2019, in addition to using the documentation in the medical record of the certifying physician or of the acute or post-acute care facility (where home health services were furnished to an individual who was directly admitted to the HHA from such facility), the Secretary may use documentation in the medical record of the HHA as supporting material, as appropriate to the case involved. We believe the BBA of 2018 provisions are consistent with our 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).[51] The sub-regulatory guidance describes the circumstances in which HHA documentation can be used along with the certifying physician and/or acute/post-acute care facility medical record to support the patient's homebound status and skilled need. Specifically, we state that information from the HHA, such as the 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, can be incorporated into the certifying physician's medical record for the patient and used to support the patient's homebound status and need for skilled care. However, this information must 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. This means that the appropriately incorporated HHA information, along with the certifying physician's and/or the acute/post-acute care facility's medical record, creates a clinically consistent picture that the patient is eligible for Medicare home health services. The certifying physician officially incorporates the HHA information into his/her medical record for the patient by signing and dating the material. Once incorporated, the documentation from the HHA, in conjunction with the certifying physician and/or acute/post-acute care facility documentation, must substantiate the patient's eligibility for home health services.

While we believe the provisions in section 51002 of the BBA of 2018 do not require a change to the current regulations because the provisions are consistent with existing CMS policy, we are discretionarily proposing to amend the regulations text at 42 CFR 424.22(c) to align the regulations text with current sub-regulatory guidance to allow

51 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

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.

We believe that this proposal incorporates existing sub-regulatory flexibilities into the regulations text that allow HHA medical record documentation to support the basis of home health eligibility. By incorporating the existing sub-regulatory guidance into regulation, HHAs are assured that HHA-generated documentation can be used as supporting material for the basis of home health eligibility, as long as all conditions are met, as described previously. HHAs have the discretion to determine the type and format of any documentation used to support home health eligibility. The expectation is that the HHA-generated supporting medical record documentation would be used to support the existing medical record of the certifying physician or the acute/post-acute care facility to create a clinically consistent picture that the individual is confined to the home and

requires skilled services. Anecdotally, we have received reports from HHAs that they typically include this supporting information on the plan of care. Generally, the certifying physician is also the physician who establishes the plan of care and the plan of care must be signed by the physician. Consequently, no additional burden is incurred by either the HHA or the certifying physician. As existing sub-regulatory guidance allows HHA-generated documentation to be used as supporting material for the physician's determination of eligibility for home health services, we expect that most HHAs already have a process in place to provide this information to the certifying physician or the acute/post-acute care facility. We welcome comments on this assumption.

We invite comments on this proposal to amend the regulations text at §424.22(c), which would codify subregulatory guidance allowing HHA-generated medical record documentation to be used as supporting material to the certifying physician's or the acute and/or post-acute care facility's medical record documentation as part of the certification and/or recertification of eligibility for home health services, under certain circumstances. The corresponding proposed regulations text changes can be found in section VIII. of this proposed rule.

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

In the CY 2018 HH PPS proposed rule (82 FR 35378), we invited public comments about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. Specifically, we asked the public to submit their ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to reduce burdens for hospitals,

physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. We specifically stated that CMS would not respond to the comment submissions in the final rule. Instead, we would review the comments submitted in response to the requests for information and actively consider them as we develop future regulatory proposals or future sub-regulatory policy guidance.

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 sub-regulatory 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).

The Home Health CoP at § 484.60(a)(2) sets forth the requirements for the content of the home health plan of care, which includes the types of services, supplies, and equipment required, as well as, the frequency and duration of visits to be made. Commenters stated that the plan of care requirement already includes the frequency and duration of visits to be made and is an estimate of how much longer home health services are expected to be required by the patient. They observed that including this information as part of the recertification statement is duplicative and unnecessary. Commenters went on to say that because the certifying physician must review, sign and date the plan of care at least every 60-days, he/she is attesting to how much longer he/she thinks the patient will require home health services. Commenters also stated that this estimate appears to

have no value to the patient, the physician, the HHA, or to CMS, but failure to include the physician's estimate of how much longer skilled care will be required can result in claim denials.

We have determined that the estimate of how much longer skilled care will be required at each recertification is not currently used for quality, payment, or program integrity purposes. Given this consideration and the Home Health CoP requirements for the content of the home health plan of care, and to mitigate any potential denials of home health claims that otherwise would meet all other Medicare requirements, we are proposing 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. We believe the elimination of this recertification requirement would result in a reduction of burden for certifying physicians by reducing the amount of time physicians spend on the recertification process and would result in an overall cost savings of $14.2 million. We provided a more detailed description of this burden reduction in section VIII.C.1.c. of this proposed rule.

We invite comments regarding the proposed elimination of the requirement that the certifying physician include an estimate of how much longer skilled services will be required at each home health recertification, as well as the corresponding regulations text changes at §424.22(b)(2).

While we are not proposing any additional changes to the home health payment regulations in this proposed rule as suggested by commenters in the RFI, we will continue to consider whether future regulatory or sub-regulatory changes are warranted to

reduce unnecessary burden. We thank the commenters for taking the time to convey their thoughts and suggestions on this initiative.

H. Proposed Change Regarding Remote Patient Monitoring under the Medicare Home Health Benefit

Section 4012 of the 21st Century Cures Act directed the Centers for Medicare & Medicaid Services (CMS) to provide information on the current use of and/or barriers to telehealth services. This directive, along with advancements in technology, prompted us to examine ways in which HHAs can integrate telehealth and/or remote patient monitoring into the care planning process. Telehealth services, under section 1834(m)(4) of the Act, include services such as professional consultations, office visits, pharmacologic management, and office psychiatry services furnished via a telecommunications system by a distant site physician or practitioner to a patient located at a designated "originating site." Originating sites, as defined under section 1834(m)(4)(C) of the Act, generally must be certain kinds of healthcare settings located in certain geographic areas. This definition generally does not include the beneficiary's home. As a Medicare condition for payment, an interactive telecommunications system generally is required when furnishing telehealth services. Medicare defines "interactive telecommunication systems" as audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner (42 CFR 410.78). Telehealth services are used to substitute for professional in-person visits when certain eligibility criteria are met. For patients receiving care under the Medicare home health benefit, section 1895(e)(1)(A) of the Act prohibits payment for services furnished via a telecommunications system if such services substitute for in-

person home health services ordered as part of a plan of care certified by a physician. However, the statute does not define the term "telecommunications system" as it relates to the provision of home health care and explicitly notes that an HHA is not prevented from providing services via a telecommunications system, assuming the service is not considered a home health visit for purposes of eligibility or payment.

Remote patient monitoring, while a service using a form of telecommunications, is not considered a Medicare telehealth service as defined under section 1834(m) of the Act, but rather uses "digital technologies to collect medical and other forms of health data from individuals in one location and electronically transmit that information securely to health care providers in a different location for assessment and recommendations." 52 For example, remote patient monitoring allows the patient to collect and transmit his or her own clinical data, such as weight, blood pressure, and heart rate for monitoring and analysis. The clinical data is monitored without a direct interaction between the practitioner and beneficiary, and then reviewed by the HHA for potential consultation with the certifying physician for changes in the plan of care. Additionally, because remote patient monitoring is not statutorily considered a telehealth service, it would not be subject to the restrictions on originating site and interactive telecommunications systems technology.

We believe remote patient monitoring could be beneficial in augmenting the home health services outlined in the patient's plan of care, without replicating or replacing home health visits. The plan of care, in accordance with the home health conditions of participation (CoPs), must identify patient-specific measurable outcomes

52 http://www.cchpca.org/remote-patient-monitoring

and goals, and be established, periodically reviewed, and signed by a physician (42 CFR 484.60(a)). The HHA must also promptly alert the relevant physician(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved, or that the plan of care must be altered (42 CFR 484.60(c)). Remote patient monitoring could enable the HHA to more quickly identify any changes in the patient's clinical condition, as well as monitor patient compliance, prompting physician review of, and potential changes to, the plan of care, as required per the CoPs. Particularly in cases where the home health patient is admitted for skilled observation and assessment of the patient's condition due to a reasonable potential for complications or an acute episode, remote patient monitoring could augment home health visits until the patient's clinical condition stabilized. Fluctuating or abnormal vital signs could be monitored between visits, potentially leading to quicker interventions and updates to the treatment plan.

A review of the literature shows that utilizing remote patient monitoring in chronic disease management has the potential to "significantly improve an individual's quality of life, allowing patients to maintain independence, prevent complications, and minimize costs."53 Specifically for patients with chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF), research indicates that remote patient monitoring has been successful in reducing readmissions and long-term acute care utilization.54 Likewise, a systematic review of evidence collected by the Agency for Healthcare Research and Quality (AHRQ) revealed that remote patient monitoring of

53 Rojhan, K., Laplante, S., Sloand, J., Main, C., Ibrahim, A., Wild, J., Sturt, N. Remote Monitoring of Chronic Diseases: A Landscape Assessment of Policies in Four European Countries (2016) PLOS One. V11 (5) https://dx.doi.org/10.1371%2Fjournal.pone.0155738

54 Broad, J., Davis, C., Bender, M., Smith, T. (2014) Feasibility and Acute Care Utilization Outcomes of a Post-Acute Transitional Telemonitoring Program for Underserved Chronic Disease Patients. Journal of Cardiac Failure. Vol 20 (8S) S116. http://dx.doi.org/10.1016/j.cardfail.2014.06.328

chronic cardiac and respiratory conditions resulted in lower mortality, improved quality of life, and reductions in hospital admissions.55 If changes in condition are identified early through careful monitoring, serious complications may be avoided, potentially preventing emergency department visits and hospital admissions. Surveillance and case management are frequently occurring interventions in home health, and remote patient monitoring leverages technology to encourage patient involvement and accountability in order to improve care coordination.

Anecdotally, we have heard from various home health agencies regarding integration of remote patient monitoring into the care planning process. For example, on a recent site visit to a home health agency, CMS participated in a care coordination meeting, which included a discussion of the agency's experience implementing remote patient monitoring in home health episodes. Certain patients with chronic conditions received tablets pre-loaded with software enabling patients to take and transmit their vital signs on a daily basis. The transmitted health data was then monitored and analyzed by an outside service, which contacted the HHA with any changes or abnormalities. This example highlights how remote patient monitoring could be integrated into the home health episode of care.

Additionally, we believe that the growth of technology and new software development could be used in the provision of care and care coordination in the home, as well as empower patients to be active participants in their disease management. 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

55 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).

certified by a physician, we do not have specific policies surrounding the use of remote patient monitoring by HHAs. We anticipate that HHAs would follow clinical and manufacturer guidelines when implementing the technology into clinical practice, while still meeting all statutory requirements, conditions for payment, and the home health conditions of participation.

Medicare began making separate payment in CY 2018 for CPT code 99091 that allows physicians and other healthcare professionals to bill for the collection and interpretation of physiologic data digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional (82 CFR 53013). CPT code 99091 is paid under the Medicare physician fee schedule, and thus cannot be billed by HHAs. Additionally, it includes the interpretation of the physiologic data, whereas the HHA would only be responsible for the collection of the data. However, with this distinction, we feel the code's description accurately describes remote monitoring services. Therefore, we propose 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."

Although the cost of remote patient monitoring is not separately billable under the HH PPS and may not be used as a substitute for in-person home health services, there is nothing to preclude HHAs from using remote patient monitoring to augment the care planning process as appropriate. As such, we believe the expenses of remote patient monitoring, if used by the HHA to augment the care planning process, must be reported on the cost report as allowable administrative costs (that is, operating

expenses) that are factored into the costs per visit. Currently, costs associated with remote patient monitoring are reported on line 23.20 on Worksheet A, as direct costs associated with telemedicine. For 2016, approximately 3 percent of HHAs reported telemedicine costs that accounted for roughly 1 percent of their total agency costs on the HHA cost report. However, these costs are not allocated to the costs per visit. We propose 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. This would allow HHAs to report the costs of remote patient monitoring on the HHA cost report as part of their operating expenses. These costs would then be factored into the costs per visit. Factoring the costs associated with remote patient monitoring into the costs per visit has important implications for assessing home health costs relevant to payment, including HHA Medicare margin calculations. We are soliciting comments on the proposed definition of remote patient monitoring under the HH PPS to describe telecommunication services used to augment the plan of care during a home health episode. Additionally, we welcome comments regarding additional utilization of telecommunications technologies for consideration in future rulemaking. We are also soliciting comments on the proposed changes to the regulations at 42 CFR 409.46, to include the costs of remote patient monitoring as allowable administrative costs (that is, operating expenses), as detailed in section IX. of this proposed rule.

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

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), we began testing the HHVBP Model on January 1, 2016. The HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, we selected nine states for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified Home Health Agencies (HHAs) providing services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington (competing HHAs) are required to compete in the Model. Requiring all Medicare-certified HHAs providing services in the selected states to participate in the Model ensures that: (1) there is no selection bias; (2) participating HHAs are representative of HHAs nationally; and, (3) there is sufficient participation to generate meaningful results.

As finalized in the CY 2016 HH PPS final rule, the HHVBP Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act beginning in CY 2018 based on the competing HHAs' performance on applicable measures. Payment adjustments will be increased incrementally over the course of the HHVBP Model in the following manner: (1) a

maximum payment adjustment of 3 percent (upward or downward) in CY 2018; (2) a maximum payment adjustment of 5 percent (upward or downward) in CY 2019; (3) a maximum payment adjustment of 6 percent (upward or downward) in CY 2020; (4) a maximum payment adjustment of 7 percent (upward or downward) in CY 2021; and (5) a maximum payment adjustment of 8 percent (upward or downward) in CY 2022. Payment adjustments are based on each HHA's Total Performance Score (TPS) in a given performance year (PY) comprised of: (1) a set of measures already reported via the Outcome and Assessment Information Set (OASIS) and completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys for all patients serviced by the HHA and select claims data elements; and (2) three New Measures for which points are achieved for reporting data.

For CY 2019, we are proposing to remove five measures and add two new proposed composite measures to the applicable measure set for the HHVBP model, revise our weighting methodology for the measures, and rescore the maximum number of improvement points.

B. Quality Measures

1. Proposal to Remove Two OASIS-Based Measures Beginning with Performance Year 4 (CY 2019)

In the CY 2016 HH PPS final rule, we finalized a set of quality measures in Figure 4a: Final PY1 Measures and Figure 4b: Final PY1 New Measures (80 FR 68671 through 68673) for the HHVBP Model used in PY1, referred to as the starter set. We also stated that this set of measures will be subject to change or retirement during subsequent model years and revised through the rulemaking process (80 FR 68669).

The measures were selected for the Model using the following guiding principles: (1) use a broad measure set that captures the complexity of the services HHAs provide; (2) incorporate flexibility for future inclusion of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) measures that cut across post-acute care settings; (3) develop 'second generation' (of the HHVBP Model) measures of patient outcomes, health and functional status, shared decision making, and patient activation; (4) include a balance of process, outcome and patient experience measures; (5) advance the ability to measure cost and value; (6) add measures for appropriateness or overuse; and (7) promote infrastructure investments. This set of quality measures encompasses the multiple National Quality Strategy (NQS) domains[56] (80 FR 68668). The NQS domains include six priority areas identified in the CY 2016 HH PPS final rule (80 FR 68668) as the CMS Framework for Quality Measurement Mapping. These areas are: (1) Clinical quality of care; (2) Care coordination; (3) Population & community health; (4) Person- and Caregiver-centered experience and outcomes; (5) Safety; and (6) Efficiency and cost reduction. Figures 4a and 4b of the CY 2016 HH PPS final rule identified 15 outcome measures (five from the HHCAHPS, eight from OASIS, and two claims-based measures), and nine process measures (six from OASIS, and three New Measures, which were not previously reported in the home health setting) for use in the Model.

In the CY 2017 HH PPS final rule, we removed four measures from the measure set for PY1 and subsequent performance years: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1

56 2015 Annual Report to Congress, http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm.

and March 31?; and (4) Reason Pneumococcal Vaccine Not Received, for the reasons discussed in that final rule (81 FR 76743 through 76747).

In the CY 2018 HH PPS final rule, we removed the Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care from the set of applicable measures beginning with PY3 for the reasons discussed in that final rule (82 FR 51703 through 51704).

For PY4 and subsequent performance years, we propose to remove two OASIS-based process measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, from the set of applicable measures. We adopted the Influenza Immunization Received for Current Flu Season measure beginning PY1 of the model. Since that time, we have received input from both stakeholders and a Technical Expert Panel (TEP) convened by our contractor in 2017 that because the measure does not exclude HHA patients who were offered the vaccine but declined it and patients who were ineligible to receive it due to contraindications, the measure may not fully capture HHA performance in the administration of the influenza vaccine. In response to these concerns, we are proposing to remove the measure from the applicable measure set beginning PY4.

We also adopted the Pneumococcal Polysaccharide Vaccine Ever Received measure beginning PY1 of the model. This process measure reports the percentage of HH episodes during which patients were determined to have ever received the Pneumococcal Polysaccharide Vaccine. The measure is based on guidelines previously

issued by the Advisory Committee on Immunization Practices (ACIP)[57], which recommended use of a single dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23) among all adults aged 65 years and older and those adults aged 19-64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection.[58] In 2014, the ACIP updated its guidelines to recommend that both PCV13 and PPSV23 be given to all immunocompetent adults aged ≥ 65 years.[59] The recommended intervals for sequential administration of PCV13 and PPSV23 depend on several patient factors including: the current age of the adult, whether the adult had previously received PPSV23, and the age of the adult at the time of prior PPSV23 vaccination (if applicable). Because the Pneumococcal Polysaccharide Vaccine Ever Received measure does not fully reflect the current ACIP guidelines, we are proposing to remove this measure from the model beginning PY4.

2. Proposal to Replace Three OASIS-Based Measures with Two Composite Measures Beginning with Performance Year 4

As previously noted, one of the goals of the HHVBP Model is to study new potential quality and efficiency measures for appropriateness in the home health setting. In the CY 2018 HH PPS Final Rule, we solicited comment on additional quality measures for future consideration in the HHVBP model, specifically a Total Change in

57 The Advisory Committee on Immunization Practices was established under Section 222 of the Public Health Service Act (42 U.S.C. 2l7a), as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs. (Charter of the Advisory Committee on Immunization Practices, filed April 1, 2018. https://www.cdc.gov/vaccines/acip/committee/ACIP-Charter-2018.pdf).

58 Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 1997;46:1-24.

59 Tomczyk S, Bennett NM, Stoecker C, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014; 63: 822–5.

ADL/IADL Peformance by HHA Patients Measure, a Composite Functional Decline Measure, and behavioral health measures (82 FR 51706 through 51711). For the reasons discussed, we are proposing to replace three individual OASIS measures (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion) with two composite measures: Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility. These proposed measures use several of the same ADLs as the composite measures discussed in the CY 2018 HH PPS Final Rule (82 FR 51707). Our contractor convened a TEP in November 2017, which supported the use of two proposed composite measures in place of the three individual measures because HHA performance on the three individual measures would be combined with HHA performance on six additional ADL measures to create a more comprehensive assessment of HHA performance across a broader range of patient ADL outcomes. The TEP also noted that HHA performance is currently measured based on any change in improvement in patient status, while the composite measures would report the magnitude of patient change (either improvement or decline) across six self-care and three mobility patient outcomes.

There are currently three ADL improvement measures in the HHVBP Model (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion). The maximum cumulative score across all three measures is 30. Because we are proposing to replace these three measures with the two composite measures, we are also proposing that each of the two composite measures would have a maximum score of 15 points, to ensure that the relative weighting of ADL-based measures would stay the same if the proposal to replace the three ADL improvement

measures with the two composite measures is adopted. That is, there would still be a maximum of 30 points available for ADL related measures.

The proposed Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures would represent a new direction in how quality of patient care is measured in home health. Both of these proposed composite measures combine several existing and endorsed Home Health Quality Reporting Program (HH QRP) outcome measures into focused composite measures to enhance quality reporting. These proposed composite measures fit within the *Patient and Family Engagement*[60] domain as functional status and functional decline are important to assess for residents in home health settings. Patients who receive care from an HHA may have functional limitations and may be at risk for further decline in function because of limited mobility and ambulation.

The proposed Total Normalized Composite Change in Self-Care measure computes the magnitude of change, either positive or negative, based on a normalized amount of possible change on each of six OASIS-based quality outcomes. These six outcomes are as follows:

- 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)

---

60 2017 Measures under Consideration List. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2017-CMS-Measurement-Priorities-and-Needs.pdf

• Improvement in Eating (M1870)

The proposed Total Normalized Composite Change in Mobility measure computes the magnitude of change, either positive or negative, based on the normalized amount of possible change on each of three OASIS-based quality outcomes. These three outcomes are as follows:

• Improvement in Toilet Transferring (M1840)

• Improvement in Bed Transferring (M1850)

• Improvement in Ambulation/Locomotion (M1860)

The magnitude of possible change for these OASIS items varies based on the number of response options. For example, M1800 (grooming) has four behaviorally-benchmarked response options (0 = most independent; 3 = least independent) while M1830 (bathing) has seven behaviorally-benchmarked response options (0 = most independent; 6 = least independent). The maximum possible change for a patient on item M1800 is 3, while the maximum possible change for a patient on item M1830 is 6. Both proposed composite measures would be computed and normalized at the episode level, then aggregated to the HHA level using the following steps:

• Step 1: Calculate absolute change score for each OASIS item (based on change between Start of Care(SOC)/Resumption of Care (ROC) and discharge) used to compute the Total Normalized Composite Change in Self-Care (6 items) or Total Normalized Composite Change in Mobility (3 items) measures.

• Step 2: Normalize scores based on maximum change possible for each OASIS item (which varies across different items). The normalized scores result in a maximum

possible change for any single item equal to "1"; this score is provided when a patient achieves the maximum possible change for the OASIS item.

• Step 3: Total score for Total Normalized Composite Change in Self-Care or Total Normalized Composite Change in Mobility is calculated by summing the normalized scores for the items in the measure. Hence, the maximum possible range of normalized scores at the patient level for Total Normalized Composite Change in Self-Care is -6 to +6, and for Total Normalized Composite Change in Mobility is -3 to +3.

We created two prediction models for the proposed Total Normalized Composite Change in Self-Care (TNC_SC) and Total Normalized Composite Change in Mobility (TNC_MOB) measures using information from OASIS items and patient clinical condition categories (see Table 50 for details on the number of OASIS items and OASIS clinical categories used in the prediction models). We computed multiple ordinary least squares (OLS) analyses beginning with risk factors that were available from OASIS D items and patient condition groupings. Any single OASIS D item might have more than one risk factor because we create dichotomous risk factors for each response option on scaled (from dependence to independence) OASIS items. Those risk factors that were statistically significant at $p<0.0001$ level were kept in the prediction model. These two versions (CY 2014 and CY 2015) of the prediction models were done as "proof of concept." We are proposing that the actual prediction models that would be used if the proposed composite measures are finalized would use episodes of care that ended in CY 2017, which would be the baseline year for the quality outcome measures used to compute the two proposed composite measures, as listed previously. The baseline year for these two composite measures would be calendar year 2017.

The following Table 50 provides an overview of results from the CY 2014 and CY 2015 prediction models for each proposed measure with estimated R-squared values comparing observed vs. predicted episode-level performance.

TABLE 50: OBSERVED VERSUS PREDICTED EPISODE-LEVEL PEFORMANCE FOR THE PROPOSED TOTAL NORMALIZED COMPOSITE CHANGE MEASURES

Prediction Model for	Number of OASIS Items Used	Number of Clinical Categories	R-squared Value
2014 TNC_SC	42	14	0.299
2015 TNC_SC	41	13	0.311
2014 TNC_MOB	42	16	0.289
2015 TNC_MOB	41	18	0.288

Table 50 presents the following summary information for the prediction models for the two proposed composite measures.

• Prediction Model for: This column identifies the measure and year of data used for the two "proof of concept" prediction models created for each of the two proposed composite measures, Total Normalized Composite Change in Self-Care (TNC_SC) and Total Normalized Composite Change in Mobility (TNC_MOB). The development of the prediction models was identical in terms of the list of potential risk factors and clinical categories. The only difference was one set of prediction models used episodes of care that ended in CY 2014, while the other set of prediction models used episodes of care that ended in CY 2015.

• Number of OASIS Items Used: This column indicates the number of OASIS items used as risk factors in the prediction model. For each prediction model, the number of OASIS items used is based on the number of risk factors that were statistically significant at $p<0.0001$ level in the prediction model.

• Number of Clinical Categories: This column indicates the number of patient clinical categories (for example, diagnoses related to infections or neoplasms or endocrine disorders) that are used as risk factors in the prediction model.

• R-squared Value: The R-squared values are a measure of the proportion of the variation in outcomes that is accounted for by the prediction model. The results show that the methodology that was used to create the prediction models produced very consistent models that predict at least 29 percent of the variability in the proposed composite measures.

The prediction models are applied at the episode level to create a specific predicted value for the composite measure for each episode of care. These episode level predicted values are averaged to compute a national predicted value and an HHA predicted value. The episode level observed values are averaged to compute the HHA observed value. The HHA TNC_SC and TNC_MOB observed scores are risk adjusted based on the following formula:

$$HHA\ Risk\ Adjusted = HHA\ Observed + National\ Predicted - HHA\ Predicted$$

HHAs are not allowed to skip any of the OASIS items that are used to compute these proposed composite measures or the risk factors that comprise the prediction models for the two proposed composite measures. The OASIS items typically do not include "not available (NA)" or "unknown (UK)" response options, and per HHQRP requirements[61], HHAs must provide responses to all OASIS items for the OASIS assessment to be accepted into the CMS data repository. Therefore, while we believe the likelihood that a value for one of these items would be missing is extremely small, we

61 Data Specifications - https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/DataSpecifications.html

are proposing to impute a value of "0" if a value is "missing." Specifically, if for some reason the information on one or more OASIS items that are used to compute TNC_SC or TNC_MOB is missing, we impute the value of "0" (no change) for the missing value. Similarly, if for some reason the information on one or more OASIS items that are used as a risk factor is missing, we impute the value of "0" (no effect) for missing values that comprise the prediction models for the two proposed composite measures. Table 51 contains summary information for these two proposed composite measures. Because the proposed TNC_SC and TNC_MOB are composite measures rather than simple outcome measures, the terms "Numerator" and "Denominator" do not apply to how these measures are calculated. Therefore, for these proposed composite measures, the "Numerator" and "Denominator" columns in Table 51 are replaced with columns describing "Measure Computation" and "Risk Adjustment".

Table 51 contains the set of applicable measures under the HHVBP model, if we finalize our proposals to remove the 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, and add the two proposed OASIS-based outcome composite measures, Total Change in Self-Care and Total Change in Mobility. This measure set, if our proposals are finalized, would be applicable to PY4 and each subsequent performance year until such time that another set of applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking.

TABLE 51: MEASURE SET FOR THE HHVBP MODEL BEGINNING PY 4*

NQS Domains	Measure Title	Measure Type	Identifier	Data Source	Numerator	Denominator
Clinical Quality of Care	Improvement in Dyspnea	Outcome	NA	OASIS (M1400)	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Communication & Care Coordination	Discharged to Community	Outcome	NA	OASIS (M2420)	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Efficiency & Cost Reduction	Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health	Outcome	NQF0171	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Efficiency & Cost Reduction	Emergency Department Use without Hospitalization	Outcome	NQF0173	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Patient Safety	Improvement in Pain Interfering with Activity	Outcome	NQF0177	OASIS (M1242)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less frequent pain at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient Safety	Improvement in Management of Oral Medications	Outcome	NQF0176	OASIS (M2020)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient & Caregiver-Centered Experience	Care of Patients	Outcome		CAHPS	NA	NA

Patient & Caregiver-Centered Experience	Communications between Providers and Patients	Outcome		CAHPS	NA	NA
Patient & Caregiver-Centered Experience	Specific Care Issues	Outcome		CAHPS	NA	NA
Patient & Caregiver-Centered Experience	Overall rating of home health care	Outcome		CAHPS	NA	NA
Patient & Caregiver-Centered Experience	Willingness to recommend the agency	Outcome		CAHPS	NA	NA
Population/ Community Health	Influenza Vaccination Coverage for Home Health Care Personnel	Process	NQF0431 (Used in other care settings, not Home Health)	Reported by HHAs through Web Portal	Healthcare personnel in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: a) received an influenza vaccination administered at the healthcare facility,, or reported in writing or provided documentation that influenza vaccination was received elsewhere: or b) were determined to have a medical contraindication/ condition of severe allergic reaction to eggs or to other components of the vaccine or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; or c) declined influenza vaccination; or d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the previously mentioned numerator categories.	Number of healthcare personnel who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.
Population/ Community Health	Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?	Process	NA	Reported by HHAs through Web Portal	Total number of Medicare beneficiaries aged 60 years and over who report having ever received zoster vaccine (shingles vaccine).	Total number of Medicare beneficiaries aged 60 years and over receiving services from the HHA.

Communication & Care Coordination	Advance Care Plan	Process	NQF0326	Reported by HHAs through Web Portal	Patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	All patients aged 65 years and older.
NQS Domains	**Measure Title**	**Measure Type**	**Identifier**	**Data Source**	**Measure Computation****	**Risk Adjustment****
Patient and Family Engagement	Total Normalized Composite Change in Self-Care	Composite Outcome	NA	OASIS (M1800) (M1810) (M1820) (M1830) (M1845) (M1870)	The total normalized change in self-care functioning across six OASIS items (grooming, bathing, upper & lower body dressing, toilet hygiene, and eating)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted – HHA Predicted.
Patient and Family Engagement	Total Normalized Composite Change in Mobility	Composite Outcome	NA	OASIS (M1840) (M1850) (M1860)	The total normalized change in mobility functioning across three OASIS items (toilet transferring, bed transferring, and ambulation/locomotion)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted – HHA Predicted.

*NOTES: For more detailed information on the measures using OASIS refer to the OASIS-C2 Guidance Manual effective January 1, 2017 available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-C2-Guidance-Manual-6-29-16.pdf
For NQF endorsed measures see The NQF Quality Positioning System available at http://www.qualityforum.org/QPS. For non-NQF measures using OASIS see links for data tables related to OASIS measures at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/index.html. For information on HHCAHPS measures see https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx.
** Because the proposed Total Normalized Composite Change in Self-Care and Mobility measures are composite measures rather than simply outcome measures, the terms "Numerator" and "Denominator" do not apply.

We invite public comment on the proposals to remove two OASIS-based measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, from the set of applicable measures for PY4 and subsequent performance years. We also invite public comment on the proposals to replace three OASIS-based measures, Improvement in Ambulation-Locomotion,

Improvement in Bed Transferring, and Improvement in Bathing, with two proposed composite measures, Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility, for PY4 and subsequent performance years.

3. Proposal to Reweight the OASIS-Based, Claims-Based, and HHCAHPS Measures

In the CY 2016 HH PPS final rule, we finalized weighting measures within each of the HHVBP Model's four classifications (Clinical Quality of Care, Care Coordination and Efficiency, Person and Caregiver-Centered Experience, and New Measures) the same for the purposes of payment adjustment. We finalized weighting each individual measure equally because we did not want any one measure within a classification to be more important than another measure, to encourage HHAs to approach quality improvement initiatives more broadly, and to address concerns where HHAs may be providing services to beneficiaries with different needs. Under this approach, a measure's weight remains the same even if some of the measures within a classification group have no available data. We stated that in subsequent years of the Model, we would monitor the impact of equally weighting the individual measures and may consider changes to the weighting methodology after analysis and in rulemaking (80 FR 68679).

For PY4 and subsequent performance years, we are proposing to revise how we weight the individual measures and to amend § 484.320(c) accordingly. Specifically, we are proposing to change our methodology for calculating the Total Performance Score (TPS) by weighting the measure categories so that the OASIS-based measure category and the claims-based measure category would each count for 35 percent and the HHCAHPS measure category would count for 30 percent of the 90 percent of the TPS that is based on performance of the Clinical Quality of Care, Care Coordination and

Efficiency, and Person and Caregiver-Centered Experience measures. Note that these measures and their proposed revised weights would continue to account for the 90 percent of the TPS that is based on the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. Data reporting for each New Measure would continue to have equal weight and account for the 10 percent of the TPS that is based on the New Measures collected as part of the Model. As discussed further below, we believe that this proposed reweighting, to allow for more weight for the claims-based measures, would better support improvement in those measures.

Weights would also be adjusted under this proposal for HHAs that are missing entire measure categories. For example, if an HHA is missing all HHCAHPS measures, the OASIS and claims-based measure categories would both have the same weight (50 percent each). We believe that this approach would also increase the weight given to the claims-based measures, and as a result give HHAs more incentive to focus on improving them. Additionally, if measures within a category are missing, the weights of the remaining measures within that measure category would be adjusted proportionally, while the weight of the category as a whole would remain consistent. We are also proposing that the weight of the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure would be increased so that it has three times the weight of the Emergency Department Use without Hospitalization claims-based measure, based on our understanding that HHAs may have more control over the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure. In addition, because inpatient hospitalizations

generally cost more than ED visits, we believe improvement in the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure may have a greater impact on Medicare expenditures.

We are proposing to reweight the measures based on our ongoing monitoring and analysis of claims and OASIS-based measures, which shows that there has been a steady improvement in OASIS-based measures, while improvement in claims-based measures has been relatively flat. For example, Figures 5 and 6 show the change in average performance for the claims-based and OASIS-based performance measures used in the Model. For both figures, we report the trends observed in Model and non-Model states. In both Model and non-Model states, there has been a slight increase (indicating worse performance) in the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health measure. For all OASIS-based measures, except the Improvement in Management of Oral Medications measure and the Discharge to Community measure, there has been substantial improvement in both Model and non-Model states. Given these results, we believe that increasing the weight given to the claims-based measures, and the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health measure in particular, may give HHAs greater incentive to focus on quality improvement in the claims-based measures. Increasing the weight of the claims-based measures was also supported by the contractor's TEP.

FIGURE 5:

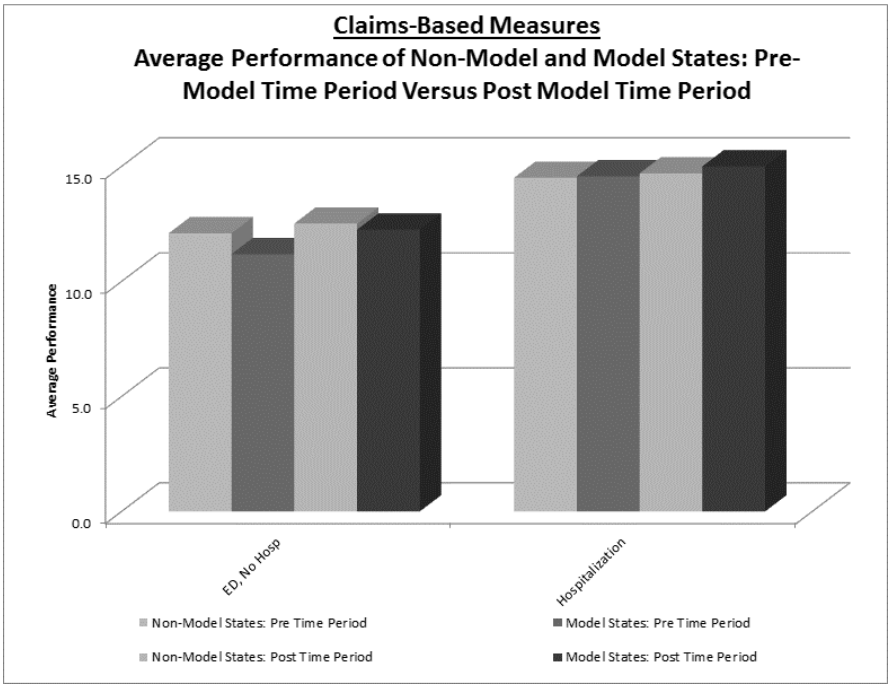

Claims-Based Measures
Average Performance of Non-Model and Model States: Pre-Model Time Period Versus Post Model Time Period
Average Performance
15.0
10.0
5.0
0.0
ED, No Hosp
Hospitalization
Non-Model States: Pre Time Period
Model States: Pre Time Period
Non-Model States: Post Time Period
Model States: Post Time Period

FIGURE 6:

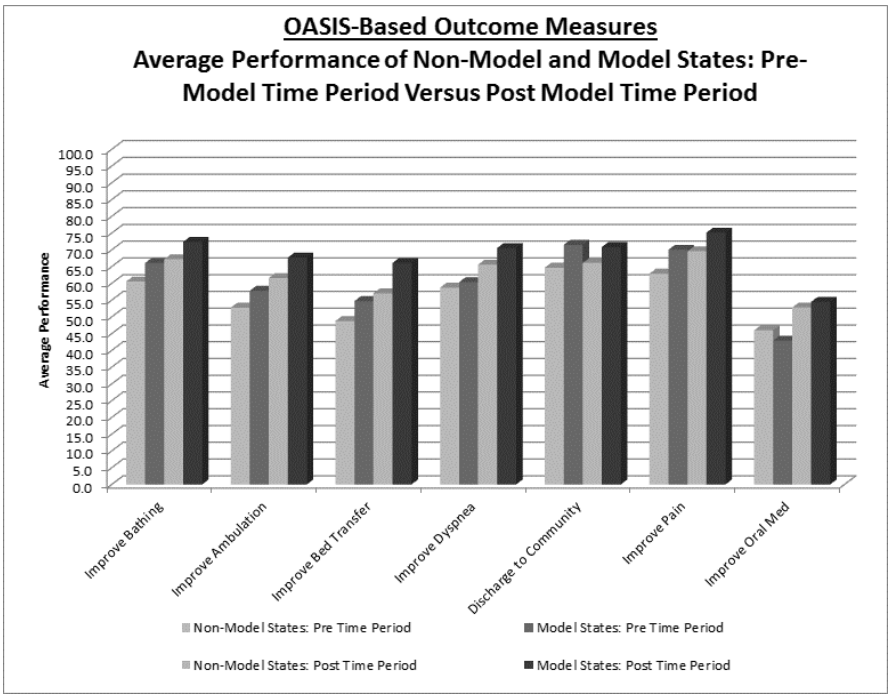


Table 52 shows the current and proposed weights for each measure based on this proposal to change the weighting methodology from weighting each individual measure equally to weighting the OASIS, claims-based, and HHCAHPS measure categories at 35-percent, 35-percent and 30-percent, respectively. Table 52 also shows the proposed weighting methodology based on various scoring scenarios. For example, for HHAs that are exempt from their beneficiaries completing HHCAHPS surveys, the total weight given to OASIS-based measures scores would be 50 percent, with all OASIS-based measures (other than the two proposed composite measures) accounting for an equal proportion of that 50 percent, and the total weight given to the claims-based measures

scores would be 50 percent, with the Acute Care Hospitalization: Unplanned Hospitalizations measure accounting for 37.50 percent and the ED Use without Hospitalization measure accounting for 12.50 percent. Finally, Table 52 shows the change in the number of HHAs, by size, that would qualify for a TPS and payment adjustment under the current and proposed weighting methodologies, using CY 2016 data. We note that Table 52 reflects only the proposed changes to the weighting methodology and not the other proposed changes to the HHVBP model for CY 2019 which, if finalized, would change the proposed weights as set forth in Table 52. We refer readers to Table 65 in section X. of this proposed rule, which reflects the weighting that would apply if all of our proposed changes, including the proposed changes to the applicable measure set, are adopted for CY 2019. As reflected in that table, the two proposed composite measures, if finalized, would have weights of 7.5 percent when all three measure categories are reported.

TABLE 52: CURRENT AND PROPOSED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES

	Current Weights (equal weighting)				Proposed Weights (OASIS 35%; Claims 35%; HHCAHPS 30%)			
	All Measures (n=1,026)	No HHCAHPS (n=465)	No claims (n=20)	No claims or HHCAHPS (n=99)	All Measures (n=1,026)	No HHCAHPS (n=460)	No claims (n=20)	No claims or HHCAHPS (n=73)
Large HHAs	*1023*	*382*	*20*	*49*	*1023*	*380*	*20*	*39*
Small HHAs	*3*	*83*	*0*	*50*	*3*	*80*	*0*	*34*
OASIS								
Flu vaccine ever received*	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Pneumococcal vaccine*	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Bathing**	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Bed Transfer**	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Ambulation**	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Oral Meds	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Dyspnea	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Pain	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Discharge to Community	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Total weight for OASIS measures	*56.25%*	*81.82%*	*64.26%*	*100.00%*	*35.00%*	*50.00%*	*53.85%*	*100.00%*
Claims								
Hospitalizations	6.25%	9.09%	0.00%	0.00%	26.25%	37.50%	0.00%	0.00%
Outpatient ED	6.25%	9.09%	0.00%	0.00%	8.75%	12.50%	0.00%	0.00%
Total weight for claims measures	*12.50%*	*18.18%*	*0.00%*	*0.00%*	*35.00%*	*50.00%*	*0.00%*	*0.00%*
HHCAHPS								
Care of patients	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Communication between provider and patient	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Discussion of specific care issues	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Overall rating of care	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Willingness to recommend HHA to family or friends	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Total weight for HHCAHPS measures	*31.25%*	*0.00%*	*35.70%*	*0.00%*	*30.00%*	*0.00%*	*46.15%*	*0.00%*

Notes: *Measures are proposed to be removed from the applicable measure set beginning CY 2019/PY 4.

**Measures are proposed to be removed if proposed composite measures are added to the applicable measure set beginning CY 2019/PY 4.

We invite public comment on the proposal to reweight the measures within the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience classifications so that the OASIS-based measures account for 35-percent, the claims-based measures account for 35-percent, and the HHCAHPS account for 30-percent of the 90 percent of the TPS that is based on performance on these measures, for PY4 and subsequent performance years. We are also proposing to amend §484.320 to reflect these proposed changes. Specifically, we are proposing to amend §484.320 to state that for performance years 4 and 5, CMS will sum all points awarded for each applicable measure within each category of measures (OASIS-based, claims-based, and HHCAHPS) excluding the New Measures, weighted at 35-percent for the OASIS-based measure category, 35-percent for the claims-based measure category, and 30-percent for the HHCAHPS measure category, to calculate a value worth 90-percent of the Total Performance Score. Table 53 is a sample calculation to show how this proposal, in connection with the proposed changes to the measure set, would affect scoring under the model as set forth in prior rulemaking (80 FR 68679 through 68686) when all three measure categories are reported.

TABLE 53: SAMPLE HHVBP TOTAL PERFORMANCE SCORE CALCULATION UNDER CURRENT and PROPOSED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES

	Points for Current Measures	Current Weight	Points for Proposed Measures	Proposed Weight	Weighted Points
OASIS					
Composite self-care	N/A	0.00%	7.661	7.50%	9.19
Composite mobility	N/A	0.00%	5.299	7.50%	6.36
Flu vaccine ever received	7.662	6.25%	N/A	0.00%	N/A
Pneumococcal vaccine	8.162	6.25%	N/A	0.00%	N/A
Improvement in bathing	5.064	6.25%	N/A	0.00%	N/A
Improvement in bed transfer	4.171	6.25%	N/A	0.00%	N/A
Improvement in ambulation	3.725	6.25%	N/A	0.00%	N/A
Improve oral meds	3.302	6.25%	3.302	5.00%	2.64
Improve Dyspnea	4.633	6.25%	4.633	5.00%	3.71
Improve Pain	4.279	6.25%	4.279	5.00%	3.42
Discharge to community	0.618	6.25%	0.618	5.00%	0.49
Claims					
Outpatient ED	0	6.25%	0	8.75%	0.00
Hospitalizations	1.18	6.25%	1.18	26.25%	4.96
HHCAHPS					
Care of patients	10	6.25%	10	6.00%	9.60
Communication between provider and patient	10	6.25%	10	6.00%	9.60
Discussion of special care issues	10	6.25%	10	6.00%	9.60
Overall rating of care	5.921	6.25%	5.921	6.00%	5.68
Willingness to recommend HHA to family and friends	8.406	6.25%	8.406	6.00%	8.07
Total	**87.123**	**100.00%**		**100.00%**	**57.776**

Total Performance Score Calculation		
	Current	**Proposed**
Raw score	87.123	57.776
Scaled score (adjusted for # of measures present)	58.082	57.776
Weighted score (90% of scaled score)	52.274	51.998
New measure score	100.000	100.000
Weighted new measure score (10% of new measure score)	10	10
TPS (sum of weighted score and weighted new measure score)	62.274	61.998

C. Performance Scoring Methodology

1. Proposal to Rescore the Maximum Amount of Improvement Points

In the CY 2016 HH PPS final rule, we finalized that an HHA could earn 0-10 points based on how much its performance in the performance period improved from its performance on each measure in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience classifications during the

baseline period. We noted, in response to public comment about our scoring methodology for improvement points, that we would monitor and evaluate the impact of awarding an equal amount of points for both achievement and improvement and may consider changes to the weight of the improvement score relative to the achievement score in future years through rulemaking (80 FR 68682).

We are proposing to reduce the maximum amount of improvement points, from 10 points to 9 points, for PY4 and subsequent performance years for all measures except for, if finalized, the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which the maximum improvement points would be 13.5. The maximum score of 13.5 represents 90-percent of the maximum 15 points that could be earned for each of the two proposed composite measures. The HHVBP Model focuses on having all HHAs provide high quality care and we believe that awarding more points for achievement than for improvement beginning with PY4 of the model would support this goal. We expect that at this point several years into participation in the Model, participating HHAs have had enough time to make the necessary investments in quality improvement efforts to support a higher level of care, warranting a slightly stronger focus on achievement over improvement on measure performance.

We believe that reducing the maximum improvement points to 9 would encourage HHAs to focus on achieving higher performance levels and incentivizing in this manner would encourage HHAs to rely less on their improvement and more on their achievement.

This proposal would also be consistent with public comments, and suggestions provided by our contractor's TEP. As summarized in the CY 2016 HH PPS final rule, we received comments encouraging us to focus on rewarding the achievement of specified quality scores, and reduce the emphasis on improvement scores after the initial 3 years of the HHVBP Model. Some commenters suggested measuring performance primarily based on achievement of specified quality scores with a declining emphasis over time on improvement versus achievement (80 FR 68682).

The TEP also agreed with reducing the maximum number of improvement points, which they believed would better encourage HHAs to pursue improved health outcomes for beneficiaries. We note that for the Hospital Value-Based Purchasing (HVBP) Program, CMS finalized a scoring methodology where hospitals could earn a maximum of 9 improvement points if their improvement score falls between the improvement threshold and the benchmark (76 FR 26515). Similarly, HHVBP is now proposing a scoring methodology where HHAs could earn a maximum of 9 improvement points.

We propose that an HHA would earn 0–9 points based on how much its performance during the performance period improved from its performance on each measure in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience classifications during the baseline period. A unique improvement range for each measure would be established for each HHA that defines the difference between the HHA's baseline period score and the same state level benchmark for the measure used in the achievement scoring calculation, according to the proposed improvement formula. If an HHA's performance on the measure during the performance period was--

• Equal to or higher than the benchmark score, the HHA could receive an improvement score of 9 points (an HHA with performance equal to or higher than the benchmark score could still receive the maximum of 10 points for achievement);

• Greater than its baseline period score but below the benchmark (within the improvement range), the HHA could receive an improvement score of 0–9 (except for, if finalized, the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which the maximum improvement score would be 15) for each of the two proposed composite measures) based on the formula and as illustrated in the examples below; or,

• Equal to or lower than its baseline period score on the measure, the HHA could receive zero points for improvement.

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

2. Examples of Calculating Achievement and Improvement Scores

For illustrative purposes we present the following examples of how the proposed changes to the performance scoring methodology would be applied in the context of the measures in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver Centered Experience classifications. These HHA examples are based on data from 2015 (for the baseline period) and 2016 (for the performance year). Figure 7 shows the scoring for HHA 'A' as an example. The benchmark calculated for the improvement in pain measure is 97.676 for HHA A (note that the benchmark is

calculated as the mean of the top decile in the baseline period for the state). The achievement threshold was 75.358 (this is defined as the performance of the median or the 50th percentile among HHAs in the baseline period for the state). HHA A's Year 1 performance rate for the measure was 98.348, which exceeds the benchmark so the HHA earned the maximum 10 points based on its achievement score. Its improvement score is irrelevant in the calculation because measure performance exceeded the benchmark.

Figure 7 also shows the scoring for HHA 'B.' As referenced below, HHA B's performance on this measure went from 52.168 (which was below the achievement threshold) in the baseline period to 76.765 (which is above the achievement threshold) in the performance period. Applying the achievement scale, HHA B' would earn 1.067 points for achievement, calculated as follows: 9 * (76.765 -75.358)/(97.676-75.358) + 0.5 = 1.067[62]. Calculating HHA B's improvement score yields the following result: based on HHA B's period-to-period improvement, from 52.168 in the baseline year to 76.765 in the performance year, HHA B would earn 4.364 points, calculated as follows: 9 * (76.765 - 52.168)/(97.676 - 75.358) - 0.5 = 4.364[63]. Because the higher of the achievement and improvement scores is used, HHA B would receive 4.364 points for this measure.

In Figure 8, HHA 'C' yielded a decline in performance on the improvement in pain measure, falling from 70.266 to 58.487. HHA C's performance during the performance period was lower than the achievement threshold of 75.358 and, as a result, the HHA would receive 0 points based on achievement. It would also receive 0 points for

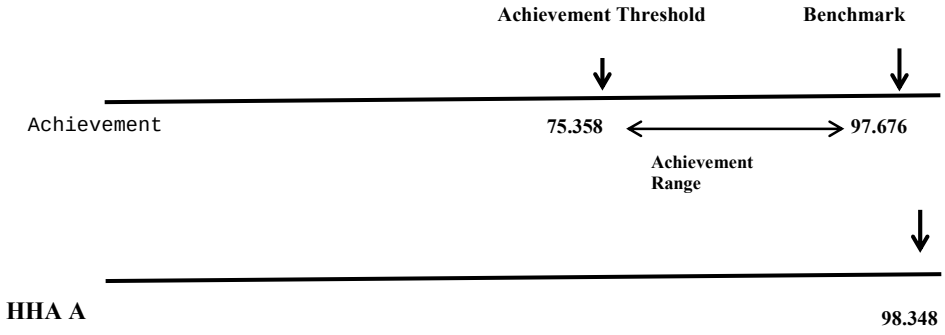
62 Achievement points are calculated as 9 * (HHA Performance Year Score- Achievement Threshold)/(Benchmark- Achievement threshold) +0.5

63 The formula for calculating improvement points is 9 * (HHA Performance Year Score – HHA Baseline Period Score)/(HHA Benchmark – HHA Baseline Period Score) - 0.5

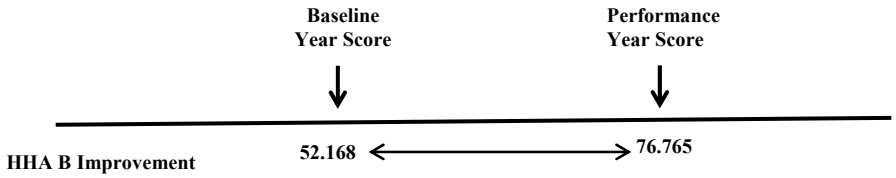
improvement, because its performance during the performance period was lower than its performance during the baseline period.

FIGURE 7: EXAMPLE OF AN HHA EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING

Measure: Improvement in Pain

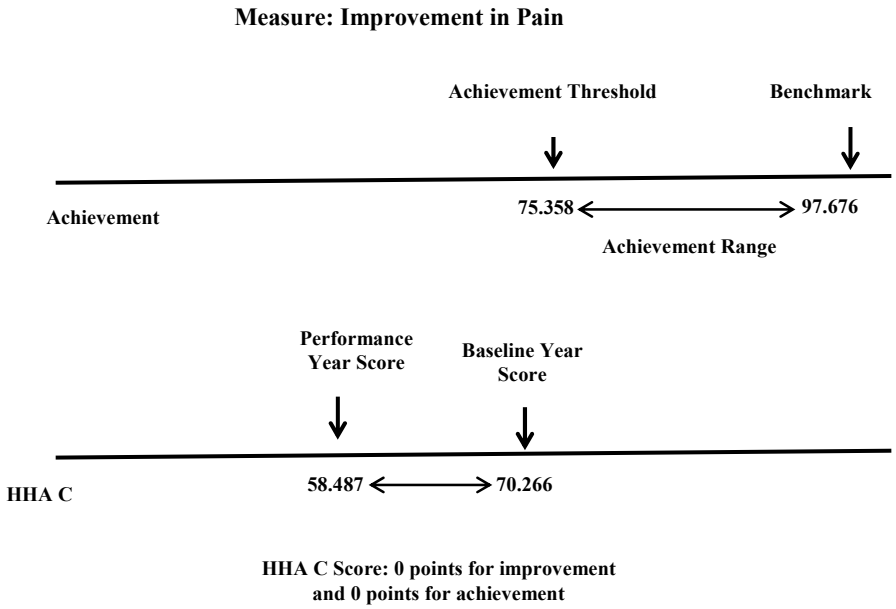


HHA A Score: 10 maximum points for achievement



HHA B Score: The greater of 1.067 points for achievement and 4.364 points for improvement.

FIGURE 8: EXAMPLE OF AN HHA NOT EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING



We would monitor and evaluate the impact of reducing the maximum improvement points to 9 and would consider whether to propose more changes to the weight of the improvement score relative to the achievement score in future years through rulemaking.

We invite public comment on the proposal to reduce the maximum amount of improvement points, from 10 points to 9 points for PY 4 and subsequent performance years.

D. Update on the Public Display of Total Performance Scores

In the CY 2016 HH PPS final rule (80 FR 68658), we stated that one of the three goals of the HHVBP Model is to enhance the current public reporting processes. We reiterated this goal and continued discussing the public display of HHAs' Total Performance Scores (TPSs) in the CY 2017 HH PPS final rule (81 FR 76751 through 76752). We believe that publicly reporting a participating HHA's TPS will encourage providers and patients to use this information when selecting an HHA to provide quality care. We are encouraged by the previous stakeholder comments and support for public reporting that could assist patients, physicians, discharge planners, and other referral sources to choose higher-performing HHAs.

In the CY 2017 HH PPS final rule, we noted that one commenter suggested that we not consider public display until after the Model was evaluated. Another commenter favored the public display of the TPS, but recommended that CMS use a transparent process and involve stakeholders in deciding what will be reported, and provide a review period with a process for review and appeal before reporting.

As discussed in the CY 2017 HH PPS final rule, we are considering public reporting for the HHVBP Model after allowing analysis of at least eight quarters of performance data for the Model and the opportunity to compare how these results align with other publicly reported quality data (81 FR 76751). While we are not making a specific proposal at this time, we are soliciting further public comment on what information, specifically from the CY 2017 Annual Total Performance Score and Payment Adjustment Reports and subsequent annual reports, should be made publicly available. We note that HHAs have the opportunity to review and appeal their Annual Total Performance Score and Payment Adjustment Reports as outlined in the appeals process finalized in the CY 2017 HH PPS final rule (81 FR 76747 through 76750). Examples of the information included in the Annual Total Performance Score and Payment Adjustment Report include the agency: name, address, TPS, payment adjustment percentage, performance information for each measure used in the Model (for example, quality measure scores, achievement, and improvement points), state and cohort information, and percentile ranking. Based on the public comments received, we will consider what information, specifically from the annual reports, we may consider proposing for public reporting in future rulemaking.

V. Proposed Updates to the Home Health Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of the Social Security Act (the Act) requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data with respect to a year in accordance with this clause, the Secretary is directed to reduce the HH market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, for 2015 and each subsequent year (except 2018), the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP and further reduction of the increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

For more information on the policies we have adopted for the HH QRP, we refer readers to the CY 2007 HH PPS final rule (71 FR 65888 through 65891), the CY 2008 HH PPS final rule (72 FR 49861 through 49864), the CY 2009 HH PPS update notice (73 FR 65356), the CY 2010 HH PPS final rule (74 FR 58096 through 58098), the CY 2011 HH PPS final rule (75 FR 70400 through 70407), the CY 2012 HH PPS final rule (76 FR 68574), the CY 2013 HH PPS final rule (77 FR 67092), the CY 2014 HH PPS final rule (78 FR 72297), the CY 2015 HH PPS final rule (79 FR 66073 through 66074),

the CY 2016 HH PPS final rule (80 FR 68690 through 68695), the CY 2017 HH PPS final rule(81 FR 76752), and the CY 2018 HH PPS final rule (82 FR 51711 through 51712).

Although we have historically used the preamble to the HH PPS proposed and final rules each year to remind stakeholders of all previously finalized program requirements, we have concluded that repeating the same discussion each year is not necessary for every requirement, especially if we have codified it in our regulations. Accordingly, the following discussion is limited as much as possible to a discussion of our proposals for future years of the HH QRP, and represents the approach we intend to use in our rulemakings for this program going forward.

B. General Considerations Used for the Selection of Quality Measures for the HH QRP

1. Background

For a detailed discussion of the considerations we historically used for measure selection for the HH QRP quality, resource use, and others measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696).

2. Accounting for Social Risk Factors in the HH QRP Program

In the CY 2018 HH PPS final rule (82 FR 51713 through 51714) we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the

quality of health care.[64] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.[65] As we noted in the CY 2018 HH PPS final rule (82 FR 51713 through 51714), ASPE's report to Congress, which was required by the IMPACT Act, found that, in the context of value based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. ASPE is continuing to examine this issue in its second report required by the IMPACT Act, which is due to Congress in the fall of 2019. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[66] The trial period ended in April 2017 and a final report is available at: http://www.qualityforum.org/SES_Trial_Period.aspx. The trial concluded that "measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship" between social risk factors and the outcomes measured. This discrepancy

64 See, for example United States Department of Health and Human Services. "Healthy People 2020: Disparities. 2014." Available at: http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

65 Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), "Report to Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs." December 2016. Available at: https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.

66 Available at http://www.qualityforum.org/SES_Trial_Period.aspx.

may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[67] allowing further examination of social risk factors in outcome measures.

In the CY 2018/FY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors could be used to stratify or risk adjust the measures (beyond dual eligibility), to consider the full range of differences in patient backgrounds that might affect outcomes, to explore risk adjustment approaches, and to offer careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to

67 Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.

more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, we are considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

C. Proposed Removal Factors for Previously Adopted HH QRP Measures

As a part of our Meaningful Measures Initiative, discussed in section I.D.1 of this proposed rule, we strive to put patients first, ensuring that they, along with their clinicians, are empowered to make decisions about their own healthcare using data-driven information that is increasingly aligned with a parsimonious set of meaningful quality measures. We began reviewing the HH QRP measure set in accordance with the Meaningful Measures Initiative discussed in section I.D.1 of this proposed rule, and we are working to identify how to move the HH QRP forward in the least burdensome manner possible, while continuing to prioritize and incentivize improvement in the

quality of care provided to patients.

Specifically, we believe the goals of the HH QRP and the measures used in the program overlap with the Meaningful Measures Initiative priorities, including making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable.

We also evaluated the appropriateness and completeness of the HH QRP's current measure removal factors. In the CY 2017 HH PPS final rule (81 FR 76754 through 76755), we adopted a process for retaining, removing, and replacing previously adopted HH QRP measures. To be consistent with other established quality reporting programs, we are proposing to replace the six criteria used when considering a quality measure for removal, finalized in the CY 2017 HH PPS final rule (81 FR 76754 through 76755), with the following seven measure removal factors, finalized for the LTCH QRP in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615) , for the SNF QRP in the FY 2016 SNF PPS final rule (80 FR 46431 through 46432), and for the IRF QRP in the CY 2013 OPPS/ASC final rule (77 FR 68502 through 68503), for use in the HH QRP:

- Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

• Factor 5. A measure that is more proximal in time to desired patient outcomes for the particular topic is available.

• Factor 6. A measure that is more strongly associated with desired patient outcomes for the particular topic is available.

• Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

We believe these measure removal factors are substantively consistent with the criteria we previously adopted (only we are changing the terminology to call them "factors") and appropriate for use in the HH QRP. However, even if one or more of the measure removal factors applies, we might nonetheless choose to retain the measure for certain specified reasons. Examples of such instances could include when a particular measure addresses a gap in quality that is so significant that removing the measure could result in poor quality, or in the event that a given measure is statutorily required. Furthermore, we note that consistent with other quality reporting programs, we apply these factors on a case-by-case basis.

We finalized in the CY 2017 HH PPS final rule (81 FR 76755) that removal of a HH QRP measure would take place through notice and comment rulemaking, unless we determined that a measure was causing concern for patient safety. Specifically, in the case of a HH QRP measure for which there was a reason to believe that the continued collection raised possible safety concerns, we would promptly remove the measure and publish the justification for the removal in the Federal Register during the next rulemaking cycle. In addition, we would immediately notify HHAs and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings. If we removed a measure from the HH QRP under these

circumstances but also collected data on that measure under different statutory authority for a different purpose, we would notify stakeholders that we would also cease collecting the data under that alternative statutory authority.

In this proposed rule, we are proposing to adopt an additional factor to consider when evaluating potential measures for removal from the HH QRP measure set:

• Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discussed in section I.D.1 of this proposed rule, with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the HH QRP measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to the following:

- Provider and clinician information collection burden and burden associated with the submitting/reporting of quality measures to CMS.
- The provider and clinician cost associated with complying with other HH programmatic requirements.
- The provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs.
- The cost to CMS associated with the program oversight of the measure, including measure maintenance and public display.

- The provider and clinician cost associated with compliance with other federal and state regulations (if applicable).

For example, it may be of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice). It may also be costly for HHAs to track confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. We may also have to expend resources to maintain the specifications for the measure, including the tools needed to collect, validate, analyze, and publicly report the measure data.

When these costs outweigh the evidence supporting the continued use of a measure in the HH QRP, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the HH QRP is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data is of limited use because it cannot be easily interpreted by beneficiaries and used to influence their choice of providers. In these cases, removing the measure from the HH QRP may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on proposed Factor 8 on a case-by-case basis. For example, we may decide to retain a measure that is burdensome for HHAs to report if we conclude that the benefit to beneficiaries is so high that it justifies the reporting burden. Our goal is to move the HH QRP program forward in the

least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposals to replace the six criteria used when considering a quality measure for removal with the seven measure removal factors currently adopted in the LTCH QRP, IRF QRP, and SNF QRP. We are also inviting public comment on our proposal to adopt new measure removal Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

D. Quality Measures Currently Adopted for the HH QRP

The HH QRP currently has 31 measures for the CY 2020 program year, as outlined in Table 54.

TABLE 54: MEASURES CURRENTLY ADOPTED FOR THE CY 2020 HH QRP

Short Name	Measure Name & Data Source
OASIS-based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (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 (#0519).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
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 (NQF #0537).
Influenza	Influenza Immunization Received for Current Flu Season (NQF #0522).
Oral Medications	Improvement in Management of Oral Medications (NQF #0176).
Pain	Improvement in Pain Interfering with Activity (NQF #0177).
PPV	Pneumococcal Polysaccharide Vaccine Ever Received.
Pressure Ulcer/Injury	Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), removed as of January 1, 2019. Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure, effective January 1, 2019.
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 HH (NQF #0171).
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP).
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173).
ED Use without Readmission	Emergency Department Use without Hospital Readmission During the First 30 Days of HH (NQF #2505).
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
Rehospitalization	Rehospitalization During the First 30 Days of HH (NQF #2380).
HHCAHPS-based	
Communication	How well did the home health team communicate with patients.

Short Name	Measure Name & Data Source
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	Will patients recommend the home health agency to friends and family.

E. Proposed Removal of HH QRP Measures Beginning with the CY 2021 HH QRP

To address the Meaningful Measures Initiative described in section I.D.1 of this proposed rule, we are proposing to remove seven measures from the HH QRP beginning with the CY 2021 HH QRP.

1. Proposed Removal of the Depression Assessment Conducted Measure

We are proposing to remove the Depression Assessment Conducted Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Depression Assessment Conducted Measure beginning with the CY 2010 HH QRP. Depression in the elderly is associated with disability, impaired well-being, service utilization,[68] and mortality.[69] This process measure reports the percentage of HH episodes in which patients were screened for depression (using a standardized depression screening tool) at start of care/resumption of care (SOC/ROC). The measure is calculated solely using the OASIS Item M1730, Depression Screening.[70] Item M1730 is additionally used at SOC/ROC as a risk

68 Beekman AT, Deeg DJ, Braam AW, et al.: Consequences of major and minor depression in later life: a study of disability, well-being and service utilization. Psychological Medicine 27:1397–1409, 1997.
69 Schulz, R., Beach, S. R., Ives, D. G., Martire, L. M., Ariyo, A. A., & Kop, W. J. (2000). Association between depression and mortality in older adults – The Cardiovascular Health Study. Archives of Internal Medicine, 160(12), 1761–1768.
70 Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

adjuster in the calculation of several other OASIS-based outcome measures currently adopted for the HH QRP.[71]

In our evaluation of the Depression Assessment Conducted Measure, we found that HHA performance is very high and that meaningful distinctions in improvements in performance cannot be made. The mean and median agency performance scores for this measure in 2017 (96.8 percent and 99.2 percent, respectively) when compared to the mean and median agency performance scores for this measure in 2010 (88.0 percent and 96.6 percent, respectively) indicate that an overwhelming majority of patients are screened for depression in the HH setting. Further, these performance scores demonstrate the improvement in measure performance since its adoption in the HH QRP. In addition, in 2017 the 75th percentile measure score (100 percent) and the 90th percentile measure score (100 percent) are statistically indistinguishable from each other, meaning that the measure scores do not meaningfully distinguish scores between HHAs. Further, the Truncated Coefficient of Variation (TCV)[72] for this measure is 0.03, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.

For these reasons, we are proposing to remove the Depression Assessment Conducted Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

---

71 The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in the calculation of the measure 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).

72 The truncated coefficient of variation (TCV) is the ratio of the standard deviation to the mean of the distribution of all scores, excluding the 5 percent most extreme scores. A small TCV (≤ 0.1) indicates that the distribution of individual scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual performance scores.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M1730, Depression Screening at SOC/ROC for the purposes of this measure beginning January 1, 2020. HHAs would however continue to submit data on M1730 at the time point of SOC/ROC as a risk adjuster for several other OASIS-based outcome measures currently adopted for the HH QRP[73]. If finalized as proposed, data for this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

2. Proposed Removal of the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure

We are proposing to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure beginning with the CY 2010 HH QRP. This process measure reports the percentage of HH quality episodes in which diabetic foot care and patient/caregiver education were included in the physician-ordered plan of care and implemented (at the time of or at any time since the most recent SOC/ROC assessment). The measure numerator is calculated using

73 The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in the calculation of the measure 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).

OASIS Item M2401 row a, Intervention Synopsis: Diabetic foot care.[74]

In our evaluation of the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure, we found that HHA performance is very high and that meaningful distinctions in improvements in performance cannot be made. The mean and median agency performance scores for this measure in 2017 (97.0 percent and 99.2 percent, respectively) when compared to the mean and median agency performance score for this measure in 2010 (86.2 percent and 91.7 percent, respectively), indicate that an overwhelming majority of HH episodes for patients with diabetes included education on foot care. Further, these scores demonstrate the improvement in measure performance since the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure's adoption in the HH QRP. In addition, in 2017 the 75th percentile measure score (100 percent) and the 90th percentile score (100 percent) are statistically indistinguishable from each other, meaning that the measure scores do not meaningfully distinguish between HHAs. Further, the TCV for this measure is 0.03, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.

For these reasons, we are proposing to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP beginning with CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item

---

74 Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

M2401 row a, Intervention Synopsis: Diabetic foot care at the time point of Transfer to an Inpatient Facility (TOC) and Discharge from Agency — Not to an Inpatient Facility (Discharge) for the purposes of the HH QRP beginning January 1, 2020. HHAs may enter an equal sign (=) for M2401, row a, at the time point of TOC and Discharge on or after January 1, 2020. If finalized as proposed, data for this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

3. Proposed Removal of the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure

We are proposing to remove the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure[75] beginning with the CY 2010 HH QRP. This process measure reports the percentage of HH quality episodes in which patients had a multifactor fall risk assessment at SOC/ROC. The measure is calculated using OASIS Item M1910, Falls Risk Assessment.[76]

In our evaluation of the Multifactor Fall Risk Assessment Conducted For All Patients

[75] At the time, this measure was adopted as "Falls risk assessment for patients 65 and older." The name of this measure was updated in the CY 2018 HH PPS final rule (82 FR 51717).

76 Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

Who Can Ambulate (NQF #0537) Measure, we found that HHA performance is very high and that meaningful distinctions in improvements in performance cannot be made. The mean and median agency performance scores for this measure in 2017 (99.3 percent and 100.0 percent, respectively) when compared to the mean and median agency performance score for this measure in 2010 (94.8 percent and 98.9 percent, respectively), indicate that an overwhelming majority of patients in an HHA have had a multifactor fall risk assessment at SOC/ROC and demonstrates the improvement in measure performance since its adoption. In addition, in 2017 the 75th percentile measure score (100 percent) and the 90th percentile measure score (100 percent) are statistically indistinguishable from each other, meaning that the measure scores do not meaningfully distinguish between HHAs. Further, the TCV for this measure is 0.01, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.

For these reasons, we are proposing to remove the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M1910, Falls Risk Assessment at SOC/ROC beginning January 1, 2020. HHAs may enter an equal sign (=) for M1910 at the time point of SOC and ROC beginning January 1, 2020. If finalized as proposed, data for this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

4. Proposed Removal of the Pneumococcal Polysaccharide Vaccine Ever Received Measure

We are proposing to remove the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 3. A measure does not align with current clinical guidelines or practice.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Pneumococcal Polysaccharide Vaccine Ever Received Measure beginning with CY 2010 HH QRP. This process measure reports the percentage of HH quality episodes during which patients were determined to have ever received the Pneumococcal Polysaccharide Vaccine. The measure is calculated using OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received.[77]

At the time that this measure was adopted in the HH QRP, the Advisory Committee on Immunization Practices (ACIP)[78] , which sets current clinical guidelines, recommended use of a single dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23) among all adults aged 65 years and older and those adults aged 19 to 64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection.[79]

Since this measure was added to the HH QRP, the ACIP has updated its pneumococcal

77 Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

78The Advisory Committee on Immunization Practices was established under section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs. (Charter of the Advisory Committee on Immunization Practices, filed April 1, 2018. https://www.cdc.gov/vaccines/acip/committee/ACIP-Charter-2018.pdf.)

79 Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 1997;46:1-24.

vaccination recommendations.[80] Two pneumococcal vaccines are currently licensed for use in the United States: the 13-valent pneumococcal conjugate vaccine (PCV13) and the 23-valent pneumococcal vaccine (PPSV23). The ACIP currently recommends that both PCV13 and PPSV23 be given to all immunocompetent adults aged ≥ 65 years. The recommended intervals for sequential administration of PCV13 and PPSV23 depend on several patient factors including: the current age of the adult, whether the adult had previously received PPSV23, and the age of the adult at the time of prior PPSV23 vaccination (if applicable).

The specifications for the Pneumococcal Polysaccharide Vaccine Ever Received Measure do not fully reflect the current ACIP guidelines. Therefore, we believe that the Pneumococcal Polysaccharide Vaccine Ever Received Measure no longer aligns with the current clinical guidelines or practice. For this reason, we are proposing to remove the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 3. A measure does not align with current clinical guidelines or practice.

If finalized as proposed, HHAs would no longer be required to submit OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received at the time point of TOC and Discharge for the purposes of the HH QRP beginning January 1, 2020. HHAs may enter an equal sign (=) for Items M1051 and M1056 at the time point of TOC and Discharge on or after January 1, 2020. If finalized as proposed, data for this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

---

80 Tomczyk S, Bennett NM, Stoecker C, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014;63: 822–5.

5. Proposed Removal of the Improvement in the Status of Surgical Wounds Measure

We are proposing to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

In the CY 2008 HH PPS final rule (72 FR 49861 through 49863), we adopted the Improvement in the Status of Surgical Wounds Measure for the HH QRP beginning with the CY 2008 program year. This risk-adjusted outcome measure reports the percentage of HH episodes of care during which the patient demonstrates an improvement in the condition of skin integrity related to the surgical wounds. This measure is solely calculated using OASIS Items M1340, Does this patient have a Surgical Wound? and M1342, Status of Most Problematic Surgical Wound that is Observable.[81] Items M1340 and M1342 are also used at the time points of SOC/ROC as risk adjusters in the calculation of several other OASIS-based outcome measures currently adopted for the HH QRP[82] Additionally, Items M1340 and M1342 are used at the time point of Discharge for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance that is used by HH surveyors during the survey process.[83]

The Improvement in the Status of Surgical Wounds Measure is limited in scope to surgical wounds incurred by surgical patients and excludes HH episodes of care where the

81 Measure specifications can be found in the Home Health Outcomes Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-C2_4-11-18.pdf).

82 The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in the calculation of the measure 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), and Improvement in Management of Oral Medications (NQF #0176).

83 Measure specifications can be found in the Home Health Potentially Avoidable Events Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-PAE-Measures-Table-OASIS-C2_4-11-18.pdf).

patient, at SOC/ROC, did not have any surgical wounds or had only a surgical wound that was unobservable or fully epithelialized. As a result, the majority of HHAs are not able to report data on the measure and the measure is limited in its ability to compare how well HHAs address skin integrity. For example, in 2016, only 13 percent of HH patients had a surgical wound at the beginning of their HH episode and only 36.6 percent of HHAs were able to report data on the measure with respect to that year.

In contrast, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) Measure (NQF #0678)[84] and its replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury Measure more broadly assess the quality of care furnished by HHAs with respect to skin integrity. These measures encourage clinicians to assess skin integrity in the prevention of pressure ulcers, as well as to monitor and promote healing in all HH patients, not just those with surgical wounds.

Therefore, we are proposing to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

If finalized as proposed, HHAs would no longer be required to submit OASIS Items M1340, Does this patient have a Surgical Wound? and M1342, Status of Most Problematic Surgical Wound that is Observable at the time points of SOC/ROC and Discharge for the purposes of this measure beginning with January 1, 2020 episodes of care. However, HHAs would still be required to submit data on Items M1340 and M1342 at the time point of SOC/ROC as risk adjusters for several other OASIS-based outcome measures currently adopted

84 To be replaced with a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP.

for the HH QRP[85], and also at the time point of Discharge for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance[86] that is used by HH surveyors during the survey process. If finalized as proposed, data on this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

6. Proposed Removal of the Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure

We are proposing to remove the Emergency Department (ED) Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available).

In the CY 2014 HH PPS final rule (78 FR 72298 through 72301), we adopted the claims-based ED Use without Hospital Readmission during the first 30 days of HH (NQF #2505) Measure beginning with CY 2014 HH QRP. The particular topic for this measure is ED utilization, as it estimates the risk-standardized rate of ED use without acute care hospital admission during the 30 days following the start of the HH stay for patients with an acute inpatient hospitalization in the 5 days before the start of their HH stay. The ED Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure is limited to Medicare FFS patients with a prior, proximal inpatient stay. Recent analyses from 2016 and

85 The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in the calculation of the measure 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), and Improvement in Management of Oral Medications (NQF #0176).
86Measure specifications can be found in the Home Health Potentially Avoidable Events Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-PAE-Measures-Table-OASIS-C2_4-11-18.pdf).

2017 show that this measure annually captured approximately 2.5 million (25.1 percent in 2016 and 25.1 percent in 2017) of Medicare FFS HH stays and was reportable for less than two-thirds of the HHAs (62.1 percent in 2016 and 62.6 percent in 2017).

The ED Use without Hospitalization During the First 60 Days of HH (NQF #0173) Measure also addresses the topic of ED utilization during a HH stay. This measure reports the percentage of Medicare FFS HH stays in which patients used the ED but were not admitted to the hospital during the 60 days following the start of the HH stay. The ED Use without Hospitalization during the First 60 days of HH (NQF #0173) Measure includes Medicare FFS patients irrespective of whether or not they had an acute inpatient hospitalization in the five days prior to the start of the HH stay and spans the first 60 days of a HH episode. Recent analyses using 2016 and 2017 data show this measure annually captures approximately 8.3 million stays (81.9 percent in 2016 and 81.8 percent in 2017) and is reportable by a greater number of HHAs (88.8 percent in 2016 and 88.1 percent in 2017) than the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure.

The ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure addresses outcomes of Medicare FFS patients for a 30-day interval after the start of their HH care, regardless of the length of their HH stay. The more broadly applicable ED Use without Hospitalization during the First 60 days of HH (NQF #0173) Measure addresses these same outcomes for a greater number of Medicare FFS patients during the first 60 days of a HH stay and includes the 30-day interval of the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure. The measure specifications for both measures are otherwise harmonized along several measure dimensions, including data source, population, denominator exclusions, numerator, and risk adjustment

methodology. As a result, removing the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure in favor of the ED Use without Hospitalization during the First 60 days of HH (NQF #173) Measure will not result in a loss of the ability to measure the topic of ED utilization for HH patients.

For these reasons, we are proposing to remove the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. If finalized as proposed, data for this measure would be reported on HH Compare until January 2020.

We are inviting public comment on this proposal.

7. Proposed Removal of the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure

We are proposing to remove the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

In the CY 2014 HH PPS final rule (78 FR 72297 through 72301), we adopted the claims-based Rehospitalization during the first 30 Days of HH Measure beginning with the CY 2014 HH QRP. The measure was NQF-endorsed (NQF #2380) in December 2014. The Rehospitalization during the first 30 Days of HH (NQF #2380) Measure addresses the particular topic of acute care hospital utilization during a HH stay. This measure estimates the risk-standardized rate of unplanned, all-cause hospital readmissions for patients who had an

acute inpatient hospitalization in the 5 days before the start of their HH stay and were admitted to an acute care hospital during the 30 days following the start of the HH stay (78 FR 72297 through 72301). The Rehospitalization During the First 30 Days of HH (NQF #2380) Measure only includes Medicare FFS patients. Recent analyses from 2016 and 2017 show that this measure annually captured approximately 2.5 million (25.1 percent in 2016 and 25.1 percent in 2017) of Medicare FFS HH stays and was reportable for less than two-thirds of the HHAs (62.1 percent in 2016 and 62.6 percent in 2017).

In the CY 2013 HH PPS final rule (77 FR 67093 through 67094), we finalized the claims-based Acute Care Hospitalization Measure. The measure's title was later updated to Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) to improve clarity.[87] The Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) Measure also addresses the topic of acute care hospital utilization during a HH stay. This measure reports the percentage of HH stays in which Medicare FFS patients were admitted to an acute care hospital during the 60 days following the start of the HH stay. The Acute Care Hospitalization during the First 60 Days of HH (NQF #0171) Measure includes Medicare FFS patients irrespective of whether or not they had an acute inpatient hospitalization in the five days prior to the start of the HH stay and spans the first 60 days of a HH episode. Recent analyses using 2016 and 2017 data show this measure annually captures approximately 8.3 million stays (81.9 percent in 2016 and 81.8 percent in 2017) and is reportable by a greater number of HHAs (88.8 percent in 2016 and 88.1 percent in 2017) than the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure.

The Rehospitalization during the First 30 Days of HH (NQF #2380) Measure addresses

87 All-Cause Admissions and Readmissions 2015-2017 Technical Report, National Quality Forum, Washington DC, 2017. (http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85033) page 20.

outcomes of Medicare FFS patients for a 30-day interval after the start of their HH care, regardless of the length of their HH stay. In contrast, the Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) Measure is broader because it addresses these same outcomes for a greater number of Medicare FFS patients during the first 60 Days of a HH stay, which includes the 30-day interval of the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure. The measure specifications for both measures are otherwise harmonized along several measure dimensions, including data source, population, denominator exclusions, numerator, and risk adjustment methodology. As a result, removing the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure in favor of the Acute Care Hospitalization during the First 60 Days of HH (NQF #0171) Measure will not result in a loss of the ability to measure the topic of acute care hospital utilization across the HH setting.

For these reasons, we are proposing to remove the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for particular topic is available. If finalized as proposed, data for this measure would be publicly reported on HH Compare January 2020.

We are inviting public comment on this proposal.

F. IMPACT Act Implementation Update

In the CY 2018 HH PPS final rule (82 FR 51731), we stated that we intended to specify two measures that would satisfy the domain of accurately communicating the existence and provision of the transfer of health information and care preferences under section 1899B(c)(1)(E) of the Act no later than January 1, 2019 and intend to propose to adopt them for the CY 2021 HH QRP, with data collection beginning on or about January 1, 2020.

As a result of the input provided during a public comment period between November 10, 2016 and December 11, 2016, input provided by a technical expert panel (TEP) convened by our contractor, and pilot measure testing conducted in 2017, we are engaging in continued development work on these two measures, including supplementary measure testing and providing the public with an opportunity for comment in 2018. Further, we reconvened a TEP for these measures in April 2018. We now intend to specify the measures under section 1899B(c)(1)(E) of the Act no later than January 1, 2020, and intend to propose to adopt the measures beginning with the CY 2022 HH QRP, with data collection at the time point of SOC, ROC and Discharge beginning with January 1, 2021. For more information on the pilot testing, we refer readers 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.

G. Form, Manner, and Timing of OASIS Data Submission

Our home health regulations, codified at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey® (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. We are proposing to revise §484.250(a) to clarify that not all OASIS data described in § 484.55(b) and (d) are needed for purposes of complying with the requirements of the HH QRP. OASIS data items may be submitted for other established purposes unrelated to the HH QRP, including payment, survey, the HH VBP Model, or care planning. Any OASIS data that are not submitted for the purposes of the HH QRP are not used for purposes of HH QRP compliance.

We are inviting public comment on our proposal to revise our regulations at

§484.250(a) to clarify that not all OASIS data described in § 484.55(b) and (d) are needed for purposes of complying with the requirements of the HH QRP.

H. Proposed Policies Regarding Public Display for the HH QRP

Section 1899B(g) of the Act requires that data and information of PAC provider performance on quality measures and resource use and other measures be made publicly available beginning not later than 2 years after the applicable specified 'application date'. In the CY 2018 HH PPS final rule (82 FR 51740 through 51741), we finalized that we would publicly display the Medicare Spending Per Beneficiary (MSPB)-PAC HH QRP beginning in CY 2019 based on one year of claims data on discharges from CY 2017.

In this proposed rule, we are proposing to increase the number of years of data used to calculate the MSPB-PAC HH QRP for purposes of display from 1 year to 2 years. Under this proposal, data on this measure would be publicly reported in CY 2019, or as soon thereafter as operationally feasible, based on discharges from CY 2016 and CY 2017. Increasing the measure calculation and public display periods from 1 to 2 years of data increases the number of HHAs with enough data adequate for public reporting for the MSPB-PAC HH QRP measure from 90.7 percent (based on August 1st, 2014 – July 31st, 2015 Medicare FFS claims data) to 94.9 percent (based on August 1st, 2014 – July 31st, 2016 Medicare FFS claims data). Increasing measure public display periods to 2 years also aligns with the public display periods of these measures in the IRF QRP, LTCH QRP and SNF QRP.

We invite public comment on our proposal to increase the number of years of data used to calculate the MSPB-PAC HH QRP for purposes of display from 1 year to 2 years.

I. Home Health Care Consumer Assessment of Healthcare Providers and Systems® (HHCAHPS)

We are not proposing changes to the Home Health Care Consumer Assessment of Healthcare Providers and Systems® (HHCAHPS) Survey requirements for CY 2019. Therefore, HHCAHPS Survey requirements are as codified in §484.250 and the HHCAHPS survey vendors' data submission deadlines are as posted on HHCAHPS Website at https://homehealthcahps.org.

VI. Medicare Coverage of Home Infusion Therapy Services

In this section of the rule, we discuss the new home infusion therapy benefit that was established in section 5012 of the 21st Century Cures Act. This benefit covers the nursing, patient training and education, and monitoring services associated with administering infusion drugs in a patient's home. This proposed rule would establish health and safety standards for home infusion therapy and consistency in coverage for home infusion therapy services. Section 1861(iii)(3)(D)(III) of the Act, as added by section 5012(b) of the 21st Cures Act, requires that a qualified home infusion therapy supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and modifying the list of designated AOs. Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021. In addition, this proposed rule establishes regulations for the approval and oversight of accrediting organizations that provide accreditation to home infusion therapy suppliers. This rule also provides information on temporary transitional payments for home infusion therapy services for CYs 2019 and 2020, as mandated by section 50401 of the BBA of 2018, proposes a regulatory definition of "Infusion Drug Administration Calendar Day", and solicits comments regarding payment for home infusion therapy services for CY 2021 and subsequent years as required by section 5012(d) of the 21st Century Cures Act.

A. General Background

1. Overview

Infusion drugs and administration services can be provided in multiple health care settings, including inpatient hospitals, skilled nursing facilities (SNFs), hospital outpatient

departments (HOPDs), physician offices, and in the home. Traditional Fee-for-Service (FFS) Medicare provides coverage for infusion drugs, equipment, supplies, and administration services. However, Medicare coverage requirements and payment vary for each of these settings. Infusion drugs, equipment, supplies, and administration are all covered by Medicare in the inpatient hospital, SNFs, HOPDs, and physician's offices. Generally, Medicare payment under Part A for the drugs, equipment, supplies, and services are bundled, meaning a single payment is made on the basis of expected costs for clinically-defined episodes of care. For example, if a beneficiary is receiving an infusion drug during an inpatient hospital stay, the Part A payment for the drug, supplies, equipment, and drug administration is included in the diagnosis-related group (DRG) payment to the hospital under the Medicare inpatient prospective payment system. Beneficiaries are liable for the Medicare inpatient hospital deductible. Similarly, if a beneficiary is receiving an infusion drug while in a SNF under a Part A stay, the payment for the drug, supplies, equipment, and drug administration are included in the SNF prospective payment system payment. After 20 days of SNF care, there is a daily beneficiary cost-sharing amount through day 100 when the beneficiary becomes responsible for all costs for each day after day 100 of the benefit period. Under Medicare Part B, certain items and services are paid separately while other items and services may be packaged into a single payment together. For example, in an HOPD and in a physician's office, the drug is paid separately, generally at the average sales price (ASP) plus 6 percent. There is also a separate payment for drug administration in which the payment for infusion supplies and equipment is packaged in the payment for administration. The separate payment for infusion drug administration in an HOPD and in a physician's office generally includes a base payment amount for the first hour and a payment add-on that is a different amount for each additional

hour of administration. The beneficiary is responsible for the 20 percent coinsurance under Medicare Part B. Medicare FFS covers outpatient infusion drugs under Part B, "incident to" a physician's services, provided the drugs are not usually self- administered by the patient. Drugs that are "not usually self-administered," are defined in our manual according to how the Medicare population as a whole uses the drug, not how an individual patient or physician may choose to use a particular drug. For the purpose of this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. The term "by the patient" means Medicare beneficiaries as a collective whole. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from Part B coverage. This determination is made on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.[88] The MACs update Self-Administered Drug (SAD) exclusion lists on a quarterly basis.[89]

Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home. Certain drugs can be infused in the home, but the nature of the home setting presents different challenges than the settings previously described. The components needed to perform home infusion include the drug (for example, antibiotics, immune globulin), equipment (for example, a pump), and supplies (for example, tubing and catheters). Likewise, nursing services are necessary to train and educate the patient and caregivers on the safe administration of infusion drugs in the home. Visiting nurses often play a large role in home infusion. Nurses typically train the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to provide catheter

[88]https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
[89] www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D

and site care. Depending on patient acuity or the complexity of the drug administration, certain infusions may require more nursing time, especially those that require special handling or pre- or post-infusion protocols. The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies. With regard to payment for home infusion therapy under traditional Medicare, drugs are generally covered under Part B or Part D. Certain infusion pumps, supplies (including home infusion drugs), and nursing are covered in some circumstances through the Part B durable medical equipment (DME) benefit, the Medicare home health benefit, or some combination of these benefits.

Medicare Part B covers a limited number of home infusion drugs through the DME benefit if: (1) the drug is necessary for the effective use of an external or implantable infusion pump classified as DME and determined to be reasonable and necessary for administration of the drug; and (2) the drug being used with the pump is itself reasonable and necessary for the treatment of an illness or injury. Only certain types of infusion pumps are covered under the DME benefit. The Medicare *National Coverage Determinations Manual,* chapter 1, part 4, §280.1 describes the types of infusion pumps that are covered under the DME benefit.90 For DME infusion pumps, Medicare Part B covers the infusion drugs and other supplies and services necessary for the effective use of the pump, but does not explicitly require or pay separately for any associated home infusion nursing services beyond what is necessary for teaching the patient and/or caregiver on how to operate the equipment in order to administer the

90 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html

infusion safely and effectively.[91] Through local coverage policies, the DME Medicare administrative contractors (MACs) specify the details of which infusion drugs are covered with these pumps. Examples of covered Part B DME infusion drugs include, among others, certain IV drugs for heart failure and pulmonary arterial hypertension, immune globulin for primary immune deficiency (PID), insulin, antifungals, antivirals, and chemotherapy, in limited circumstances.

2. Home Infusion Therapy Legislation

Section 5012 of the 21st Century Cures Act (Pub. L. 114-255) (Cures Act) creates a separate Medicare Part B benefit category under 1861(s)(2)(GG) of the Act for coverage of home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously, or subcutaneously through a pump that is an item of DME, effective January 1, 2021. The infusion pump and supplies (including home infusion drugs) will continue to be covered under the DME benefit. Section 1861(iii)(2) of the Act defines home infusion therapy to include the following items and services: the professional services (including nursing services), furnished in accordance with the plan, training and education (not otherwise included in the payment for the DME), remote monitoring, and other monitoring services for the provision of home infusion therapy furnished by a qualified home infusion therapy supplier in the patient's home. Section 1861(iii)(3)(B) of the Act defines the patient's home to mean a place of residence used as the home of an individual as defined for purposes of section 1861(n) of the Act. As outlined in section 1861(iii)(1) of the Act, i to be eligible to receive home infusion therapy services under the home infusion therapy benefit, the patient

91 See 42 CFR 424.57(c)(12), which states that the DME "supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively."

must be under the care of an applicable provider, defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant, and the patient must be under a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. The plan of care must be periodically reviewed by the physician in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C) of the Act). Section 1861(iii)(3)(C) of the Act defines a "home infusion drug" under the home infusion therapy benefit as a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the patient's home, through a pump that is an item of DME as defined under section 1861(n) of the Act. This definition does not include insulin pump systems or any self-administered drug or biological on a self-administered drug exclusion list.

Section 1861(iii)(3)(D)(i) of the Act defines a qualified home infusion therapy supplier as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are provided. The provision specifies qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by an organization designated by the Secretary; and meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector. The supplier may subcontract with a pharmacy, physician, other qualified supplier or provider of medical services, in order to meet these requirements.

Section 1834(u) of the Act requires the Secretary to implement a payment system under

which a single payment is made to a home infusion therapy supplier for the items and services (professional services, including nursing services; training and education; remote monitoring, and other monitoring services), beginning January 1, 2021. The single payment must take into account, as appropriate, types of infusion therapy, including variations in utilization of services by therapy type. In addition, the single payment amount is required to be adjusted to reflect geographic wage index and other costs that may vary by region, patient acuity, and complexity of drug administration. The single payment may be adjusted to reflect outlier situations, and other factors as deemed appropriate by the Secretary, which are required to be done in a budget neutral manner. Section 1834(u)(3) of the Act specifies that annual updates to the single payment are required to be made beginning January 1, 2022, by increasing the single payment amount by the percent increase in the Consumer Price Index (CPI) for all urban consumers for the 12-month period ending with June of the preceding year, reduced by the multi-factor productivity adjustment. The unit of single payment for each infusion drug administration calendar day, including the required adjustments and the annual update, cannot exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services if furnished in a physician's office, and the single payment amount cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. Section 1834(u)(4) of the Act also allows the Secretary discretion, as appropriate, to consider prior authorization requirements for home infusion therapy services. Finally, section 5012(c)(3) of the Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the HH PPS beginning on January 1, 2021.

B. Proposed Health and Safety Standards for Home Infusion Therapy

1. Introduction

Section 5012 of the Cures Act requires that, to receive payment under the Medicare home infusion therapy benefit, home infusion therapy suppliers must select a CMS-approved accreditation organization (AO) and undergo an accreditation review process to demonstrate that the home infusion therapy supplier meets the AO's standards. Section 1861(iii) of the Act, as added by section 5012 of the Cures Act, sets forth four elements for home infusion therapy in the following areas: (1) requiring that the patient be under the care of a physician, nurse practitioner, or physician assistant; (2) requiring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient specific needs; (3) providing patients with education and training on the effective use of medications and equipment in the home (not otherwise paid for as durable medical equipment); and (4) providing monitoring and remote monitoring services associated with administering infusion drugs in a patient's home.

The Journal of Infusion Nursing standards of practice specifically address patient education, and state that it is the clinician's role to educate the patient, caregiver, and/or surrogate about the prescribed infusion therapy and plan of care including, but not limited to, purpose and expected outcome(s) and/or goals of treatment, infusion therapy administration; infusion device-related care; potential complications; or adverse effects associated with treatment. (Infusion Therapy Standards of Practice, 2015).92

Currently, standards for home infusion therapy have been established by the current AOs; however, they are not necessarily consistent. In order to assure consistency in the areas

92 Infusion Therapy: Standards of Practice, Journal of Infusion Nursing, Wolters Kluwer: Jan/Feb 2016 pp S25-S26

identified in the Act, we are establishing basic standards that all AOs would be required to meet or exceed. We are proposing universal standards for Medicare-participating qualified home infusion therapy suppliers to ensure the quality and safety of home infusion therapy services for all beneficiaries that these suppliers serve.

In preparation for developing these standards and to gain a clear understanding of the current home infusion therapy supplier private sector climate, we reviewed the requirements established by section 5012 of the Cures Act, performed an extensive review of the standards from all six AOs that accredit home infusion suppliers (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), and reviewed various other government and industry publications listed in this proposed rule. In addition to the standards, we reviewed the following documents related to coverage:

- Government Accountability Office-10-426 report, which describes the state of coverage of home infusion therapy components under Medicare fee-for-service prior to the enactment of the Cures Act (GAO, 2010).[93]

- Medicare and Home Infusion white paper written by the National Home Infusion Association (NHIA), which provided an overview of Medicare coverage provided for Home Infusion Therapy services prior to the enactment of the Cures Act, as well as results of a study conducted by Avalere Health on the potential savings that could result from Medicare coverage of infusion therapy provided in the home (National Home Infusion Therapy Association, NDS).

93 Government Accountability Office. (2010). Home Infusion Therapy. Differences between Medicare and Private Insurers' coverage. (GAO Publication No. 10-426). Washington, D.C.: U.S. Government Printing Office.

94

• American Society of Health System Pharmacists Guidelines on Home Infusion Pharmacy Services, which provided an in-depth overview of specialized, complex. pharmaceuticals, best practices on providing home infusion therapy in the home or alternative site settings, and the plans to execute and manage the therapy (American Society of Health-System Pharmacists. ASHP guidelines on Home Infusion Pharmacy Service, 2014).95

• The requirements of numerous Medicare Advantage plans, Medicare FFS, and private insurance plans.

Upon review of these materials, we believe that there is a sufficient private-sector framework already in place to address many of the areas that would typically be included in the establishment of basic health and safety standards for home infusion therapy. For example, existing AO standards include requirements related to plan of care, monitoring, patient assessment, quality improvement, and infection control. While the exact content of the AO standards vary, we believe that the standards are adequate to ensure patient health and safety. The AO representing the largest number of home infusion therapy suppliers requires that home infusion pharmacies provide certain services to ensure safe and appropriate therapy, in compliance with nationally recognized standards of practice. Patient training and education activities, as part of their required admission procedures, include the use of medical and disposable equipment, medication storage, emergency procedures, vascular access device

94 National Home Infusion therapy Association. Medicare and Home Infusion White Paper. Retrieved from https://www.nhia.org/resource/legislative/documents/NHIAWhitePaper-Web.pdf

95 American Society of Health-System Pharmacists. ASHP guidelines on Home Infusion Pharmacy Service, 2014. Retrieved from: https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/home-infusion-pharmacy-services.ashx?la=en&hash=255092A51D0AE4746C151C51AC7BF82217AC2F76

management, recognition of a drug reaction, and when to report any adverse drug event. As such, we conclude that it is appropriate at this time to propose requirements for only those elements specifically identified in section 1861(iii) of the Act. Through the CMS accreditation organization process, we would monitor home infusion therapy suppliers to assure that services are provided in a safe and effective manner, and would consider future rulemaking to address any areas that may need improvement in the future. We are seeking public comment on this approach and invite comments related to the home infusion therapy proposed standards. Specifically, are the standards sufficient for Medicare beneficiaries, should CMS consider additional standards and would additional standards impose additional burden?

2. Home Infusion Therapy Supplier Requirements (Proposed Part 486, Subpart I)

We propose to add a new 42 CFR part 486, subpart I, to incorporate the home infusion therapy supplier requirements. The proposed regulations would provide a framework for CMS to approve home infusion therapy accreditation organizations and give them the authority to approve Medicare certification for home infusion therapy suppliers. Proposed subpart I would include General Provisions (Basis and Scope, and Definitions) and Standards for Home Infusion Therapy (Plan of Care and Required Services).

a. Basis and Scope (Proposed §486.500)

We propose to set forth the basis and scope of part 486 at §486.500. Part 486 is based on sections 1861(iii)(2)(D) of the Act, which establishes the requirements that a home infusion therapy supplier must meet in order to participate in the Medicare program. These provisions serve as the basis for survey activities for the purposes of determining whether a home infusion therapy supplier meets the requirements for participation in Medicare. Section 1834(u) of the Act serves as the basis for the establishment of a prospective payment system for home infusion

therapy covered under Medicare. In addition, 1834(u)(5) of the Act establishes the factors for the Secretary to designate organizations to accredit suppliers furnishing home infusion therapy and requires that organizations be designated not later than January 1, 2021.

b. Definitions (Proposed §486.505)

At §486.505, we propose to define certain terms that would be used in the home infusion therapy requirements. We propose to define the terms "applicable provider", "home", "home infusion drug", and "qualified home infusion therapy supplier" in accordance with the definitions set forth in section 1861(iii) of the Act. Furthermore, section 1861(iii) of the Act includes a definition of the term "home infusion therapy" that is the basis of the proposed health and safety requirements set forth in this rule. In accordance with the Act, we propose the following definitions:

• "Applicable provider" would mean a physician, a nurse practitioner, and a physician assistant.

• "Home" would mean a place of residence used as the home of an individual, including an institution that is used as a home. However, an institution that is used as a home may not be a hospital, CAH, or SNF as defined in sections 1861(e), 1861(mm)(1), and1819 of the Act, respectively.

• "Home infusion drug" would mean 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 durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list.

• "Qualified home infusion therapy supplier" would mean a supplier of home infusion

therapy that meets the all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act: (1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; (3) is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act; and (4) meets such other requirements as the Secretary determines appropriate.

c. Standards for Home Infusion Therapy

Proposed subpart I, as required by section 5012 of the Cures Act, would specify that the qualified home infusion therapy supplier ensure that all patients have a plan of care established by a physician.

(1) Plan of Care (Proposed §486.520)

At §486.520(a), we propose to require that all patients must be under the care of an "applicable provider" as defined at §486.505. At §486.520(b) we would require that the qualified home infusion therapy supplier ensure that all patients must have a plan of care established by a physician that prescribes the type, amount, and duration of home infusion therapy services that are furnished. The plan of care would also include the specific medication, the prescribed dosage and frequency as well as the professional services to be utilized for treatment. In addition, the plan of care would specify the care and services necessary to meet the patient-specific needs.

We also propose, at §486.520(c), that the qualified home infusion therapy supplier must ensure that the plan of care for each patient is periodically reviewed by the physician. We do not propose to establish a specific time frame for review requirements, but the expectation is

that the physician is active in the patient's care and can make appropriate decisions related to the course of therapy if changes are necessary in regards to the progress of the patient and goal achievement with the infusion therapy. We welcome comments regarding the proposed home infusion therapy plan of care requirements and if we should include specific review timeframes for the plan of care.

(2) Required Services (Proposed §486.525)

Section 1861(iii)(2)(D)(II) of the Act specifically mandates that qualified home infusion therapy suppliers ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis. Infusion drugs are administered directly into a vein or under the skin, eliciting a more rapid clinical response than with oral medications. Consequently, an adverse effect or a medication error could result in a quicker and/or more severe complication. Therefore, at §486.525(a), we propose to require the provision of professional services, including nursing services, furnished in accordance with the plan of care. We propose to require that home infusion therapy suppliers ensure that professional services are available on a 7-day-a-week, 24-hour-a-day basis in order to ensure that patients have access to expert clinical knowledge and advice in the event of an urgent or emergent infusion-related situation. This proposed requirement is imperative, as the success of home infusion therapy is often dependent upon the professional services being available during all hours and days of the week that allows for the patient to safely and effectively manage all aspects of treatment.

At §486.525(b), we propose to require patient training and education, not otherwise paid for as durable medical equipment, and as described in 42 CFR 424.57(c)(12). This proposed requirement is consistent with section 1861(iii)(2)(B). In addition, the proposed patient training and education requirements are consistent with standards that are already in place, as

established by the current AOs of home infusion therapy suppliers. This is a best practice, as home infusion therapy may entail the use of equipment and supplies with which patients' may not be comfortable or familiar.

At §486.525(c), we propose to require qualified home infusion therapy suppliers to provide remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs furnished by a qualified home infusion therapy supplier. This proposed requirement is also consistent with section 1861(iii)(2)(B). Monitoring the patient receiving infusion therapy in their home is a vital standard of practice that is an integral part of providing medical care to patients in their home.96 The expectation is that home infusion therapy suppliers would provide ongoing patient monitoring and continual reassessment of the patient to evaluate response to treatment, drug complications, adverse reactions, and patient compliance. Remote monitoring may be completed through follow-up telephone or other electronic communication, based on patient preference of communication. However, we do not propose to limit remote monitoring to these methods. Suppliers would be permitted to use all available remote monitoring methods that are safe and appropriate for their patients and clinicians and as specified in the plan of care as long as adequate security and privacy protections are utilized. Monitoring may also be performed directly during in-home patient visits. Additional discussion on remote monitoring and monitoring services can be found in section II.C.2.d. of this proposed rule. We invite the public to submit comments regarding the proposed home infusion therapy supplier service requirements.

96 Infusion Therapy: Standards of Practice, Journal of Infusion Nursing, Wolters Kluwer: Jan/Feb 2016 pp S25-S26

C. Approval and Oversight of Accrediting Organizations for Home Infusion Therapy Suppliers

1. Background

Section 1861(iii)(3)(D)(III) of the Social Security Act (the Act), as added by section 5012(b) of the Cures Act, requires that a home infusion therapy supplier be accredited by an AO designated by the Secretary in accordance with section 1834 (u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and modifying the list of designated AOs. These statutory factors are: (1) the ability of the organization to conduct timely reviews of accreditation applications; (2) the ability of the organization take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act); (3) whether the organization has established reasonable fees to be charged to suppliers applying for accreditation; and, (4) such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021. However, at this time, there are six AOs that are providing accreditation to home infusion therapy suppliers. These AOs are: (1) The Joint Commission (TJC); (2) Accreditation Commission for Health Care (ACHC); (3) Compliance Team (TCT); (4) Community Health Accreditation Partner (CHAP); (5) Healthcare Quality Association on Accreditation; and (6) National Association of Boards of Pharmacy. These AOs are accrediting home infusion therapy suppliers as part of the deeming accreditation of home health agencies. However, these AOs have not been separately approved by Medicare for accreditation of home infusion therapy services.

We are proposing to publish a solicitation notice in the Federal Register, in which we would invite national AOs to apply to accredit home infusion therapy suppliers for the

Medicare program. We are proposing that this solicitation notice would be published after the final rule is published, so that we can designate AOs to accredit home infusion therapy suppliers by no later than January 1, 2021 as required by 1834(u)(5)(B) of the Act. Any AOs that respond to this solicitation notice would be required to submit an application for CMS-approval of their home infusion therapy accreditation program. The application submitted by an AO that respond to the solicitation notice would be required to meet all requirements set forth in proposed §488.1010 and demonstrate that their substantive requirements are equal to or more stringent than our proposed regulations at part 485, subpart I

Section 1861(iii)(3)(D) of the Act requires "qualified home infusion therapy suppliers" to be accredited by a CMS-approved AO. We are also proposing that, in order for the home infusion therapy suppliers accredited by the six AOs that currently provide non-Medicare approved home infusion therapy accreditation to continue receiving payment for the home infusion therapy services they provide, the 6 existing AOs must submit applications to CMS for Medicare approval of their home infusion therapy accreditation program. The accreditation currently being provided by these six AOs to the home infusion therapy suppliers is part of another accreditation program that has not be separately approved by CMS. These AOs have not submitted an application to CMS for approval of a specific home infusion therapy accreditation program that meets the requirements of section 1861(iii) and section 1834(u)(5) of the Act; therefore, CMS has not been able to determine whether the home infusion therapy accreditation program standards used by these AOs meets or exceeds those of Medicare.

We are proposing that the home infusion therapy accreditation program submitted to CMS by these existing AOs be a separate and distinct accreditation program from the AO's home health accreditation program. This would mean that these AOs must have a separate

accreditation program with separate survey processes and standards for the accreditation of home infusion therapy suppliers. In addition, we would require that the application submitted by the six AOs that currently provide non-Medicare approved accreditation to home infusion therapy suppliers meet the requirements set forth in the proposed regulations at §488.1010 and enforce the substantive health and safety standards proposed to be set out at 42 CFR part 485, subpart I.

Section 1834(u)(5)(C)(ii) of the Act states that in the case where the Secretary removes a home infusion therapy AO from the list of designated home infusion therapy AOs, any home infusion therapy supplier that is accredited by the home infusion therapy AO during the period beginning on the date on which the home infusion therapy AO is designated as an CMS-approved home infusion therapy AO and ending on the date on which the home infusion therapy AO is removed from such list, shall be considered to have been accredited by an home infusion therapy AO designated by the Secretary for the remaining period such accreditation is in effect. Under section 1834(u)(5)(D) of the Act, in the case of a home infusion therapy supplier that is accredited before January 1, 2021 by a home infusion therapy AO designated by the Secretary as of January 1, 2019, such home infusion therapy supplier shall be considered to be accredited by a home infusion therapy AO designated by the Secretary as of January 1, 2023, for the remaining period such accreditation is in effect. Home infusion therapy suppliers are required to receive accreditation before receiving Medicare payment for services provided to Medicare beneficiaries.

Section 1861(iii)(3)(D) of the Act defines "qualified home infusion therapy suppliers" as being accredited by a CMS-approved AO. CMS is proposing to establish regulations for the approval and oversight of AOs that accredit home infusion therapy suppliers that address the

following: (1) the required components to be included in a home infusion therapy AO's initial or renewal application for CMS approval of the AO's home infusion therapy accreditation program; (2) the procedure for CMS' review and approval of the home infusion therapy AOs application for CMS approval of its home infusion therapy accreditation program; and (3) the ongoing monitoring and oversight of CMS-approved home infusion therapy AOs.

2. Proposed Process and Standards for Home Infusion Therapy Accreditation and the Approval and Oversight of Accrediting Organizations with CMS-Approved Accreditation Programs for Home Infusion Therapy Services

a. Establishment of Regulatory Requirements

We propose to establish new regulations in a new subpart L in 42 CFR part 488 that would govern CMS' approval and oversight of AOs that accredit home infusion therapy suppliers. We believe these proposed new regulations would provide CMS with reasonable assurance that the home infusion therapy AO's accreditation program requirements are consistent with the appropriate Medicare accreditation program requirements. Further, we believe that these proposed regulations would provide CMS with a way to provide oversight for AOs that accredit home infusion therapy suppliers, and provide CMS with authority over the home infusion therapy suppliers.

We are proposing to implement a comprehensive, consistent and standardized set of AO oversight regulations for accreditors of home infusion therapy suppliers. It is our intention to provide home infusion therapy AOs with the flexibility to innovate within the framework of these proposed regulations while assuring that their accreditation standards meet, or exceed the appropriate Medicare requirements, and their survey processes are comparable to those of Medicare. "Flexibility to innovate" means that AOs retain the freedom to develop their own

accreditation standards and survey processes, so long as the AO ensures that they meet the proposed health and safety standards (contained in 42 CFR part 486, subpart B) and the AO meets the requirements of the proposed AO approval and oversight regulations.

The proposed regulations would reflect requirements similar to those in place for the oversight of national AOs for Medicare-certified providers and suppliers which are codified at 42 CFR 488.1 through 488.9 and 42 CFR part 489, but would be modified, as appropriate, to be applicable for accreditors of home infusion therapy suppliers. We believe that it is important to have AO approval and oversight regulations that are as consistent as possible across all AOs and to treat all AOs in a similar manner.

b. Consideration of Existing Regulations

In formulating our approach to implementing the statutory requirements related to accreditation organizations, we had considered using the regulations at 42 CFR 488.1 to 488.13 for the approval and oversight of AOs that accredit home infusion therapy suppliers. However, we decided not to do so because Congress, by setting out separate accreditation organization approval standards for home infusion therapy suppliers at 1834(u)(5)(A) of the Act, intended approval for this accreditation program to be a discrete process. We believe that having a separate set of approval regulations applicable only to home infusion therapy suppliers will best reflect Congress's intent.

Only limited portions of the regulations at §§488.1 through 488.13 would apply to AOs that accredit home infusion therapy suppliers. For example, §488.6, which provides that a supplier or provider that has been granted "deemed status" by CMS by virtue of its accreditation from a CMS-approved accreditation program is eligible to participate in the Medicaid program if they are not required under Medicaid regulations to comply with any

requirements other than Medicare participation requirements would not apply to home infusion therapy suppliers because home infusion therapy suppliers cannot be deemed. The deeming process only applies to certain types of Medicare certified providers and suppliers, such as hospitals.

Section 488.7 titled "Release and use of accreditation surveys" and §488.8 titled "Ongoing review of accrediting organizations" would apply to AOs that accredit home infusion therapy suppliers. However, §488.9 titled "Validation surveys" would not apply to home infusion therapy suppliers because the State Survey Agency (SA) only performs validation surveys for Medicare providers that have an agreement with Medicare. Home infusion therapy suppliers are enrolled in the Medicare program but do not enter into an agreement with Medicare, therefore the SA will not perform validation surveys of home infusion therapy suppliers. Also, section 1864(a) of the Act provides, that by agreement with the Secretary, the SA shall provide services to the following Medicare certified healthcare providers: hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, or ambulatory surgical centers.

Section 488.10, titled "State survey agency review: Statutory provisions", § 488.11 titled "State survey agency functions" and § 488.12 titled "Effect of survey agency certification" would also not apply to home infusion therapy AOs. This is because, as stated previously, the SA does not perform validation surveys for AOs that accredit home infusion therapy providers. Section 488.13, titled "Loss of accreditation" provides that "if an accrediting organization notifies CMS that it is terminating a provider or supplier due to non-compliance with its CMS-approved accreditation requirements, the SA will conduct a full review in a

timely manner." This section would also not apply to AOs that accredit home infusion therapy suppliers because this regulation section requires use of the SA.

Section 488.14 titled, "Effect of QIO review" provides that "when a QIO is conducting review activities under section 1154 of the Act and part 466 of this chapter, its activities are in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), and 1861(k) of the Act." This section would not apply to home infusion therapy suppliers because it is only applicable only to hospitals.

Finally, § 488.18, titled "Documentation of findings" states that "the findings of the State agency with respect to each of the conditions of participation, requirements (for SNFs and NFs), or conditions for coverage must be adequately documented." This section would not apply to AOs that accredit home infusion therapy suppliers because it involves the finding of the SA related only to SNFs and NFs,

In conclusion, a majority of sections contained in §§ 488.1 through 488.13 do not apply to home infusion therapy AOs and home infusion therapy suppliers. Therefore, we are proposing to create a separate set of regulations that are specifically applicable to home infusion therapy AOs and suppliers.

We seek comment on our decision not to use the existing regulation at §§ 488.1 through 488.13.

c. Consideration of a Validation Process for Accrediting Organizations that Accredit Home Infusion Therapy Suppliers

Our conventional validation process involves the participation of the CMS Regional Offices (ROs) to request the State Survey Agency to conduct an onsite validation (follow-up) survey within 60 days of an AO's onsite survey. The purpose of a validation survey is to

evaluate the ability of that AO's survey process to identify serious, condition level deficiencies.

We are not proposing to establish a validation program requirement for home infusion therapy AOs and suppliers due to a number of resource constraints. Several factors limit our ability to establish and implement a validation program for home infusion therapy AOs. First, the SAs are not available to perform validation surveys for home infusion therapy AOs suppliers and other similar non-certified providers and suppliers. Section 1864(a) of the Act provides the SA, by agreement with the Secretary, provides services to the following Medicare certified healthcare providers: hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, or ambulatory surgical centers.

Second, a validation program for home infusion therapy supplier AOs would require the use of contractors. Third, achieving sample sizes that are statistically significant from which to draw reliable conclusions about AO performances across all home infusion therapy suppliers would be problematic as there are a limited number of home infusion therapy suppliers. Due to the factors stated previously, we are not proposing to include validation requirements in the proposed new regulations for the oversight of AOs that accredit suppliers at this time. We seek public comment on the decision not to propose a validation process at this time.

Even though we would not have a formal validation process in place, we would be able to monitor the performance of the home infusion therapy AOs as part of the ongoing AO oversight process provided for in the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050. For example, under proposed §488.1030 we would have the ability to perform performance reviews to evaluate the

performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis; comparability reviews to assess the equivalency of a home infusion therapy AO's CMS-approved program requirements with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare accreditation requirements; and standards reviews when a home infusion therapy accrediting organization proposes to adopt new or revised accreditation standards. We may also perform CMS-approved home infusion therapy accreditation program review if a comparability or performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy AO's CMS-approved home infusion therapy accreditation program with the requirements of this subpart. (See proposed §488.1005 below for a definition of substantial non-compliance).

In addition, proposed §488.1035 would require the home infusion therapy AOs to submit information to CMS which will help us monitor the AO's performance. This information would also help to ensure that the home infusion therapy suppliers accredited by the AO provide care that meets the proposed health and safety standards contained in 42 CFR part 486, subpart B. This information includes the following:

- Copies of all home infusion therapy supplier accreditation surveys, together with any survey-related information.
- Notice of all accreditation decisions.
- Notice of all complaints related to the AO's accredited suppliers.
- Information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation.

- Annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

- Notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process.

d. Application Requirement for AOs That Currently Provide Accreditation for Home Infusion Therapy Suppliers

In this rule, we are proposing to establish regulations for the approval and oversight of AOs for home infusion therapy suppliers. We are also proposing the health and safety standards which home infusion therapy suppliers must meet, and which the home infusion AOs must meet or exceed in their accreditation standards. These health and safety standards are set forth at 42 CFR part 486, subpart I. The AOs that currently accredit home infusion therapy suppliers have not heretofore been governed by any CMS regulations related to home infusion therapy accreditation or health and safety standards. These AOs have each created their own set of accreditations standards. These accreditation standards vary from AO to AO.

Section 1834(u)(5)(C) of the Act requires home infusion therapy suppliers to be accredited in order to receive payment for the services they provide. We propose to require that the home infusion therapy accreditation program submitted to CMS for approval by each of the AOs that currently accredit home infusion therapy suppliers be separate and distinct accreditation programs that are not part of the AOs home health accreditation program. We would further require that the AOs home infusion therapy accreditation standards meet or exceed the proposed health and safety standards for home infusion therapy suppliers. Finally, we would require that the application meet the requirements of proposed 42 CFR 488.1010.

We solicit comments on these proposals.

e. Oversight of Home Infusion Therapy Accrediting Organizations

As noted previously, we are proposing to create a new set of regulations titled, "Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations" at 42 CFR part 488, subpart L. These proposed regulations would set forth the application and reapplication procedures for national AOs seeking approval or re-approval of authority to accredit home infusion therapy suppliers; ongoing CMS oversight processes for approved AOs that accredit home infusion therapy suppliers; and, appeal procedures for AOs that accredit home infusion therapy suppliers. In this section of the proposed rule, we describe our proposed regulatory provisions.

The following sections discuss the proposed regulations, in their proposed order.

(1) Basis and Scope (§ 488.1000)

We propose at § 488.1000 to set forth the statutory authority related to this set of proposed regulations. Sections 1834(u)(5) and 1861(iii) of the Act would be the statutory basis for these proposed regulations. These sections of the Act provide the Secretary with the authority necessary to carry out the administration of the Medicare program. Section 1861 of the Act defines services, supplier types and benefits, and over whom Medicare may have authority. Section 1861(d) defines the term "supplier." Section 1834(u)(5) of the Act governs accreditation of home infusion therapy suppliers.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that home infusion therapy suppliers be accredited by an organization designated under section 1834(u)(5)of the Act. Section 1834(u)(5) of the Act requires that the Secretary establish factors in designating accrediting organizations and designate accrediting organizations to accredit suppliers furnishing home infusion therapy by January 1, 2021.

Proposed § 488.1000(a) would set forth the statutory authority for the accreditation of home infusion therapy suppliers by the home infusion therapy AOs. Title 42 CFR 488.1000(b) would set forth the scope of the proposed regulation, which is the application and reapplication procedures for national AOs seeking approval or re-approval of authority to accredit home infusion therapy suppliers; ongoing CMS oversight processes for approved of home infusion therapy AOs; and, appeal procedures for AOs of home infusion therapy suppliers.

(2) Definitions (§ 488.1005)

We are proposing to use the following definitions at § 488.1005:

- Accredited home infusion therapy supplier means a supplier that has demonstrated substantial compliance with a CMS-approved national home infusion therapy AO's applicable CMS-approved home infusion therapy accreditation program standards, which meet or exceed those of Medicare, and has been awarded accreditation by that AO.

- Qualified home infusion therapy supplier means an entity that meets the following criteria which are set forth at 1861(iii)(3)(D)(i): (1) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; (3) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and (4) meets such other requirements as the Secretary determines appropriate.

- Immediate jeopardy means a situation in which the 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, as codified at §488.1.

- National accrediting organization means an organization that accredits supplier

entities under a specific program and whose accredited supplier entities under each program are widely dispersed geographically across the United States. In addition, the specific program is active, fully implemented, and operational. This definition is codified at § 488.1.

- Reasonable assurance means an AO has demonstrated to CMS' satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements. This definition is codified at § 488.1.

- Rural area means an area as defined at section 1886(d)(2)(D) of the Act.

- Substantial allegation of non-compliance means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in the newspaper, magazine articles or other media, that would, if found to be present, adversely affect the health and safety of patients and raises doubts as to a supplier's compliance with any of the Medicare home infusion therapy accreditation requirements. This definition is codified at §488.1.

(3) Application and Reapplication Procedures for National Accrediting Organizations (§ 488.1010)

Proposed § 488.1010 would contain application and re-application procedures for all national AOs seeking CMS-approval of an accreditation program for home infusion therapy suppliers. Proposed § 488.1010(a) would provide a comprehensive listing of the information, supporting documentation, certifications, written statements and other data that prospective AOs for home infusion therapy suppliers would be required to include in their application for approval to accredit home infusion therapy suppliers. The requirements under this section would apply to both initial applications for CMS-approval as well as applications for re-approval of an existing CMS-approved home infusion therapy accreditation program. This

section would also require the AOs for home infusion therapy supplies to furnish CMS with information that demonstrates that their accreditation program requirements meet or exceed the applicable Medicare requirements.

Proposed § 488.1010(a)(1) would require AOs for home infusion therapy suppliers seeking initial or renewed CMS-approval of their home infusion therapy accreditation program to demonstrate that they meet the definition of a "national accrediting organization." Section 1865 of the Act requires that accrediting organizations be national in scope.

We believe that because home infusion therapy suppliers are located throughout the country, it is necessary for AOs to demonstrate their ability to provide accreditation services in a variety of regions across the country. In the May 22, 2015 final rule entitled, "Medicare and Medicaid Programs: Revisions to Deeming Authority, Survey, Certification and Enforcement Procedures" (80 FR 29802), we stated that the term "national in scope" indicated a program already fully implemented, operational, and widely dispersed geographically throughout the country. However, we also stated that we would not establish a minimum or a specific geographic distribution for provider entities that the program must have already accredited. It is our intent that this proposed section would require a home infusion therapy AO to demonstrate that their accreditation program meets the "national in scope" description as previously defined.

Proposed § 488.1010(a)(2) would require AOs to specifically identify the Medicare supplier type for which they are requesting CMS-approval or reapproval. We believe it is necessary for an AO to establish separate accreditation requirements for each supplier type they accredit. There are many AOs that provide accreditation programs for multiple types of provider and supplier types. When we receive an application from such an AO, we would not

know which type of accreditation program the AO has submitted for CMS approval. For example, the AO could be submitting a renewal application for one of its existing accreditation programs. Therefore, it is helpful to CMS if the AO identifies the type of accreditation for which they are seeking approval at the beginning of the application.

Proposed § 488.1010(a)(3) would require AOs to demonstrate their ability to take into account the capacities of home infusion therapy suppliers in rural areas (as defined in section 1834(u)(5)(A)(ii) of the Act. Rural home infusion therapy suppliers may have limitations or access to care issues that do not apply to suburban and urban home infusion therapy suppliers. These limitation may include, but are not limited to the number of home infusion therapy suppliers available in rural areas and limited home infusion therapy services offered in rural areas. While we certainly would not permit AOs that accredit any type of supplier to modify their accreditation standards for suppliers in rural areas, these factors must be taken into account as in accordance with section 1834(u)(5)(A)(ii) of the Act.

Proposed § 488.1010(a)(4) would require the home infusion therapy AO to provide information that documents their knowledge, expertise, and experience in the healthcare field for which they offer accreditation and for which they are requesting approval. We believe that to successfully develop accreditation program standards that can provide CMS with reasonable assurance that accredited home infusion therapy suppliers meet or exceed each of the applicable Medicare requirements, evaluate compliance, support entities in their efforts to identify and implement necessary corrective actions and monitor ongoing compliance, an AO must possess subject matter expertise and experience in that field.

Proposed § 488.1010(a)(5) would require the AO to submit a detailed crosswalk (in table format) that identifies, for each of the applicable Medicare health and safety requirements,

the exact language of the accrediting organization's comparable accreditation requirements and standards. This requirement would allow CMS to evaluate whether the accreditation program standards meet or exceed the applicable Medicare requirements. We note that an AO for home infusion therapy suppliers could set standards that exceed the Medicare requirements in the accreditation program it submits to CMS for approval. However, at a minimum, AOs for home infusion therapy suppliers would have to provide evidence that their accreditation program utilizes standards and procedures that met or exceeded applicable Medicare requirements.

Proposed § 488.1010(a)(6) would require each AO for home infusion therapy suppliers to provide a detailed description of its survey process. This requirement is intended to allow CMS to gain a better understanding of an AO's proposed survey process and ensure that its survey and enforcement processes are comparable to Medicare's health and safety standards (contained in 42 CFR part 486, subpart I). The specific type of information to be provided under this section is set forth in proposed § 488.1010(a)(6)(i) through (vii) and includes, but is not limited to, the following: (1) a detailed description of the survey process; (2) type and frequency of surveys performed; (3) copies of the AO's survey forms; (4) documentation that the survey reports identify the comparable Medicare home infusion therapy health and safety requirements for each finding of non-compliance with accreditation standards; (5) timeline and procedures for monitoring home infusion therapy suppliers found to be out of compliance; (6) process for addressing deficiencies; and (7) the ability of the AO to conduct timely review of accreditation applications.

We propose at § 488.1010(a)(6)(viii) to require the AOs for home infusion therapy suppliers to acknowledge, that as a condition for CMS approval, the AO agrees to provide CMS with information extracted from each accreditation onsite survey, offsite audit or other

evaluation strategy as part of its data submission required under § 488.1010(a)(21)(ii). Upon request, the AO must also provide CMS with a copy of the most recent accreditation onsite survey, offsite audit, or other evaluation strategy together and any other information related to the survey process as CMS may require, including, but not limited to corrective action plans.

Proposed § 488.1010(a)(6)(ix) would require the AOs for home infusion therapy suppliers to provide a statement acknowledging that they will notify CMS within two business days, using a CMS specified format, when an accreditation survey or complaint investigation identifies the presence of an immediate jeopardy situation. For purposes of this section, the term "immediate jeopardy" is defined in proposed § 488.1005.

We propose at § 488.1010(a)(7) to require the AOs for home infusion therapy suppliers to establish procedures related to performance of onsite surveys, offsite audits, and other survey activities. Proposed § 488.1010(a)(7)(i) would require the home infusion therapy AOs that performs onsite surveys to make sure that they are unannounced and that they establish procedures to prevent against unannounced surveys from becoming known to the supplier in advance of the visit. The purpose of unannounced onsite surveys is to prevent the supplier from performing significant preparations for the survey to the extent that their environment would be so modified that it does not represent the normal daily operating conditions of the home infusion therapy supplier's office. If a provider is given advanced notice of a survey, they may attempt to make extensive preparations for the survey to the extent that they may attempt to hide patient safety issues such as a broken or malfunctioning medication infusion pump, areas of risk such as infection control, and ensuring that the patient receives the correct type and dosage of medication, poor quality of care such as failure to properly cleanse the insertion site before inserting IV access, and failure to perform periodic IV site care, or non-compliance that

would normally be present.

Proposed § 488.1010(a)(7)(ii) would require home infusion therapy AOs that use offsite audits, or other evaluation strategies to evaluate the quality of services provided by a home infusion therapy supplier, to follow up these offsite audits with periodic onsite visits. We believe that it is very important for the AOs that accredit home infusion therapy suppliers to follow-up off-site survey reviews with periodic on-site visits to ensure that the home infusion therapy supplier is complying with all accreditation standards and meeting all health and safety regulations. The requirements of this section are consistent with existing CMS policy related to the performance of unannounced surveys specified in Chapter 2 of the CMS State Operations Manual (SOM). Chapter 2 of the State Operations Manual (SOM) applies to Medicare-certified providers and suppliers. Our intent for referencing Chapter 2 of the SOM is to show that the proposed provisions related to onsite surveys for home infusion therapy suppliers are consistent with the requirements for Medicare-certified providers and suppliers. Also, it is our intent is to have consistent regulations for the approval and oversight of AOs, to the extent possible, across all AOs.

We propose at § 488.1010(a)(8), to require an AO for home infusion therapy suppliers to provide a description of the criteria for determining the size and composition of the onsite survey or offsite audit teams or teams used for other accreditation evaluation strategies. These teams would perform onsite surveys at individual home infusion therapy supplier locations, offsite audits, and any other types of accreditation review activity that is performed by the AO. The AO's criteria should include, but not be limited to, the following information:

- The expected number of individual home infusion therapy supplier locations to be surveyed using an onsite survey.

- The expected number of home infusion therapy suppliers to be surveyed using off-site audits.
- A description of other types of accreditation review activities to be used.
- The reasons for each type of survey (that is, initial accreditation survey, reaccreditation survey; and complaint surveys).

Adherence to the requirements of this section would help CMS ensure that each home infusion therapy AO has established criteria for determining the appropriate size and composition of its survey teams. It is important that an AO assemble survey teams that are large enough and have the required knowledge, experience and training to properly and adequately survey home infusion therapy suppliers. We believe that surveys performed by competent, well trained surveyor teams would provide CMS with reasonable assurance that accredited home infusion therapy suppliers meet or exceed the applicable quality standards.

We propose at §488.1010(a)(9) to require that an AO for home infusion therapy suppliers provide CMS with information regarding the overall adequacy of the number of surveyors, auditors, and other staff available to perform all survey related activities. Under this section, the home infusion therapy AO would also be required to provide an explanation as to how it would maintain an adequate number of trained surveyors on staff. The home infusion therapy AO must also describe its ability to increase the size of survey, audit, and other survey program staff to match growth in the number of accredited home infusion therapy suppliers while maintaining re-accreditation intervals for existing accredited home infusion therapy suppliers. The intent of these proposed requirements is to ensure that AOs for home infusion therapy suppliers maintain sufficient staffing levels over time which would enable them to meet the needs of their clients and also perform timely and accurate surveys. We recognize that

within a given accreditation program, there can be variations in the size and complexity of individual home infusion therapy suppliers. Therefore, we believe that adding a regulatory requirement to specify a uniform size and composition of an AO survey teams would not be appropriate.

We propose at § 488.1010(a)(10) to require that an AO for home infusion therapy suppliers provide CMS with detailed information about the individuals who perform survey activities, including onsite surveys, offsite audits and other review processes, for the purpose of ensuring accredited home infusion therapy suppliers maintain adherence to the accreditation program requirements. More specifically, proposed § 488.1010(a)(10)(i) would require the AOs to furnish information about the numbers of professional and technical staff available for accreditation related activities, as well as the educational background and experience requirements for its surveyors, auditors and reviewers. Proposed § 488.1010(a)(10)(ii) would require the AO to provide information about the educational, past experience and employment requirements surveyors must meet. Proposed § 488.1010(a)(10)(iii) would require the AO to provide information about the content and length of the orientation program for newly hired surveyors, auditors and reviewers.

These requirements would help ensure that AOs for home infusion therapy suppliers hires survey team staff members that possess the requisite knowledge, expertise, training, and experience specific to home infusion therapy suppliers. We believe it is imperative that surveys be performed by properly educated and trained staff in order to be valid and accurate. This proposed section is also intended to help ensure that the home infusion therapy AO maintains an adequate number of properly trained surveyors so that it would be able to meet the demand for all surveys, both initial and re-accreditation, to be performed for all clients.

We propose at § 488.1010(a)(11) to require each AO for home infusion therapy suppliers to describe the content, frequency and types of in-service training provided to survey and audit personnel. This requirement would help ensure that AO personnel who perform surveys, audits and other review-related activities maintain the skills and knowledge necessary to perform their work with competency. We believe that surveys performed by competent, well trained surveyor teams would provide CMS with reasonable assurance that accredited home infusion therapy suppliers meet or exceed the applicable quality standards.

We propose at § 488.1010(a)(12) to require AOs for home infusion therapy suppliers to provide documentation which describes the evaluation systems used to monitor the performance of individual surveyors, survey teams, and staff that perform audit activities. This proposed requirement would provide CMS with insight into how each home infusion therapy AO measures the performance of their surveyors, survey teams and staff that perform audit activities. This requirement would provide CMS with the ability to assess whether an AO has a credible process for ongoing evaluations of its surveyors, survey teams, and staff that perform audit activities.

We believe that the performance evaluation of a home infusion therapy AO's surveyors, survey team and other staff that perform survey and audit activities can have a significant impact on the effectiveness of the home infusion therapy AO's survey processes.

We propose at § 488.1010(a)(13) to require the AO for home infusion therapy suppliers to provide the organization's policies and procedures for avoiding and handling conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions. This proposed provision would help CMS to determine if home infusion therapy AO has policies to avoid potential conflicts of

interest that could undermine the integrity of its accreditation program.

We propose at § 488.1010(a)(14) to require the AO for home infusion therapy suppliers to provide CMS with documentation of its policies and procedures for handling disputes filed by a home infusion therapy supplier regarding survey or audit findings, or an adverse decision. The intent of this proposed section is to ensure that a home infusion therapy AO has procedures in place to ensure that those suppliers who wish to dispute the AO's survey findings or appeal an adverse decision are provided with notice of their organizational and statutory appeal rights.

We propose at § 488.1010(a)(15) to require that home infusion therapy AOs provide CMS with copies of the policies and procedures to be used when an accredited home infusion therapy supplier either--(1) removes or ceases furnishing services for which they are accredited; or (2) adds home infusion therapy services for which they are not accredited. This proposed requirement would ensure there is timely communication between the accredited home infusion therapy supplier and the AO, when changes in the supplier's circumstances occur that would have an impact on the status of their accreditation.

We propose at § 488.1010(a)(16) to require the home infusion therapy AOs to provide CMS with the organization's policies and procedures for responding to and investigating complaints and grievances against accredited suppliers. These policies and procedures should include a specific procedure for coordinating with and making referrals, when applicable, to the appropriate licensing bodies, ombudsman's offices and CMS. It is our intent that each CMS-approved home infusion therapy AO has policies and procedures in place for handling complaints and grievances. We believe it is important that any complaints against an accredited home infusion therapy supplier be investigated promptly and fairly. It is also important that the appropriate referrals be made when necessary.

We propose at § 488.1010(a)(17) to require that the home infusion therapy AOs furnish a description of the AO's accreditation status decision-making process. Proposed § 488.1010(a)(17)(i) would require the organization to furnish its process for addressing a home infusion therapy supplier deficiencies with meeting accreditation program requirements. This section would also require the home infusion therapy AO to provide a description of the procedures used to monitor the correction of deficiencies identified during the accreditation survey and audit process. It is important for CMS to ensure that the home infusion therapy AOs are properly addressing the home infusion therapy supplier's deficiencies and requiring appropriate corrective action.

We propose at § 488.1010(a)(17)(ii) to require that the home infusion therapy AOs furnish a description of all types and categories of accreditation decisions associated with the program, including the duration of each of the organization's accreditation decisions.

Proposed § 488.1010(a)(17)(iii) would require the home infusion therapy AO to provide information about its procedures for the granting, withholding or removal of accreditation status for home infusion therapy suppliers that fail to meet the AO's standards or requirements. This proposed section would also require the home infusion therapy AO to identify the procedures related to assignment of less than full accreditation status or other actions taken by the home infusion therapy AO in response to non-compliance with its standards and requirements. Since the granting of full or less than full accreditation status is an essential component of a home infusion therapy AO's accreditation decision process, we believe that it is necessary for CMS to receive information on the policies and procedures pertaining to these types of decisions as well.

We propose at § 488.1010(a)(17)(iv) to require the home infusion therapy AO to furnish

a statement acknowledging that the organization agrees to notify CMS (in a manner specified by CMS in subregulatory guidance) of any decision to revoke or terminate, withdraw, or revise the accreditation status of a home infusion therapy supplier within 3 business days from the date the organization takes an action. "Revocation" or "termination" represents an involuntary cessation of a home infusion therapy supplier's accreditation. A revocation or termination of accreditation could include an action taken when a home infusion therapy AO concludes that a home infusion therapy supplier is substantially non-compliant with accreditation standards and has not corrected its deficient practices within the timeframe specified by the home infusion therapy AO. A home infusion therapy AO could also revoke or terminate a home infusion therapy supplier's accreditation due to the non-payment of accreditation fees. We define the term "revised" accreditation status as a change in the accreditation status of a home infusion therapy supplier based on the formal accreditation status categories used by a home infusion therapy AO. These changes could include adverse changes that fall short of revocation, as well as positive changes reflecting improved compliance. This is in contrast to a "withdrawal" which is a voluntary decision on the part of the home infusion therapy supplier to end its participation in the AO's accreditation program.

Our intent with this proposed requirement is to require that home infusion therapy AOs notify CMS when they have taken a final action concerning a change in the accreditation status of a home infusion therapy supplier. If a home infusion therapy supplier has filed a request for an administrative appeal of the AO's decision to revoke or terminate accreditation, the action on the part of the home infusion therapy AO to revoke or terminate accreditation cannot be finalized until after the conclusion of the administrative appeals process. In this case, the home infusion therapy AO would be required to send notice of their final action to CMS no later than

three business days after that appeals process has concluded and a final AO determination has been made.

We propose at §488.1010(a)(18) to require a home infusion therapy AOs to provide CMS with a list of all home infusion therapy suppliers currently accredited by that home infusion therapy AO. This list must include the type and category of accreditation held by each home infusion therapy supplier and the expiration date of each supplier's current accreditation.

We propose at § 488.1010(a)(19) to require that the home infusion therapy AOs provide CMS with a schedule of all survey activity (including but not limited to onsite surveys, offsite audits and other types if survey strategies), expected to be conducted by the home infusion therapy AO during the 6-month period following submission of the application. This proposed requirement would apply to both initial and renewal applications. Under this proposed section, the home infusion therapy AO would be required to provide us with its survey activity schedule for the 6-month period following submission of their application for approval to survey and accredit home infusion therapy suppliers. We would use the survey schedule to plan our survey observation as part of our review of the home infusion therapy AO's application.

We propose at § 488.1010(a)(20) to require that the home infusion therapy AO submit a written statement or document that demonstrates the organization's ability to furnish CMS with the electronic data the home infusion therapy AO must report to CMS as required by proposed § 488.1035. The information and data to be provided under this section would assist us in providing effective oversight of the approved home infusion therapy accreditation programs. This information is necessary for effective assessment and validation of the home infusion therapy AO's survey process.

These proposed regulations will require the AO to submit documentation to CMS on a

periodic basis. The intent of this requirement is to ensure that the AO is able to provide CMS with the required data electronically. CMS is cutting down of the use of printed documents and maximizing the use of electronic document storage.

We propose at § 488.1010(a)(21) to require that the home infusion therapy AO provide a description of the organization's data management and analysis system with respect to its surveys and accreditation decisions. Proposed § 488.1010(a)(21)(i) would require the home infusion therapy AO to furnish a detailed description of how the home infusion therapy AO uses its data to assure compliance of its home infusion therapy accreditation program with the corresponding Medicare requirements.

We propose at § 488.1010(a)(21)(ii) to require the home infusion therapy AO to submit a written statement in which the home infusion therapy AO acknowledges that it agrees to submit timely, accurate, and complete data, which CMS determines necessary for evaluation of the home infusion therapy AO's performance, and which would not be unduly burdensome to submit. The data to be submitted, according to proposed § 488.1010(a)(21)(ii)(B) would include, accredited home infusion therapy supplier identifying information, survey findings, quality measures, and notices of accreditation decisions. The home infusion therapy AO would further agree to submit the necessary data according to the instructions and timeframes CMS specifies through subregulatory guidance.

This data would allow CMS to obtain information about how the home infusion therapy AO would use its data management systems to meet or exceed Medicare home infusion therapy accreditation requirements as set forth in this subpart. The proposed data would also assist us in providing effective oversight of the approved home infusion therapy accreditation program.

We propose at §488.1010(a)(22) to require the home infusion therapy AO to furnish the

three most recent annual audited financial statements from their organization. The purpose of this proposed requirement would be to verify that the home infusion therapy AO's staffing, funding, and other resources are adequate to perform the required surveys, audits and related activities in order to maintain the home infusion therapy accreditation program on a national basis. This requirement is also intended to insure that a home infusion therapy AO has the financial stability to ensure ongoing, stable operations and longevity.

Proposed § 488.1010(a)(23) would require the home infusion therapy AOs to provide a written statement, in which the home infusion therapy AO acknowledges, as a condition for approval, that the organization agrees to the items set forth in § 488.1010(a)(23)(i) through (vi).

Proposed § 488.1010(a)(23)(i) would require the home infusion therapy AO to provide a written statement acknowledging that, as a condition for approval, that if the home infusion therapy AO decides to voluntarily terminate its accreditation program, the home infusion therapy AO must provide written notification to CMS and all home infusion therapy suppliers accredited by that AO. This written notice must be provided at least 90 calendar days in advance of the effective date of the home infusion therapy AOs decision to voluntarily terminate its CMS-approved accreditation program. This notice must contain the all of following information:

- Notice that the home infusion therapy AO is voluntarily terminating its home infusion therapy accreditation program.
- The effective date of the termination.
- The implications for the home infusion therapy supplier's payment status once their current term of accreditation expires in accordance with the requirements set forth at § 488.1045(a).

Proposed § 488.1010(a)(23)(ii) would require the home infusion therapy AO to provide a written statement acknowledging that, as a condition for approval, that, a home infusion therapy AO must provide written notification of an involuntary withdrawal of CMS approval of its home infusion therapy accreditation program to all its accredited home infusion therapy suppliers. This written notice must be provided by the home infusion therapy AO to all of its accredited home infusion therapy suppliers no later than 30 calendar days after the public notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of the accreditation program in accordance with the requirements at § 488.1045(b). This **Federal Register** notice must state the implications for the providers' or suppliers' payment status once their current term of accreditation expires. Home infusion therapy suppliers would no longer be eligible to receive Medicare payments upon expiration of the current term of accreditation. Therefore, it is critical that the home infusion therapy supplier seek accreditation immediately through another CMS-approved home infusion therapy accreditor.

Proposed § 488.1010(a)(23)(ii)(A) would require the home infusion therapy AO to acknowledge that they must send a second written notification, as a reminder to all accredited home infusion therapy suppliers within ten calendar days of the organization's removal from the list of CMS-designated home infusion therapy AOs. We believe that this second reminder to the accredited home infusion therapy suppliers who are in danger of having a lapse of accreditation is very important. This notice would remind the home infusion therapy suppliers that they must seek another home infusion therapy accreditor to avoid a lapse in accreditation, and subsequently a lapse in Medicare payment.

Proposed § 488.1010(a)(23)(ii)(B) would require the home infusion therapy AO to acknowledge that they will notify CMS, in writing, (either electronically or in hard copy

format) within 2 business days of identification of an immediate jeopardy situation that has been identified in any accredited home infusion therapy supplier. An immediate jeopardy situation is presented when a provider or supplier exhibits a deficiency hat poses serious risk of harm or death to the home infusion therapy supplier's patients, staff or visitors, or poses a hazard to the general public. Immediate jeopardy situations are of such a serious nature that it is important that they be identified and removed as quickly as possible. We propose the 2-day notification requirement because CMS must notified of immediate jeopardy situations as quickly as possible so that we can monitor these serious situations and take action as appropriate.

We propose at §488.1010(a)(23)(iii) to require the home infusion therapy AO to provide CMS with an annual summary of accreditation activity data and trends, including, but not limited to, deficiencies, complaints, terminations, withdrawals, denials, accreditation decisions, and other survey related activities as specified by CMS. We believe that it is important for CMS to monitor this information as part of our oversight of the home infusion therapy AOs performance.

Proposed § 488.1010(a)(23)(iv), would require a home infusion therapy AO to work collaboratively with CMS in the event that CMS terminates the home infusion therapy AO's approved status, to direct its accredited home infusion therapy suppliers to the remaining CMS-approved home infusion therapy AOs within a reasonable period of time. We would require the terminated home infusion therapy AO to perform this task because its accredited home infusion therapy suppliers would be left with no accreditation as a result of the termination of the home infusion therapy AOs CMS-approval. Therefore, we believe that the terminated home infusion therapy AO has some responsibility to help their accredited home infusion therapy suppliers

seek alternative accreditors as soon as possible.

Proposed § 488.1010(a)(23)(v), would require the home infusion therapy AOs to notify CMS of any significant proposed changes in its CMS-approved accreditation program requirements or survey process. Under this section, the home infusion therapy AO would be required to submit their notice of revised program requirements or changes in the survey process to CMS in writing no less than 60 days in advance of the proposed implementation date. As required by proposed § 488.1030(c)(1), the home infusion therapy AO would be required to agree not to implement the proposed changes without prior written notice of continued program approval from CMS, except as provided for at § 488.1030(c)(4).

Proposed § 488.1010(a)(23)(vi), would require the home infusion therapy AOs to provide a statement acknowledging that if they receive a written notice from CMS which states that there has been a change in the applicable Medicare home infusion therapy substantive health and safety requirements, the home infusion therapy AO must provide CMS with proposed corresponding changes in the home infusion therapy accreditation requirements for its CMS-approved home infusion therapy accreditation program. This requirement is intended to ensure that the AO's accreditation standards continue to meet or exceed those of Medicare, and that the AO's survey process remains comparable with that of Medicare.

Section 488.1010(a)(23)(vi) provides that in the event that CMS makes a change in the applicable home infusion therapy accreditation requirements, the home infusion therapy AO must comply with several requirements. First, proposed § 488.1010(a)(23)(vi)(A) would require the home infusion therapy AO to submit its responsive proposed changes in their accreditation requirements and survey processes to CMS within 30 calendar days of the date of the written CMS notice to the home infusion therapy AO or by a date specified in the notice,

whichever is later. However, CMS will give due consideration to a home infusion therapy AO's request for an extension of the deadline as long as it is submitted prior to the due date. Second, proposed § 488.1010(a)(23)(vi)(B) would require that the home infusion therapy AO not implement its proposed responsive changes without prior written notice of continued program approval from CMS, except as provided for at § 488.1030(b)(1)(v).

Proposed § 488.1010(a)(24) would require the home infusion therapy AOs to provide CMS with a listing of the organization's proposed fees for home infusion therapy accreditation. The home infusion therapy AO must notify CMS of any plans for reducing the burden and cost of accreditation to small or rural home infusion therapy suppliers. While CMS does not undertake to set or regulate the fees charges by a home infusion therapy AO, we do review fees charged by AOs to determine whether they are reasonable as directed by sections 1834(u)(5)(A)(iii) of the Act.

Proposed § 488.1010(b) would require home infusion therapy AOs to agree to submit any additional information, documentation, or attestations, including items not previously listed that CMS may deem necessary to make a determination for approval or denial of the home infusion therapy AO's application. Should we require this additional information, we would notify the home infusion therapy AO of the request and provide the home infusion therapy AO with a reasonable timeframe to submit the requested information.

We propose at § 488.1010(c) to allow a home infusion therapy AO to withdraw its initial application for CMS's approval of its home infusion therapy accreditation program at any time before we publish the final **Federal Register** notice described at § 488.1020(b). The intent of this provision is to provide home infusion therapy AOs that have encountered difficulty meeting the requirements described at § 488.1010(a) during the application process

with the option to voluntarily withdraw their application before CMS publishes the final decision in the **Federal Register** as required by proposed § 488.1020(b). Proposed § 488.1020(b) would require that the final notice, published by CMS, specify the basis for our decision. Because the **Federal Register** is a public forum, we believe it is likely that home infusion therapy AOs would choose to voluntarily withdraw their application instead of having information about the non-compliance of their home infusion therapy accreditation program made publicly available. This may be especially true for those home infusion therapy AOs that wish to reapply for approval of their accreditation program in the future. A voluntary withdrawal of an application by the home infusion therapy AO would terminate the application review process prior to publication of the final decision in the **Federal Register**.

Proposed § 488.1010(d) would require CMS to complete its review of an application submitted by a home infusion therapy AO within 210 calendar days from the date that CMS determines that the application is complete. We propose that to determine completeness, each application would be assigned to a technical review team upon receipt by CMS. This team would perform a completeness review to determine if the application contains all documents and supplemental information required by proposed § 488.1010(a). Lastly, we propose that if the application is not complete, the review team would contact the home infusion therapy AO and request that they submit any missing information or documents in accordance with § 488.1010(b).

We seek public comment on the proposal related to the proposed application requirements set forth in proposed §488.1010. We further seek comments on the burden related to the requirements of the application procedure.

(4) Resubmitting a Request (§ 488.1015)

Proposed § 488.1015(a) would require that except as provided in paragraph (b), a home infusion therapy AO whose request for CMS's approval or re-approval of a home infusion therapy accreditation program was denied, or an organization that has voluntarily withdrawn an initial application, could resubmit its application if the organization had: (1) revised its accreditation program to address the issues related to the denial of its previous request or its voluntary withdrawal; and (2) resubmitted the application in its entirety.

Proposed § 488.1015(b) would provide that a home infusion therapy AO that had asked for reconsideration of an application denial by CMS could not submit a new application until the pending reconsideration was administratively final. This provision would ensure that review of accreditation matters on reconsideration are pending before only one administrative agency and one administrative level at a time.

We seek public comments on the requirements of proposed §488.1015.

(5) Public Notice and Comment (§ 488.1020)

Proposed § 488.1020(a) would require CMS to publish a notice in the **Federal Register** upon receipt of a complete application package. The notice would identify the organization, the type of home infusion therapy suppliers covered by the accreditation program, and provides for at least a 30-day public comment period (which begins on the date of publication of the **Federal Register** notice). The purpose of the **Federal Register** notice is to notify the public that a national AO has filed an application for approval of a home infusion therapy accreditation program and to seek public comment in response to this application. The requirement for the publication of a notice in the **Federal Register** when an application is received is an existing regulatory procedural requirement for all other AO types. We have added this requirement to the home infusion therapy AO approval and oversight regulations for

consistency.

Proposed § 488.1020(b) would require that when CMS approves or re-approves an application for approval of a home infusion therapy AO's accreditation program, a final notice would be published in the **Federal Register**. This notice would have to specify the basis for CMS' decision. Proposed § 488.1020(b)(1), would require that our final notice include at a minimum, the following information: (1) how the accreditation program met or exceeded Medicare accreditation program requirements; (2) the effective date of the CMS approval, which is not later than the publication date of the notice; and (3) the term of the approval (6 years or less).

If CMS makes a decision to disapprove a home infusion therapy AOs application, our final notice would state the deficiencies found in the application and the reason why the AOs accreditation program did not met or exceeded Medicare accreditation program requirements. However, an AO has the option of voluntarily withdrawing its application at any time up until the publication of the final notice.

We propose at § 488.1020(b)(2) that if CMS did not approve a home infusion therapy AO's application for approval of its home infusion therapy accreditation program, the final notice would explain how the home infusion therapy AO failed to meet Medicare home infusion therapy accreditation program requirements. This notice would indicate the effective date of the decision.

We seek comment on the requirements of proposed §488.1020, including on the appropriate term for approval of an AO.

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

Proposed § 488.1025 would require a home infusion therapy AO to include, in its

accreditation agreement with each home infusion therapy supplier, an acknowledgement that the home infusion therapy supplier agrees to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require, including the home infusion therapy supplier's corrective action plans. Proposed § 488.1025(a) would provide that CMS may determine that a home infusion therapy supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

Proposed § 488.1025(b) would prohibit CMS from disclosing home infusion therapy survey reports or survey related information according to section 1865(b) of the Act. However, CMS would be permitted to publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information is related to an enforcement action taken by CMS.

CMS would use the home infusion therapy supplier accreditation survey information for purposes such as: (1) confirmation of the home infusion therapy supplier's eligibility for Medicare participation; (2) to review and approve the home infusion therapy AO's recommendations regarding accreditation; (3) to review the home infusion therapy AO's investigations of complaints; and (4) to review the corrective action taken by the AO when deficiencies are found on survey.

We seek public comments on the requirements of proposed §488.1025.

(7) Ongoing Review of Accrediting Organizations (§ 488.1030)

Proposed § 488.1030 would clarify that a formal accreditation program review could be opened on an ongoing basis. Specifically, this section would describe standardized requirements related to the ongoing federal review of home infusion therapy AOs and their

approved accreditation programs. This proposed section would clarify that CMS oversight of accreditation programs is consistent across home infusion therapy AOs. We are committed to treating all home infusion therapy AOs subject to our oversight in the same manner. Under proposed

§488.1030, we could conduct the following three types of reviews of an AOs home infusion therapy accreditation programs: (1) performance review; (2) comparability review; and (3) CMS-approved accreditation program review.

Proposed § 488.1030(a) would allow CMS to perform a performance review, in which we would evaluate the performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis. Specifically, we would review the following aspects of a home infusion therapy AO's for home infusion therapy program performance: The organization's survey activity, and the organization's continued fulfillment of the requirements stated in § 488.1010.

Proposed § 488.1030(b) would allow CMS to perform a comparability review to assess the equivalency of a home infusion therapy AO's CMS-approved home infusion therapy accreditation program requirements with comparable Medicare home infusion therapy accreditation requirements. Proposed § 488.1030(b)(1) would allow CMS to perform a comparability review when CMS imposes new or revised Medicare accreditation requirements. When this occurs, proposed § 488.1030(b)(1) would require CMS to provide written notice to the home infusion therapy AOs when changes have been made to the Medicare home infusion therapy accreditation requirements. Proposed § 488.1030(b)(2) would require the home infusion therapy accrediting organization to make revision to its home infusion therapy accreditation standards or survey process so as to incorporate the new or revised Medicare

accreditation requirements.

Proposed § 488.1030(b)(3) would further require that the written notice sent by CMS to the home infusion therapy AO specify a deadline (not less than 30 days) by which the home infusion therapy AO must prepare and submit their proposed home infusion therapy accreditation program requirement revisions and the timeframe for implementation. Proposed § 488.1030(b)(4) would allow a home infusion therapy AO to submit a written request for an extension of the submission deadline as long as this request was submitted prior to the original deadline.

Proposed at § 488.1030(b)(5) would require that, after completing the comparability review, CMS would provide written notification to the home infusion therapy AO, specifying whether or not their revised home infusion therapy accreditation program standards continued to meet or exceed all applicable Medicare requirements. We propose at § 488.1030(b)(6) that if, no later than 60 days after receipt of the home infusion therapy AO's proposed accreditation standard changes, CMS did not provide the written notice to the home infusion therapy AO, then the revised home infusion therapy program accreditation standards would be deemed to meet or exceed all applicable Medicare requirement and the accreditation program would have continued CMS-approval without further review or consideration.

Proposed § 488.1030(b)(7) would provide that if a home infusion therapy AO was required to submit a new application because CMS imposed new regulations or made significant substantive revisions to the existing regulations, CMS would provide notice of the decision to approve or disapprove the application within the time period specified in § 488.1010(d).

We propose at § 488.1030(b)(8) that if a home infusion therapy AO failed to submit its

proposed changes within the required timeframe, or failed to implement the proposed changes that had been determined by CMS to be comparable, CMS could open an accreditation program review in accordance with § 488.1030(d).

When a home infusion therapy AO proposes to adopt new home infusion therapy accreditation standards or changes, in its survey process, we propose at § 488.1030(c)(1) to require the home infusion therapy AO to provide notice to CMS no less than 60 days prior to the planned implementation date of the proposed changes. Proposed § 488.1030(c)(2) would prohibit the home infusion therapy AO from implementing these changes before receiving CMS' approval except as provided in § 488.1030(c)(4). Proposed § 488.1030(c)(3) would require that this written notice contain a detailed description of the changes to be made to the organization's home infusion therapy accreditation standards, including a detailed crosswalk (in table format) that states the exact language of the revised accreditation requirements and the corresponding Medicare requirements for each. The requirements of §§ 488.1030(c)(2) and 488.10(c)(3) would ensure that the home infusion therapy AO provides CMS with advance notice of any proposed changes to their home infusion therapy accreditation requirements and survey processes. This notice would allow CMS time to review these proposed changes to ensure that the revised home infusion therapy accreditation standards and survey processes continue to meet or exceed all applicable Medicare home infusion therapy requirements and continue to be comparable to all applicable Medicare home infusion therapy survey processes, and provide a response to the home infusion therapy AO. This section would also prohibit home infusion therapy AOs from implementing any of the proposed changes in their home infusion therapy accreditation requirements and survey processes, until CMS approval has been received. We seek comment on this proposal.

Proposed § 488.1030(c)(4) would require CMS to provide written notice to the home infusion therapy accrediting organization indicating whether the home infusion therapy accreditation program, including the proposed revisions, continued or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements. If CMS found that the accrediting organization's home infusion therapy accreditation program, including the proposed revisions did not continue to meet or exceed all applicable Medicare home infusion therapy requirements. CMS would have to state the reasons for these findings.

Proposed § 488.1030(c)(5) would require CMS to provide this written notice to the home infusion therapy AO by the 60th calendar day following receipt of the home infusion therapy AO's written proposed changes as to whether the home infusion therapy AO's revised home infusion therapy accreditation program standards and survey processes have been be deemed to meet or exceed all applicable Medicare home infusion therapy requirements and have continued CMS approval without further review or consideration. This proposed section would further specify that if CMS failed to provide the required written notice to the home infusion therapy AO by the 60 day deadline, the home infusion therapy AO's revised accreditation program standards would be deemed to meet or exceed all applicable Medicare requirements and have continued CMS approval without further review or consideration.

Proposed § 488.1030(c)(5) would permit CMS to open an accreditation program review, in accordance with proposed § 488.1030(d), if a home infusion therapy AO implemented changes to their home infusion therapy accreditation requirements or survey process that were not determined nor deemed by CMS to be comparable to the applicable Medicare requirements.

We propose at § 488.1030(d) to permit CMS to initiate an accreditation program review when a comparability or performance review reveals evidence that a home infusion therapy

AO's CMS–approved home infusion therapy accreditation program is in substantial non-compliance with the requirements of the proposed home infusion therapy health and safety regulations contained in 42 CFR part 486, subpart B. Proposed § 488.1030(d)(1) would require CMS to provide written notice to the home infusion therapy AO when a home infusion therapy accreditation program review is initiated. Proposed § 488.1030(d)(1)(i) through (iv) would set forth the requirements for this written notice, which should contain the following information: (i) a statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable; (ii) a description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy AO to offer factual information related to CMS' findings; (iii) a description of the possible actions that may be imposed by CMS based on the findings of the accreditation program review; and, (iv) the actions the home infusion therapy AO would have to take to address the identified deficiencies, and the length of the accreditation program review probation period, which will include monitoring of the home infusion therapy AO's performance and implementation of the corrective action plan. The probation period is not to exceed 180 calendar days from the date that CMS has approved the home infusion therapy AOs plan of correction (which is the AO written plan for correcting any deficiencies in its home infusion therapy accreditation program that were found by CMS on a program review).

At § 488.1030(d)(2), we propose that CMS would review and approve the home infusion therapy AO's plan of correction for acceptability within 30 days after receipt. Proposed §488.1030(d)(3) would provide that CMS will monitor the implementation of the home infusion therapy accrediting organization's plan of correction for a period not to exceed 180 days from the date of approval. During the 180-day review period, CMS would monitor

implementation of the accepted plan of correction as well as progress towards correction of identified issues and areas of non-compliance that triggered the accreditation program review.

We propose at § 488.1030(d)(4) to authorize CMS to place the home infusion therapy AO's CMS-approved accreditation program on probation for a subsequent period of up to 180 calendar days, if necessary. The additional period of time may be necessary if CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of an existing CMS-approved accreditation program, that the home infusion therapy AO has failed to meet any of the requirements of § 488.1010, or has made significant progress correcting identified issues or areas of non-compliance, but requires additional time to complete full implementation of corrective actions or demonstrate sustained compliance. If a home infusion therapy AO's term of approval expires before the 180-day period is completed, the probationary period will be deemed to end upon the day of expiration of the home infusion therapy AO's term of approval. In the case of a renewal application where we have placed the home infusion therapy accreditation program on probation, we propose that any approval of the applications must be conditional while the program remains on probation.

If we place a home infusion therapy AO's accreditation program on probation, proposed § 488.1030(d)(4)(i) would require CMS to issue a written determination to the home infusion therapy AO, within 60 calendar days after the end of any probationary period. The written determination must state whether or not the CMS-approved home infusion therapy accreditation program continued to meet the requirements of this section and the reasons for the determination.

If we determined that withdrawal of approval from a CMS-approved accreditation program was necessary, proposed § 488.1030(d)(4)(ii) would require CMS to send written

notice to the home infusion therapy AO which contained the following information: (1) notice of CMS' removal of approval of the home infusion therapy AOs accreditation program;(2) the reason(s) for the removal; and (3) the effective date of the removal determined in accordance with § 488.1030(d)(4)(ii).

If CMS withdrew the approval of a home infusion therapy AO accreditation program, proposed § 488.1030(d)(4)(iii) would require CMS to publish a notice of its decision to withdraw approval of the accreditation program in the **Federal Register**. This notice would have to include the reasons for the withdrawal, and a notification that the withdrawal would become effective 60 calendar days after the date of publication in the **Federal Register**. The publication of this Federal Register Notice is notice would be necessary to put interested stakeholders, such as the home infusion therapy suppliers that are accredited by the affected AO on notice about the withdrawal of CMS-approval of their AO, because this will have an effect on the status of their accreditation.

Proposed § 488.1030(e) would allow CMS to immediately withdraw the CMS approval of an home infusion therapy AO's home infusion therapy accreditation program, if at any time CMS makes a determination that the continued approval of that home infusion therapy accreditation program poses an immediate jeopardy to the patients of the entities accredited under the program; or the continued approval otherwise constitutes a significant hazard to the public health. We propose at § 488.1030(f) to mandate that any home infusion therapy AO whose CMS approval of its home infusion therapy accreditation program has been withdrawn must notify, in writing, each of its accredited home infusion therapy suppliers of the withdrawal of CMS approval and the implications for the home infusion therapy suppliers' payment status no later than 30 calendar days after the notice is published in the **Federal Register**. This

requirement would protect the home infusion therapy suppliers that have received their accreditation from a home infusion therapy AO that has had its CMS approval of their home infusion therapy accreditation program removed.

We seek public comments on the requirements of proposed §488.1030. We further seek public comment related to the burden associated with the requirements of proposed §488.1030.

(8) Ongoing Responsibilities of a CMS-approved Accreditation Organization (§ 488.1035)

Proposed § 488.1035 would require a home infusion therapy AO to provide certain information to CMS and carry out certain activities on an ongoing basis. More specifically proposed § 488.1035(a) would require the home infusion therapy AO to provide CMS with all of the following in written format (either electronic or hard copy):

- Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements);
- Notice of all home infusion therapy accreditation decisions.
- Notice of all complaints related to home infusion therapy suppliers.
- Information about all home infusion therapy accredited suppliers against which the home infusion therapy AO has taken remedial or adverse action, including revocation, withdrawal, or revision of the home infusion therapy supplier's accreditation.
- Summary data specified by CMS that relate to the past year's home infusion therapy accreditation activities and trends which is to be provided on an annual basis.
- Notice of any proposed changes in its home infusion therapy accreditation standards or requirements or survey process.

Proposed § 488.1035(b) would require a home infusion therapy AO to submit an

acknowledgment of receipt of CMS' notification of a change in CMS requirements within 30 days from the date of the notice. Proposed § 488.1035(c) would require that a home infusion therapy AO permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

Proposed § 488.1035(d) would require that within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy AO must provide CMS with written notice of the deficiency and any adverse action implemented by the home infusion therapy AO. Proposed § 488.1035(e) would require that within 10 calendar days after our notice to a CMS-approved home infusion therapy AO that CMS intends to withdraw approval of the home infusion therapy AO, the home infusion therapy AO must provide written notice of the withdrawal to all of the organization's accredited home infusion therapy suppliers.

We seek public comment on the requirements of proposed § 488.1035. We further seek public comments related to the burden associated with the requirements of proposed § 488.1035.

(9) Onsite Observations of Accrediting Organization Operations (§488.1040)

We propose at §488.1040(a) and (b) to permit CMS to conduct an onsite inspection of the home infusion therapy AOs operations and offices at any time to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. Activities to be performed by CMS staff during the onsite inspections may include, but are not limited to: (1) interviews with various home infusion therapy AO staff; (2) review of documents, and survey files, audit tools and related records; (3) observation of meetings concerning the accreditation process; (4) auditing meetings concerning the accreditation

process, (5) observation of in-progress surveys and audits; (6) evaluation of the home infusion therapy AO's survey results and accreditation decision-making process.

CMS would perform onsite visits to a home infusion therapy AOs offices only for specific reasons. For example, when an AO had filed an initial or renewal application for approval of its home infusion therapy accreditation program, CMS would perform an onsite visit to the AOs offices as part of the application review process. If CMS has opened a program review and put the home infusion therapy AO on probation for a 180 day period, we would perform an onsite visit to the AOs offices to check of the AOs progress in implementing the plan of correction.

If CMS decides to perform on onsite visit to the home infusion therapy AOs offices, we would notify the AO. We would coordinate with the AO staff to schedule the onsite visit at mutually agreed upon date and time.

The intended purpose of this section is to provide CMS with an opportunity to observe, first hand, the daily operations of home infusion therapy AOs and to ensure that the home infusion therapy accreditation program is fully implemented and operational as presented in the written application. Onsite inspections would strengthen our continuing oversight of the home infusion therapy AO performance because they provide an opportunity for us to corroborate the verbal and written information submitted to CMS by the home infusion therapy AO in their initial and renewal applications. In addition, onsite inspections would allow CMS to assess the home infusion therapy AO's compliance with its own policies and procedures.

We seek public comments on the requirements of proposed § 488.1040. We also seek comments regarding the burden related to § 488.1040.

(10) Voluntary and Involuntary Termination (§ 488.1045)

The proposed provisions related to the voluntary and involuntary termination of CMS approval of a home infusion therapy AO's accreditation program are set out at proposed § 488.1045. Proposed § 488.1045(a) would address voluntary termination of a home infusion therapy AO's accreditation program by the home infusion therapy AO. A home infusion therapy AO that decides to voluntarily terminate its CMS-approved accreditation program must provide written notice to CMS and each of its accredited home infusion therapy suppliers at least 90 days in advance of the effective date of the termination. This written notice must state the implications for the home infusion therapy supplier's payment should there be a lapse in their accreditation status.

Proposed standard § 488.1045(b) would address CMS involuntary termination of a home infusion therapy AO's CMS-approved accreditation program. Once CMS publishes the notice in the **Federal Register** announcing its decision to terminate the accrediting organization's home infusion therapy accreditation program, the home infusion therapy AO would have to provide written notification to all home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice was published in the **Federal Register**. This notice would state that CMS is withdrawing its approval of the home infusion therapy AO's accreditation program and the implications for their payment, should there be a lapse in their accreditation status.

Proposed § 488.1045(c) addresses the requirements that would apply to both voluntary and involuntary terminations of CMS approval of the home infusion therapy AO. Proposed § 488.1045(c)(1) would provide that the accreditation status of affected home infusion therapy suppliers would be considered to remain in effect until their current term of accreditation expired. In the case where a home infusion therapy AO has been removed as a CMS-approved

AO, any home infusion therapy supplier that is accredited by the organization during the period beginning on the date the organization was approved by CMS until the date the organization was removed, shall be considered accredited for its remaining accreditation period.

Proposed § 488.1045(c)(2) would provide that for any home infusion therapy supplier, whose home infusion therapy AO's CMS approval has been voluntarily or involuntarily terminated by CMS, and who wishes to continue to receive reimbursement from Medicare, must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date which states that the home infusion therapy supplier has submitted an application for accreditation under another CMS-approved home infusion therapy accreditation program. This section further states that failure to comply with this 60-calendar day requirement prior to expiration of their current accreditation status could result in a suspension of payment.

Proposed § 488.1045(c)(3) would require that the terminated home infusion therapy AO must provide a second written notification to all accredited suppliers ten calendar days prior to the organization's accreditation program effective date of termination.

The proposed notice provisions at § 488.1045(c)(2) and (3) could help prevent home infusion therapy suppliers from suffering financial hardship that could result from a denial of payment of Medicare claims if their home infusion therapy accreditation lapses as a result of the voluntary or involuntary termination of a CMS-approved home infusion therapy AO program.

We propose at § 488.1045(d), that if a home infusion therapy supplier requests a voluntary withdrawal from accreditation, it will not be possible for the withdrawal to become effective until the home infusion therapy AO completes three required steps. First, the AO

would have to contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intended to voluntarily withdraw from the accreditation program. Second, the home infusion therapy AO would have to advise home infusion therapy supplier, in writing, of the statutory requirement at 1861(iii)(3)(D)(i)(III) of the Act for requiring accreditation for all home infusion therapy suppliers. Third, the home infusion therapy AO would have to advise the home infusion therapy supplier of the possible payment consequence for a lapse in accreditation status. Proposed §488.1045(d)(3) would require the home infusion therapy AO to submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier five business days after the request for voluntary withdrawal was ultimately processed and effective.

We believe that it is important that the home infusion therapy seek confirmation that the home infusion therapy supplier has indeed requested a voluntary termination of their accreditation. This confirmation would prevent the erroneous termination of the accreditation of a home infusion therapy supplier that did not request it or had subsequently withdrawn their request for voluntary termination.

We believe that it is also important for the home infusion therapy AO to provide the required written notice to the home infusion therapy supplier that requests a voluntary withdrawal from accreditation, so that the home infusion therapy supplier has been fully informed of the requirements for accreditation according to section 1861(iii)(3)(D)(i)(III) and the payment consequences of being unaccredited. If there is a lapse in the accreditation status of the home infusion therapy supplier, they will not be eligible to receive payment from Medicare for services furnished to Medicare beneficiaries. A home infusion therapy infusion therapy supplier that is unaware of this payment consequence could suffer financial hardship

due to furnishing services to Medicare beneficiaries for which they cannot be reimbursed after a lapse in accreditation.

We seek public comments on the requirements of proposed § 488.1045. We also seek comments regarding the burden related to § 488.1045.

(11) Reconsideration (§ 488.1050)

We propose at § 488.1050 to set forth the appeal process through which a home infusion therapy AO may request reconsideration of an unfavorable decision made by CMS. At proposed § 488.1050(b)(1), the home infusion therapy AO would have to submit a written request for reconsideration within 30 calendar days of the receipt of the CMS notification of an adverse determination or non-renewal. Proposed § 488.1050(b)(2) would require the home infusion therapy AOs to submit a written request for reconsideration which specifies the findings or issues with which the home infusion therapy AO disagreed and the reasons for the disagreement. Proposed §488.1050(b)(3) would allow a home infusion therapy AO to withdraw their request for reconsideration at any time before the administrative law judge issues a decision.

We propose at § 488.1050(c)(1) to establish requirements for CMS when a request for reconsideration has been received from a home infusion therapy AO. Specifically, CMS would be required to provide the home infusion therapy AO with: the opportunity for an administrative hearing with a hearing officer appointed by the Administrator of CMS; the opportunity to present, in writing and in person, evidence or documentation to refute CMS' notice of denial, termination of approval, or non-renewal of CMS approval and designation. Section 488.1050(c)(2) would require CMS to send the home infusion therapy AO written notice of the time and place of the informal hearing at least 10 business days before the

scheduled hearing date.

We propose at § 488.1050(d)(1) to establish rules for the administrative hearing such as who may attend the hearing on behalf of each party, including but not limited to legal counsel, technical advisors, and non-technical witnesses that have personal knowledge of the facts of the case. This proposed section would also specify the type of evidence that may be introduced at the hearing. Specifically, we would specify and clarify, at proposed § 488.1050(d)(4), that the hearing officer would not have the authority to compel by subpoena the production of witnesses, papers, or other evidence. Proposed § 488.1050(d)(5) would provide that the legal conclusions of the hearing officer within 45 calendar days after the close of the hearing. Proposed § 488.1050(d)(6) would require the hearing officer to present his or her findings and recommendations in a written report that includes separately numbered findings of fact. According to proposed §488.1050(d)(7), the decision of the hearing officer would be final.

We seek public comments on the requirements of proposed § 488.1050.

C. Payment for Home Infusion Therapy Services

1. Proposed Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020

Section 50401 of the BBA of 2018 (Pub. L. 115-123) amended section 1834(u) of the Act by adding a new paragraph (7) that establishes a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of the same items and services, as defined in section 1861(iii)(2)(A) and (B) of the Act, and outlined in section IV.A.2 in this proposed rule, related to the administration of home infusion drugs. The temporary transitional payment would begin on January 1, 2019 and end the day before the full implementation of the home infusion therapy benefit on January 1, 2021, as required by section 5012(d) of the 21st Century Cures Act.

a. Transitional Home Infusion Drugs

Section 1834(u)(7)(A)(iii) of the Act defines the term "transitional home infusion drug" using the same definition as 'home infusion drug' under section 1861(iii)(3)(C) of the Act, which is a 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. However, section 1834(u)(7)(A)(iii) of the Act includes an exception to the definition of 'home infusion drug' if the drug is identified under section 1834(u)(7)(C) of the Act. This provision specifies the HCPCS codes for the drugs and biologicals covered under the Local Coverage Determinations (LCDs) for External Infusion Pumps. In addition, subsequent infusion drug additions to the LCDs and compounded infusion drugs not otherwise classified,

as identified by HCPCS codes J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified), are also included in the definition of a 'transitional home infusion drug.'

b. Infusion Drug Administration Calendar Day

Section 1834(u)(7)(E)(i) of the Act states that payment to an eligible home infusion supplier or qualified home infusion therapy supplier for an infusion drug administration calendar day in the individual's home refers to payment only for the date on which professional services, as described in section 1861(iii)(2) of the Act, were furnished to administer such drugs to such individual. This includes all such drugs administered to such individual on such day. We believe this to mean that payment is only for the day on which the nurse is in the patient's home when an infusion drug is being administered. As section 1861(iii)(2)(A) of the Act refers to the professional services, including nursing services, we believe this to mean skilled services as set out at 42 CFR 409.32. For the professional services to be necessary for the safe and effective administration of home infusion drugs, they must be furnished by skilled professionals in accordance with individual state practice acts. We understand that there may be professional services furnished that do not occur on a day the drug is being administered. However, payment for such home infusion therapy services is built into the single payment for the day on which the nurse is in the patient's home and the drug is being infused. Accordingly, under section 1834(u)(7)(D) of the Act, the temporary transitional payment is set equal to 4 hours of infusion in a physician's office even though the nurse may be in the patient's home for a much shorter timeframe. In other words, payment is made only for the day on which the administration of the infusion drug occurs even if professional services were furnished on a different day. Therefore, we propose to define in regulation that payment for an infusion drug