DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 484, 486, and 488

[CMS–1689–P]

RIN 0938–AT29

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the home health prospective payment system (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor, effective for home health episodes of care ending on or after January 1, 2019. It also proposes updates to the HH PPS case-mix weights for calendar year (CY) 2019 using the most current, complete data available at the time of rulemaking; discusses our efforts to monitor the potential impacts of the rebasing adjustments that were implemented in CYs 2014 through 2017; proposes a rebasing of the HH market basket (which includes a decrease in the labor-related share); proposes the methodology used to determine rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the Bipartisan Budget Act of 2018 hereinafter referred to as the ''BBA of 2018''; proposes regulations text changes regarding certifying and recertifying patient eligibility for Medicare home health services; and proposes to define ''remote patient monitoring'' and recognize the cost associated as an allowable administrative cost. Additionally, it proposes case-mix methodology refinements to be implemented for home health services beginning on or after January 1, 2020, including a change in the unit of payment from 60-day episodes of care to 30-day periods of care, as required by section 51001 of the BBA of 2018; includes information on the implementation of temporary transitional payments for home infusion therapy services for CYs 2019 and 2020, as required by section 50401 of the BBA of 2018; solicits comments regarding payment for home infusion therapy services for CY 2021 and subsequent years; proposes health and safety standards for home infusion therapy; and proposes an accreditation and oversight process for home infusion therapy suppliers. This rule proposes changes to the Home Health Value-Based Purchasing (HHVBP) Model to remove two OASIS-based measures, replace three OASIS-based measures with two new proposed composite measures, rescore the maximum number of improvement points, and reweight the measures in the applicable measures set. Also, the Home Health Quality Reporting Program provisions include a discussion of the Meaningful Measures Initiative and propose the removal of seven measures to further the priorities of this initiative. In addition, the HH QRP offers a discussion on social risk factors and an update on implementation efforts for certain provisions of the IMPACT Act. This proposed rule clarifies the regulatory text to note that not all OASIS data is required for the HH QRP. Finally, it would require that accrediting organization surveyors take CMS-provided training.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1689–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1689–P, P.O. Box 8013, Baltimore, MD 21244–8013. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1689–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to: *HomehealthPolicy@cms.hhs.gov.*

For general information about home infusion payment, send your inquiry via email to: *HomeInfusionPolicy@cms.hhs.gov.*

For information about the Home Health Value-Based Purchasing (HHVBP) Model, send your inquiry via email to: *HHVBPquestions@cms.hhs.gov.*

For information about the Home Health Quality Reporting Program (HH QRP) contact: Joan Proctor, (410) 786–0949.

For information about home infusion therapy health and safety standards, contact: Sonia Swancy, (410) 786–8445 or CAPT Jacqueline Leach, (410) 786–4282.

For information about health infusion therapy accreditation and oversight, contact: Caroline Gallaher (410) 786–8705.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

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I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This proposed rule would update the payment rates for home health agencies (HHAs) for calendar year (CY) 2019, as required under section 1895(b) of the Social Security Act (the Act). This proposed rule would also update the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for CY 2019. For home health services beginning on or after January 1, 2020, this rule proposes case-mix methodology refinements, which eliminate the use of therapy thresholds for case-mix adjustment purposes; and proposes to change the unit of payment from a 60-day episode of care to a 30-day period of care, as mandated by section 51001 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) (hereinafter referred to as the ''BBA of 2018''). This proposed rule also: Proposes the methodology used to determine rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the BBA of 2018; proposes regulations text changes regarding certifying and recertifying patient eligibility for Medicare home health services under sections 1814(a) and 1835(a) of the Act; and proposes to define ''remote patient monitoring'' under the Medicare home health benefit and to include the costs of such monitoring as an allowable administrative cost. Lastly, this rule proposes changes to the Home Health Value Based Purchasing (HHVBP) Model under the authority of section 1115A of the Act, and the Home Health Quality Reporting Program (HH QRP) requirements under the authority of section 1895(b)(3)(B)(v) of the Act.

2. Home Infusion Therapy Services

This proposed rule would establish a transitional payment for home infusion therapy services for CYs 2019 and 2020, as required by section 50401 of the BBA of 2018. In addition, this rule proposes health and safety standards for home infusion therapy, proposes an accreditation and oversight process for qualified home infusion therapy suppliers, and solicits comments regarding payment for the home infusion therapy services benefit for CY 2021 and subsequent years, as required by section 5012 of the 21st Century Cures Act (Pub. L. 114–255).

3. Safety Standards for Home Infusion Therapy Services

This proposed rule would establish health and safety standards for qualified home infusion therapy suppliers as required by Section 5012 of the 21st Century Cures Act. These proposed standards would establish a foundation for ensuring patient safety and quality care by establishing requirements for the plan of care to be initiated and updated by a physician; 7-day-a-week, 24-hour-a-day access to services and remote monitoring; and patient education and training regarding their home infusion therapy care.

B. Summary of the Major Provisions

1. Home Health Prospective Payment System (HH PPS)

Section III.A. of this rule discusses our efforts to monitor for potential impacts due to the rebasing adjustments implemented in CY 2014 through CY 2017, as mandated by section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted March 23, 2010) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010), collectively referred to as the ''Affordable Care Act''. In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with the most current and complete data available at the time of rulemaking. In section III.B of this rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget-neutral manner. In section III.C., we propose to rebase the home health market basket and update the payment rates under the HH PPS by the home health payment update percentage of 2.1 percent (using the proposed 2016-based Home Health Agency (HHA) market basket update of 2.8 percent, minus 0.7 percentage point for multifactor productivity) as required by section 1895(b)(3)(B)(vi)(I) of the Act. Also in section III.C. of this proposed rule, we propose to decrease the labor-related share from 78.5 to 76.1 percent of total costs on account of the rebasing of the home health market basket. Lastly, in

section III.C. of this rule, we propose to update the CY 2019 home health wage index using FY 2015 hospital cost report data. In section III.D. of this proposed rule, we are proposing a new methodology for applying rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the BBA of 2018. In section III.E. of this rule, we are proposing to reduce the fixed-dollar loss ratio from 0.55 to 0.51 for CY 2019 in order to increase outlier payments as a percentage of total payments so that this percentage is closer to, but no more than, 2.5 percent.

In the CY 2018 HH PPS proposed rule, CMS proposed an alternative case-mix model, called the Home Health Groupings Model (HHGM). Ultimately the HHGM, including a proposed change in the unit of payment from 60 days to 30 days, was not finalized in the CY 2018 HH PPS final rule in order to allow CMS additional time to consider public comments for potential refinements to the model and other alternative case-mix models (82 FR 51676). In section III.F. of this proposed rule, we are again proposing to implement case-mix methodology refinements and a change in the unit of payment from a 60-day episode of care to a 30-day period of care; however, these changes would be effective January 1, 2020 and would be implemented in a budget neutral manner, as required by section 51001 of the BBA of 2018. Since the proposed case-mix methodology refinements represent a more patient-driven approach to payment we are renaming the proposed case-mix adjustment methodology refinements, formerly known as the Home Health Groupings Model or ''HHGM'', as the ''Patient-Driven Groupings Model'' or PDGM. The proposed PDGM relies more heavily on clinical characteristics and other patient information to place patients into meaningful payment categories and eliminates the use of therapy service thresholds, as required by section 51001(a)(3) of the BBA of 2018, that are currently used to case-mix adjust payments under the HH PPS. There is also a proposal regarding how CMS would determine whether 30-day periods of care are subject to a Low-Utilization Payment Adjustment (LUPA). The LUPA add-on policy, the partial episode payment adjustment policy, and the methodology used to calculate payments for high-cost outliers would remain unchanged except for occurring on a 30-day basis rather than a 60-day basis.

In section III.G. of this proposed rule, we are proposing regulation text changes at 42 CFR 424.22(b)(2) to eliminate the requirement that the certifying physician must estimate how much longer skilled services will be needed as part of the recertification statement. In addition, in section III.G of this rule, consistent with section 51002 of the BBA of 2018, we are proposing to align the regulations text at 42 CFR 424.22(c) with current subregulatory guidance to allow medical record documentation from the HHA to be used to support the basis for certification and/or recertification of home health eligibility, if certain requirements are met.

In section III.H. of this proposed rule, 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. Additionally in this section of the rule, we propose changes to the regulations at 42 CFR 409.46 to include costs of remote patient monitoring as allowable administrative costs.

2. Home Health Value Based Purchasing

In section IV of this proposed rule, we are proposing changes to the Home Health Value Based Purchasing (HHVBP) Model implemented January 1, 2016. We are proposing, beginning with performance year (PY) 4, to: Remove two Outcome and Assessment Information Set (OASIS) based measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, from the set of applicable measures; replace three OASIS-based measures (Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing) with two proposed composite measures on total normalized composite change in self-care and mobility; change how we calculate the Total Performance Scores by changing the weighting methodology for the OASIS-based, claims-based, and HHCAHPS measures; and change the scoring methodology by reducing the maximum amount of improvement points an HHA could earn, from 10 points to 9 points. While we are not making a specific proposal at this time, we are also providing an update on the progress towards developing public reporting of performance under the HHVBP Model and seeking comment on what information should be made publicly available.

3. Home Health Quality Reporting Program

In section V. of this proposed rule, we are proposing to update our policy for removing previously adopted Home Health (HH) Quality Reporting Program (QRP) measures and to adopt eight measure removal factors to align with other QRPs, to remove seven measures beginning with the CY 2021 HH QRP, and to update our regulations to clarify that not all OASIS data is required for the HH QRP. We are also providing an update on the implementation of certain provisions of the IMPACT Act, and a discussion of accounting for social risk factors in the HH QRP. Finally, we are proposing to increase the number of years of data used to calculate the Medicare Spending per Beneficiary measure for purposes of display from 1 year to 2 years.

4. Home Infusion Therapy

In section VI.A. of this proposed rule, we discuss general background of home infusion therapy services and how that will relate to the implementation of the new home infusion benefit. In section VI.B. of this proposed rule, we are proposing to add a new subpart I under the regulations at 42 CFR part 486 to incorporate health and safety requirements for home infusion therapy suppliers. The proposed regulations would provide a framework for CMS to approve home infusion therapy accreditation organizations. Proposed subpart I would include General Provisions (Scope and Purpose, and Definitions) and Standards for Home Infusion Therapy (Plan of Care and Required Services). In section VI.C. of this proposed rule, we include 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, and solicits comments on the proposed regulatory definition of ''Infusion Drug Administration Calendar Day''. Also in section VI.C. of this proposed rule, we solicit 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.

In section VI.D. of this proposed rule, we discuss the requirements set forth in section 1861(iii)(3)(D)(III) of the Act, which mandates that suppliers of home infusion therapy receive accreditation from a CMS-approved Accrediting Organization (AO) in order to receive Medicare payment. The Secretary must designate AOs to accredit suppliers furnishing Home Infusion therapy (HIT) not later than January 1, 2021. Qualified

HIT suppliers are required to receive accreditation before receiving Medicare payment for services provided to Medicare beneficiaries.

At this time, no regulations exist to address the following elements of CMS' approval and oversight of the AOs that accredit suppliers of Home Infusion Therapy: (1) The required components to be included in a Home Infusion Therapy AO's initial or renewal accreditation program application; (2) regulations related to CMS' review and approval of the Home Infusion Therapy AOs application for approval of its accreditation program; and (3) the ongoing monitoring and oversight of CMS-approved Home Infusion Therapy AOs. Therefore in this rule, we propose to establish a set of regulations that will govern the CMS approval and oversight process for all HIT AOs.

We also propose to modify the regulations for oversight for AOs that accredit any Medicare-certified providers and suppliers at 42 CFR 488.5 by adding a requirement that the AOs must include a statement with their application acknowledging that all AO surveyors are required to complete the relevant program specific CMS online trainings initially, and thereafter, consistent with requirements established by CMS for state and federal surveyors. We would also add another requirement at § 488.5 that would require the AOs for Medicare certified providers and suppliers to provide a written statement with their application stating that if a fully accredited and facility deemed to be in good-standing provides written notification that they wish to voluntarily withdraw from the AO's CMS-approved accreditation program, the AO must continue the facility's current accreditation until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

C. Summary of Costs, Transfers, and Benefits

TABLE 1—SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision description	Costs and cost savings	Transfers	Benefits
CY 2019 HH PPS Payment Rate Update.	.....	The overall economic impact of the HH PPS payment rate update is an estimated $400 million (2.1 percent) in increased payments to HHAs in CY 2019.	To ensure home health payments are consistent with statutory payment authority for CY 2019.
CY 2019 Temporary Transitional Payments for Home Infusion Therapy Services.	.....	The overall economic impact of the temporary transitional payment for home infusion therapy services is an estimated $60 million in increased payments to home infusion therapy suppliers in CY 2019.	To ensure temporary transitional payments for home infusion therapy are consistent with statutory authority for CY 2019.
CY 2019 HHVBP Model	.....	The overall economic impact of the HHVBP Model provision for CY 2018 through 2022 is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry (none of which is attributable to the changes proposed in this proposed rule). As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.	
CY 2020 OASIS Changes	The overall economic impact of the HH QRP and the case-mix adjustment methodology changes is annual savings to HHAs of an estimated $60 million.	.....	A reduction in burden to HHAs of approximately 73 hours annually for a savings of approximately $5,150 annually per HHA.
CY 2020 Case-Mix Adjustment Methodology Changes, Including a Change in the Unit of Service from 60 to 30 days.	.....	The overall economic impact of the proposed case-mix adjustment methodology changes, including a change in the unit of service from 60 to 30 days, for CY 2020 results in no estimated dollar impact to HHAs, as section 51001(a) of the BBA of 2018 requires such change to be implemented in a budget-neutral manner.	To ensure home health payments are consistent with statutory payment authority for CY 2020.

TABLE 1—SUMMARY OF COSTS, TRANSFERS, AND BENEFITS—Continued

Provision description	Costs and cost savings	Transfers	Benefits
Accreditation for Home Infusion Therapy suppliers.	.....	The cost related to an AO obtaining CMS approval of a home infusion therapy accreditation program is estimated to be $8,014.50 per each AO, for AOs that have previously submitted an accreditation application to CMS. The cost across the potential 6 home infusion therapy AOs would be $48,087. The cost related to each home infusion therapy AO for obtaining CMS approval of a home infusion therapy accreditation program is estimated to be $12,453 per each AO, for AOs that *have not* previously submitted an accreditation application to CMS. The cost across the potential 6 home infusion therapy AOs would be $74,718. We further estimate that each home infusion therapy AO would incur an estimated cost burden in the amount of $23,258 for compliance with the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050 (including the filing of an application). The cost across the 6 potential home infusion therapy AOs would be $139,548.	

D. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for us. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[1] This initiative is one component of our agency-wide Patients Over Paperwork Initiative [2] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and will reduce costs including, the collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);
- Provide significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 2:

TABLE 2—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections. Preventable Healthcare Harm.

[1] Meaningful Measures web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[2] See Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017 *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.*

TABLE 2—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS—Continued

Quality priority	Meaningful measure area
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals. End of Life Care according to Preferences. Patient's Experience of Care. Patient Reported Functional Outcomes.
Promote Effective Communication and Coordination of Care	Medication Management. Admissions and Readmissions to Hospitals. Transfer of Health Information and Interoperability.
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care. Management of Chronic Conditions. Prevention, Treatment, and Management of Mental Health. Prevention and Treatment of Opioid and Substance Use Disorders. Risk Adjusted Mortality.
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care. Community Engagement.
Make Care Affordable	Appropriate Use of Healthcare. Patient-focused Episode of Care. Risk Adjusted Total Cost of Care.

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers and promoting operational efficiencies.

II. Background

A. Statutory Background

1. Home Health Prospective Payment System

a. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare home health services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered home health services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled ''Prospective Payment For Home Health Services.'' Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. Section 1895(b)(2) of the Act requires that, in defining a prospective payment amount, the Secretary will consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount that includes all costs for HH services covered and paid for on a reasonable cost basis, and that such amounts be initially based on the most recent audited cost report data available to the Secretary (as of the effective date of the 2000 final rule), and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act requires the standard prospective payment amounts be annually updated by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Affordable Care Act revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for home health services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of home health services under Part A and Part B. For a complete and full

description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and linking the quality data submission to the annual applicable payment percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) amended section 421(a) of the MMA to extend the 3 percent rural add-on payment for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) through January 1, 2018. In addition, section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that CY 2018 home health payments be updated by a 1 percent market basket increase. This year, section 50208(a)(1) of the BBA of 2018 again extended the rural add-on through the end of 2018. In addition, this section of the BBA of 2018 made some important changes to the rural add-on for CYs 2019 through 2022, to be discussed below.

b. Current System for Payment of Home Health Services

Generally, Medicare currently makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 60-day episode rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is not part of the national, standardized 60-day episode rate, but is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor. Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode. Therapy service use is measured by the number of therapy visits provided during the episode and can be categorized into nine visit level categories (or thresholds): 0 to 5; 6; 7 to 9; 10; 11 to 13; 14 to 15; 16 to 17; 18 to 19; and 20 or more visits.

For episodes with four or fewer visits, Medicare pays national per-visit rates based on the discipline(s) providing the services. An episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low-utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

c. Updates to the Home Health Prospective Payment System

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the HH PPS for CY 2008. The CY 2008 HH PPS final rule included an analysis performed on CY 2005 home health claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. Case-mix represents the variations in conditions of the patient population served by the HHAs. Subsequently, a more detailed analysis was performed on the 2005 case-mix data to evaluate if any portion of the 12.78 percent increase was associated with a change in the actual clinical condition of home health patients. We identified 8.03 percent of the total case-mix change as real, and therefore, decreased the 12.78 percent of total case-mix change by 8.03 percent to get a final nominal case-mix increase measure of 11.75 percent (0.1278 * (1 − 0.0803) = 0.1175).

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

In the CY 2012 HH PPS final rule (76 FR 68526), we updated the 60-day national episode rates and the national per-visit rates. In addition, as discussed in the CY 2012 HH PPS final rule (76 FR 68528), our analysis indicated that there was a 22.59 percent increase in overall case-mix from 2000 to 2009 and that only 15.76 percent of that overall observed case-mix percentage increase was due to real case-mix change. As a result of our analysis, we identified a 19.03 percent nominal increase in case-mix. At that time, to fully account for the 19.03 percent nominal case-mix growth identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013.

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented the 1.32 percent reduction to the payment rates for CY 2013 finalized the previous year, to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from

2000 to 2010 (0.2390 * (1 − 0.1597) = 0.2008). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. Although we considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, we finalized the 1.32 percent payment reduction to the national, standardized 60-day episode rates in the CY 2012 HH PPS final rule (76 FR 68532). Section 3131(a) of the Affordable Care Act added new section 1895(b)(3)(A)(iii) to the Act, which required that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we were required to phase in any adjustment over a 4-year period in equal increments, not to exceed 3.5 percent of the payment amount (or amounts) as of the date of enactment of the Affordable Care Act in 2010, and fully implement the rebasing adjustments by CY 2017. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of $80.95 per year, increases to the national per-visit payment rates per year, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper. In the CY 2015 HH PPS final rule (79 FR 66032), we implemented the second year of the 4-year phase-in of the rebasing adjustments to the HH PPS payment rates and made changes to the HH PPS case-mix weights. In addition, we simplified the face-to-face encounter regulatory requirements and the therapy reassessment timeframes.

In the CY 2016 HH PPS final rule (80 FR 68624), we implemented the third year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as discussed previously). In the CY 2016 HH PPS final rule, we also recalibrated the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget-neutral manner and finalized reductions to the national, standardized 60-day episode payment rate in CY 2016, CY 2017, and CY 2018 of 0.97 percent in each year to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. Finally, section 421(a) of the MMA, as amended by section 210 of the MACRA, extended the payment increase of 3 percent for HH services provided in rural areas (as defined in section 1886(d)(2)(D) of the Act) to episodes or visits ending before January 1, 2018.

In the CY 2017 HH PPS final rule (81 FR 76702), we implemented the last year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined previously). We also finalized changes to the methodology used to calculate outlier payments under the authority of section 1895(b)(5) of the Act. Lastly, in accordance with section 1834(s) of the Act, as added by section 504(a) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, enacted December 18, 2015), we implemented changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act.

2. Home Infusion Therapy

Section 5012 of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255), which amended sections 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy benefit. The Medicare home infusion therapy benefit covers the professional services including nursing services furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries. Section 50401 of the BBA of 2018 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, 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 of the 21st Century Cures Act.

Home infusion therapy is a treatment option for patients with a wide range of acute and chronic conditions, ranging from bacterial infections to more complex conditions such as late-stage heart failure and immune deficiencies. Home infusion therapy affords a patient independence and better quality of life, because it is provided in the comfort of the patient's home at a time that best fits his or her needs. This is significant, because generally patients can return to their daily activities after they receive their infusion treatments and, in many cases, they can continue their activities while receiving their treatments. In addition, home infusion therapy can provide improved safety and better outcomes. The home has been shown to be a safe setting for patients to receive infusion therapy.[3] Additionally, patients receiving treatment outside of the hospital setting may be at lower risk of hospital-acquired infections, which can be more difficult to treat because of multi-drug resistance than those that are community-acquired. This is particularly important for vulnerable patients such as those who are immunocompromised, as hospital-acquired infections are increasingly caused by antibiotic-resistant pathogens.

Infusion therapy typically means that a drug is administered intravenously, but the term may also refer to situations where drugs are provided through other non-oral routes, such as intramuscular injections and epidural routes (into the membranes surrounding the spinal cord). Diseases that may require infusion therapy include infections that are unresponsive to oral antibiotics, cancer and cancer-related pain,

[3] Bhole, M.V., Burton, J., & Chapel, H.M., (2008). Self-infusion programs for immunoglobulin replacement at home: Feasibility, safety and efficacy. Immunology and Allergy Clinics of North America, 28(4), 821–832. doi:10.1016/j.iac.2008.06.005.

Souayah, N., Hasan, A., Khan, H., et al. (2011). The safety profile of home infusion of intravenous immunoglobulin in patients with neuroimmunologic disorders. Journal of Clinical Neuromuscular Disease, 12(supp 4), S1–10. doi: 10.1097/CND.0b013e3182212589.

dehydration, and gastrointestinal diseases or disorders which prevent normal functioning of the gastrointestinal system. Other conditions treated with specialty infusion therapies may include some forms of cancers, congestive heart failure, Crohn's Disease, hemophilia, hepatitis, immune deficiencies, multiple sclerosis and rheumatoid arthritis. Infusion therapy originates with a prescription order from a physician or another qualified prescriber who is overseeing the care of the patient. The prescription order is sent to a home infusion therapy supplier, which is a state-licensed pharmacy, physician, or other provider of services or suppliers licensed by the state.

A 2010 Government Accountability Office (GAO) report (10–426) found that most health insurers rely on credentialing, accreditation, or both to help ensure that plan members receive quality home infusion services from their network suppliers.[4] Home infusion AOs conduct on-site surveys to evaluate all components of the service, including medical equipment, nursing, and pharmacy. Accreditation standards can include such requirements as the CMS Conditions of Participation for home health services, other Federal government regulations, and industry best practices. All of the accreditation standards evaluate a range of provider competencies, such as having a complete plan of care, response to adverse events, and implementation of a quality improvement plan.

Sections 1861(iii)(3)(D)(III) and 1834(u)(5) of the Act, as amended by section 5012 of the Cures Act requires that, in order to participate in Medicare, home infusion therapy suppliers must select a CMS-approved AO and undergo an accreditation review process to demonstrate that the home infusion therapy program meets the accreditation organization's standards. Section 1861(iii) of the Act, as amended by section 5012 of the Cures Act, sets forth standards in three areas: (1) Ensuring 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, (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided, and (3) having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home.

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance interoperability across settings of care, including post-acute care.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (IMPACT Act) requires assessment data to be standardized and interoperable to allow for exchange of the data among post-acute providers and other providers. To further interoperability in post-acute care, CMS is developing a Data Element Library to serve as a publically available centralized, authoritative resource for standardized data elements and their associated mappings to health IT standards. These interoperable data elements can reduce provider burden by allowing the use and reuse of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision making. Once available, standards in the Data Element Library can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA).

The 2018 Interoperability Standards Advisory (ISA) is available at: *https://www.healthit.gov/standards-advisory*.

Most recently, the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. Specifically, Congress directed ONC to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' This framework (*https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement*) outlines a common set of principles for trusted exchange and minimum terms and conditions for trusted exchange in order to enable interoperability across disparate health information networks. In another important provision, Congress defined ''information blocking'' as practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, and established new authority for HHS to discourage these practices. We invite providers to learn more about these important developments and how they are likely to affect HHAs.

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

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

1. Analysis of FY 2016 HHA Cost Report Data

As part of our efforts in monitoring the potential impacts of the rebasing adjustments finalized in the CY 2014 HH PPS final rule (78 FR 72293), we continue to update our analysis of home health cost report and claims data. Previous years' cost report and claims data analyses and results can be found in the CY 2018 HH PPS proposed rule (82 FR 35277–35278). For this proposed rule, we analyzed the 2016 HHA cost report data (the most recent, complete data available at the time of this proposed rule) and 2016 HHA claims data to obtain the average number of visits per episode that match to the year of cost report data analyzed. To determine the 2016 average cost per visit per discipline, we applied the same trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) and weighted the costs per visit from the 2016 cost reports by size, facility type, and urban/rural location so the costs per visit were nationally representative according to 2016 claims data. The 2016 average number of visits was taken from 2016 claims data. We estimated the cost of a 60-day episode in CY 2016 to be $2,538.54 using 2016 cost report data (Table 2). However, the national, standardized 60-day episode payment amount in CY 2016 was $2,965.12. The difference between the 60-day episode payment rate and average cost per episode of care for CY 2016 was 16.8 percent.

[4] *https://www.gao.gov/assets/310/305261.pdf.*

TABLE 2—2016 ESTIMATED COST PER EPISODE

Discipline	2016 Average costs per visit	2016 Average NRS costs per visit	2016 Average cost + NRS per visit	2016 Average number of visits	2016 60-Day episode costs
Skilled Nursing	$132.83	$3.41	$136.24	8.81	$1,200.27
Physical Therapy	156.04	3.41	159.45	5.58	889.73
Occupational Therapy	153.53	3.41	156.94	1.56	244.83
Speech Pathology	170.06	3.41	173.47	0.32	55.51
Medical Social Services	219.73	3.41	223.14	0.14	31.24
Home Health Aides	60.50	3.41	63.91	1.83	116.96
Total	.....	.....	.....	18.24	2,538.54

Source: Medicare cost reports pulled in March 2018 and Medicare claims data from 2015 and 2016 for episodes (excluding low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes), linked to OASIS assessments for episodes ending in CY 2016.

2. Analysis of CY 2017 HHA Claims Data

In the CY 2014 HH PPS final rule (78 FR 72256), some commenters expressed concern that the rebasing of the HH PPS payment rates would result in HHA closures and would therefore diminish access to home health services. In addition to examining more recent cost report data, for this proposed rule we examined home health claims data from all four years during which rebasing adjustments were made (CY 2014, CY 2015, CY 2016, and CY 2017), the first calendar year of the HH PPS (CY 2001), and claims data for the year prior to the implementation of the rebasing adjustments (CY 2013). Preliminary analysis of CY 2017 home health claims data indicates that the number of episodes decreased by 5.3 percent and the number of home health users that received at least one episode of care decreased by 3.2 percent from 2016 to 2017, while the number of FFS beneficiaries decreased 0.1 percent from 2016 to 2017. Between 2013 and 2014 there appears to be a net decrease in the number of HHAs billing Medicare for home health services of 1.6 percent, a continued decrease of 1.7 percent from 2014 to 2015, a decrease of 3.4 percent from 2015 to 2016, and a decrease of 4.4 percent from 2016 to 2017. We note that in CY 2016 there were 2.9 HHAs per 10,000 FFS beneficiaries and 2.8 HHAs per 10,000 FFS beneficiaries in CY 2017, which remains markedly higher than the 1.9 HHAs per 10,000 FFS beneficiaries close to the inception of the HH PPS in 2001 (the HH PPS was implemented on October 1, 2000). The number of home health users, as a percentage of FFS beneficiaries, has decreased from 9.0 percent in 2013 to 8.4 percent in 2017.

TABLE 3—HOME HEALTH STATISTICS, CY 2001 AND CY 2013 THROUGH CY 2017

	2001	2013	2014	2015	2016	2017
Number of episodes	3,896,502	6,708,923	6,451,283	6,340,932	6,294,234	5,963,780
Beneficiaries receiving at least 1 episode (Home Health Users)	2,412,318	3,484,579	3,381,635	3,365,512	3,350,174	3,242,346
Part A and/or B FFS beneficiaries	34,899,167	38,505,609	38,506,534	38,506,534	38,555,150	38,509,031
Episodes per Part A and/or B FFS beneficiaries	0.11	0.17	0.17	0.17	0.16	0.15
Home health users as a percentage of Part A and/or B FFS beneficiaries	6.9%	9.0%	8.8%	8.8%	8.7%	8.4%
HHAs providing at least 1 episode	6,511	11,889	11,693	11,381	11,102	10,612
HHAs per 10,000 Part A and/or B FFS beneficiaries	1.9	3.1	3.0	3.0	2.9	2.8

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on May 14, 2014 and August 19, 2014 for CY 2013 data; accessed on May 7, 2015 for CY 2001 and CY 2014 data; accessed on April 7, 2016 for CY 2015 data; accessed on March 20, 2017 for CY 2016 data; accessed on March 8, 2018 for CY 2017 data; and Medicare enrollment information obtained from the CCW Master Beneficiary Summary File. Beneficiaries are the total number of beneficiaries in a given year with at least 1 month of Part A and/or Part B Fee-for-Service coverage without having any months of Medicare Advantage coverage.

Note(s): These results include all episode types (Normal, PEP, Outlier, LUPA) and also include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim—first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

In addition to examining home health claims data from all four years of the implementation of rebasing adjustments required by the Affordable Care Act, we examined trends in home health utilization for all years starting in CY 2001 and up through CY 2017. Figure 1, displays the average number of visits per 60-day episode of care and the average payment per visit. While the average payment per visit has steadily increased from approximately $116 in CY 2001 to $170 for CY 2017, the average total number of visits per 60-day episode of care has declined, most notably between CY 2009 (21.7 visits per episode) and CY 2010 (19.8 visits per episode), which was the first year that the 10 percent agency-level cap on HHA outlier payments was implemented. The average of total visits per episode has steadily decreased from 21.7 in 2009 to 17.9 in 2017.

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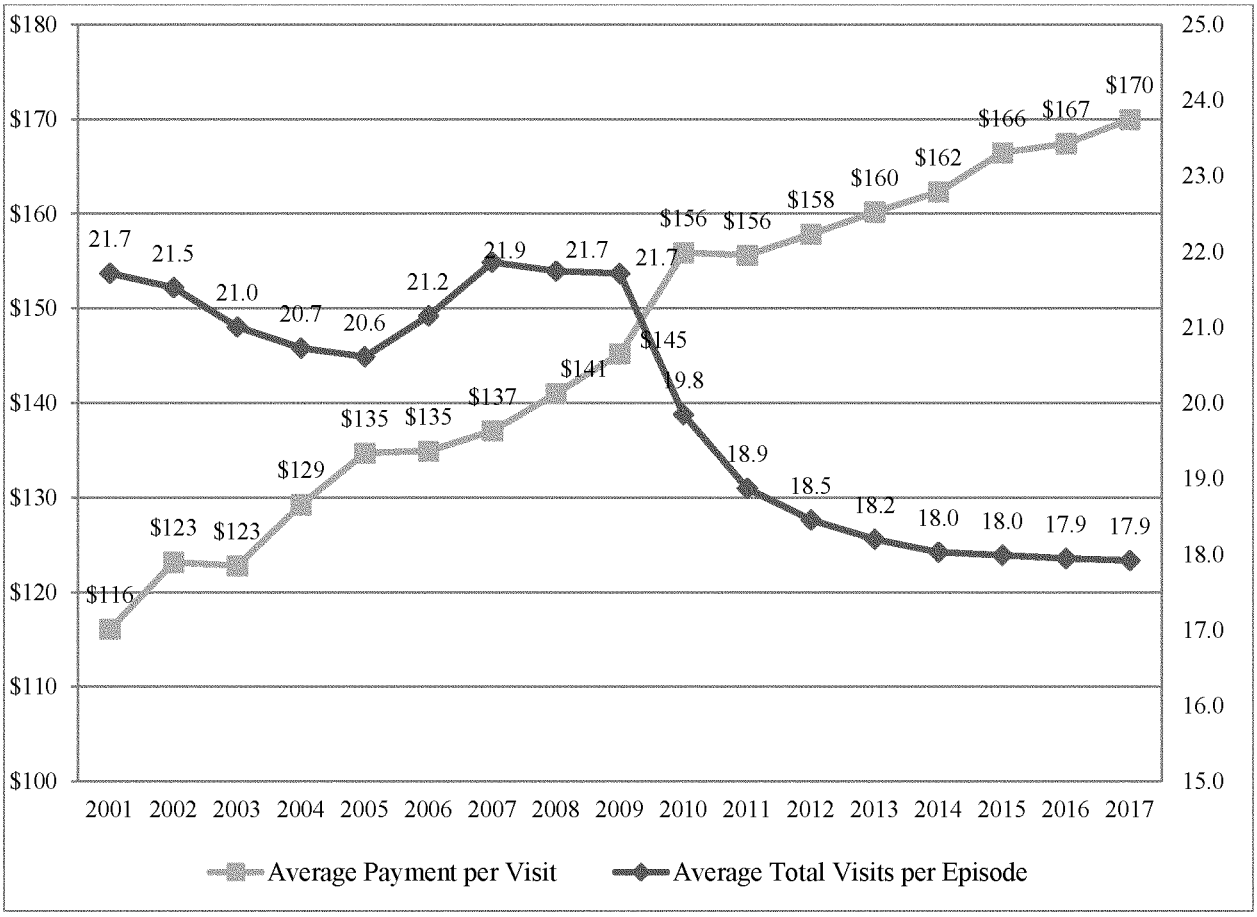
FIGURE 1: AVERAGE TOTAL NUMBER OF VISITS AND AVERAGE PAYMENT PER VISIT FOR A MEDICARE HOME HEALTH 60-DAY EPISODE OF CARE, CY 2001 THROUGH CY 2017



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) – 2001 to 2014 data accessed on May 21, 2014, CY 2015 data accessed on April 25, 2016, CY 2016 data accessed on March 16, 2017, and CY 2017 data accessed on March 6, 2018.

Note(s): These results exclude LUPA episodes, but include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

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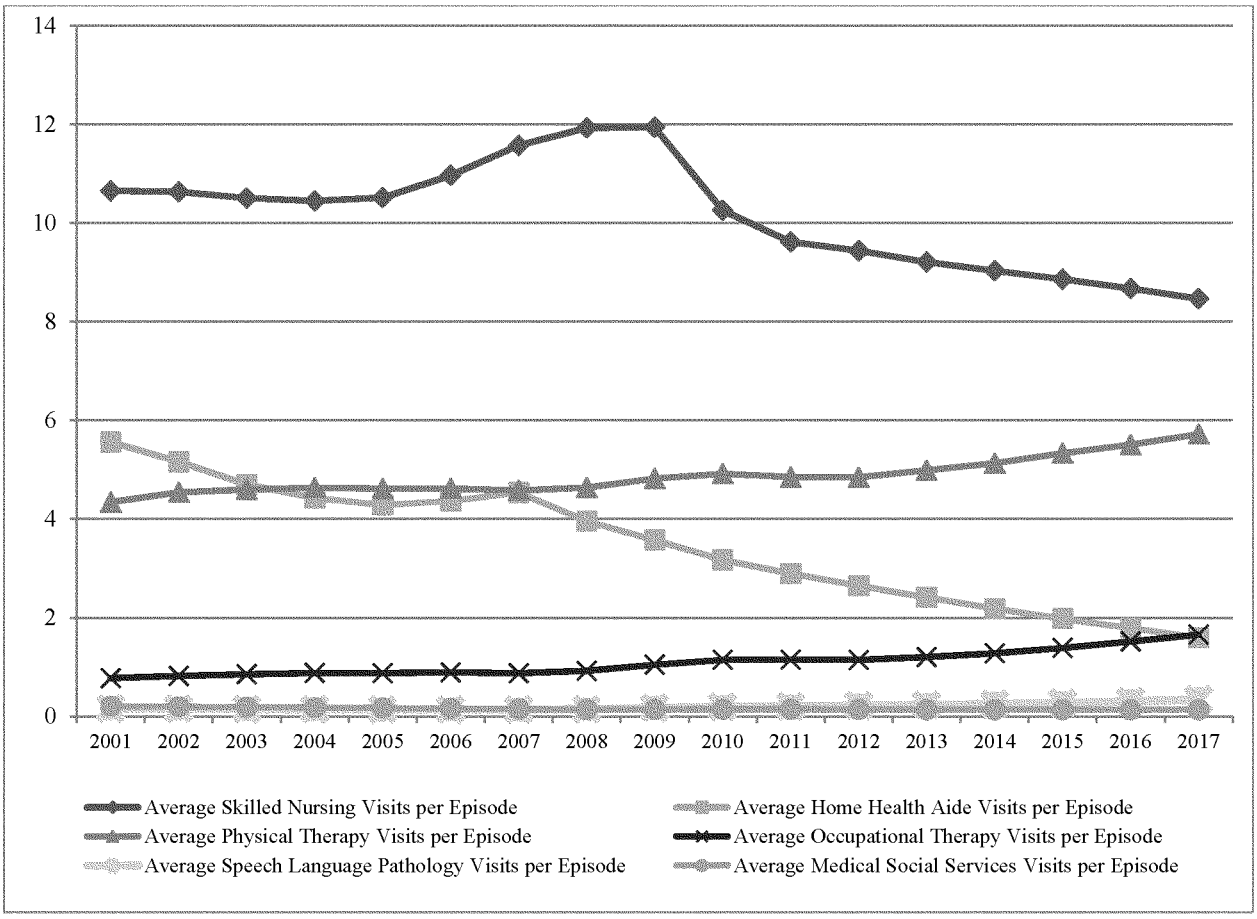
Figure 2 displays the average number of visits by discipline type for a 60-day episode of care and shows that while the number of therapy visits per 60-day episode of care has increased steadily, the number of skilled nursing and home health aide visits have decreased between CY 2009 and CY 2017. The results of the Report to Congress, ''Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations'', required by section 3131(d) of the Affordable Care Act, suggests that the current home health payment system may discourage HHAs from serving patients with clinically complex and/or poorly controlled chronic conditions who do not qualify for therapy but require a large number of skilled nursing visits.[5] The home health study results seem to be consistent with the recent trend in the decreased number of visits per episode of care driven by decreases in skilled nursing and home health aide services evident in Figures 1 and 2.

[5] Report to Congress Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations (2014). Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf.*

FIGURE 2: AVERAGE NUMBER OF VISITS BY DISCIPLINE TYPE FOR A MEDICARE HOME HEALTH 60-DAY EPISODE OF CARE, CY 2001 THROUGH CY 2017



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - – 2001 to 2014 data accessed on May 21, 2014, CY 2015 data accessed on April 25, 2016, CY 2016 data accessed on March 16, 2017, and CY 2017 data accessed on March 6, 2018.

Note(s): These results exclude LUPA episodes, but include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

As part of our monitoring efforts, we also examined the trends in episode timing and service use over time. Specifically, we examined the percentage of early episodes with 0 to 19 therapy visits, late episodes with 0 to 19 therapy visits, and episodes with 20+ therapy visits from CY 2008 to CY 2017. In CY 2008, we implemented refinements to the HH PPS case-mix system. As part of those refinements, we added additional therapy thresholds and differentiated between early and late episodes for those episodes with less than 20+ therapy visits. Early episodes are defined as the 1st or 2nd episode in a sequence of adjacent covered episodes. Late episodes are defined as the 3rd and subsequent episodes in a sequence of adjacent covered episodes. Table 4 shows that the percentage of early and late episodes from CY 2008 to CY 2017 has remained relatively stable over time. There has been a decrease in the percentage of early episodes with 0 to 19 therapy visits from 65.9 percent in CY 2008 to 61.3 percent in CY 2017 and a slight increase in the percentage of late episodes with 0 to 19 therapy visits from 29.5 percent in CY 2008 to 31.2 percent in CY 2017. In 2015, the case-mix weights for the third and later episodes of care with 0 to 19 therapy visits decreased as a result of the CY 2015 recalibration of the case-mix weights. Despite the decreases in the case-mix weights for the later episodes, the percentage of late episodes with 0 to 19 therapy visits did not change substantially. However, episode timing is not a variable in the determination of the case-mix weights for those episodes with 20+ therapy visits and the percentage of episodes with 20+ therapy visits has increased from 4.6 percent in CY 2008 to 7.6 percent in CY 2017.

TABLE 4—HOME HEALTH EPISODES BY EPISODE TIMING, CY 2008 THROUGH CY 2017

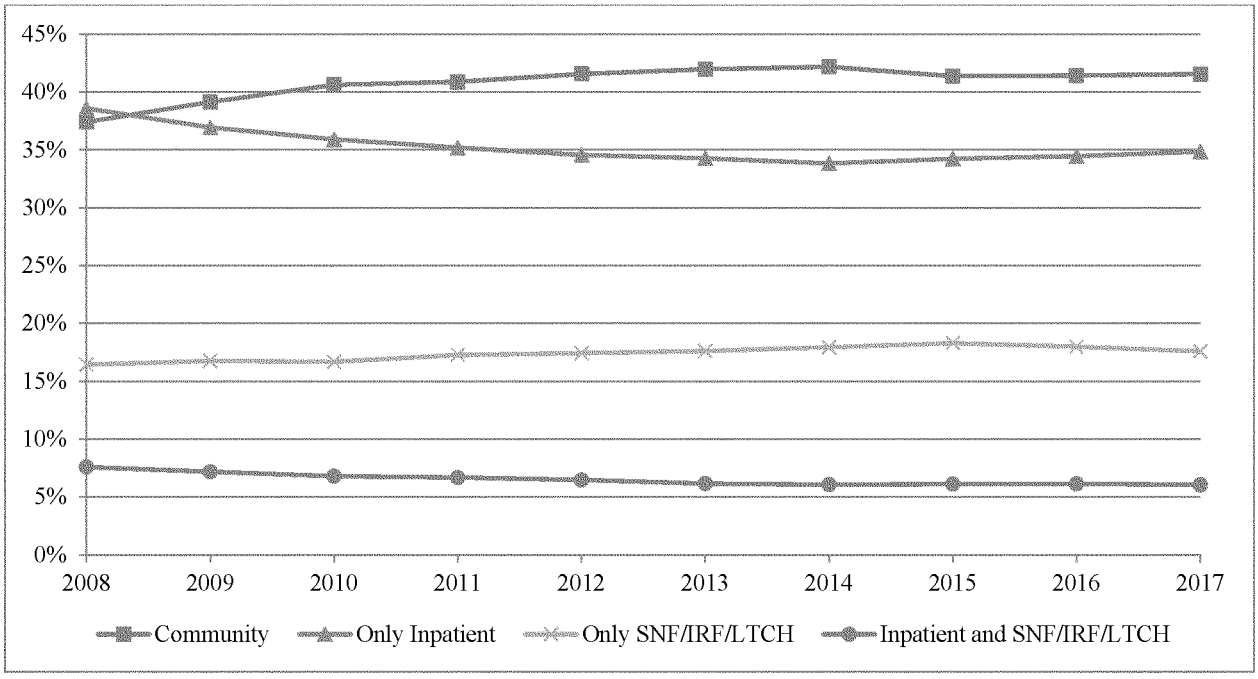
Year	All episodes	Number of early episodes (excluding episodes with 20+ visits)	% of early episodes (excluding episodes with 20+ visits)	Number of late episodes (excluding episodes with 20+ visits)	% of late episodes (excluding episodes with 20+ visits)	Number of episodes with 20+ visits	% of episodes with 20+ visits
2008	5,423,037	3,571,619	65.9	1,600,587	29.5	250,831	4.6
2009	6,530,200	3,701,652	56.7	2,456,308	37.6	372,240	5.7
2010	6,877,598	3,872,504	56.3	2,586,493	37.6	418,601	6.1
2011	6,857,885	3,912,982	57.1	2,564,859	37.4	380,044	5.5
2012	6,767,576	3,955,207	58.4	2,458,734	36.3	353,635	5.2
2013	6,733,146	4,023,486	59.8	2,347,420	34.9	362,240	5.4
2014	6,616,875	3,980,151	60.2	2,263,638	34.2	373,086	5.6
2015	6,644,922	4,008,279	60.3	2,205,052	33.2	431,591	6.5
2016	6,294,232	3,802,254	60.4	2,053,972	32.6	438,006	7.0
2017	5,963,778	3,655,636	61.3	1,857,840	31.2	450,302	7.6

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on March 6, 2018.
Note(s): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to ''0'' (''Non-payment/zero claims'') and ''2'' (''Interim—first claim'') are excluded.

We also examined trends in admission source for home health episodes over time. Specifically, we examined the admission source for the ''first or only'' episodes of care (first episodes in a sequence of adjacent episodes of care or the only episode of care) from CY 2008 through CY 2017 (Figure 3). The percentage of first or only episodes with an acute admission source, defined as episodes with an inpatient hospital stay within the 14 days prior to a home health episode, has decreased from 38.6 percent in CY 2008 to 34.8 percent in CY 2017. The percentage of first or only episodes with a post-acute admission source, defined as episodes which had a stay at a skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long term care hospital (LTCH) within 14 days prior to the home health episode, has slightly increased from 16.4 percent in CY 2008 to 17.6 percent in CY 2017. The percentage of first or only episodes with a community admission source, defined as episodes which did not have an acute or post-acute stay in the 14 days prior to the home health episode, increased from 37.4 percent in CY 2008 to 41.5 percent in CY 2017. Our findings on the trends in admission source show a similar pattern with MedPAC's as outlined in their 2015 Report to the Congress.[6] MedPAC concluded that there has been tremendous growth in the use of home health for patients residing in the community (that is, episodes not preceded by a prior hospitalization) and that these episodes have more than doubled since 2001. However, MedPAC examined admission source trends from 2002 up through 2013 and included first and subsequent episodes of care, whereas CMS analysis, as described above, included ''first or only'' episodes of care. Nonetheless, both analyses show a trend of increasing episodes of care without a preceding inpatient stay. MedPAC suggests there is significant potential for overuse, particularly since Medicare does not currently require any cost sharing for home health care.

[6] Medicare Payment Advisory Commission (MedPAC). ''Home Health Care Services.'' *Report to the Congress: Medicare Payment Policy.* Washington, DC, March 2015. P. 214. Accessed on 3/28/2017 at: *http://www.medpac.gov/docs/default-source/reports/chapter-9-home-health-care-services-march-2015-report-.pdf?sfvrsn=0.*

FIGURE 3: HOME HEALTH EPISODE TRENDS BY ADMISSION SOURCE (FIRST OR ONLY EPISODES), CY 2008 THROUGH CY 2017



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - Accessed on March 6, 2018.

Note(s): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded.

We will continue to monitor for potential impacts due to the rebasing adjustments required by section 3131(a) of the Affordable Care Act and other policy changes in the future. Independent effects of any one policy may be difficult to discern in years where multiple policy changes occur in any given year.

B. Proposed CY 2019 HH PPS Case-Mix Weights

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized a policy to annually recalibrate the HH PPS case-mix weights—adjusting the weights relative to one another—using the most current, complete data available. To recalibrate the HH PPS case-mix weights for CY 2018, we will use the same methodology finalized in the CY 2008 HH PPS final rule (72 FR 49762), the CY 2012 HH PPS final rule (76 FR 68526), and the CY 2015 HH PPS final rule (79 FR 66032). Annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns.

To generate the proposed CY 2019 HH PPS case-mix weights, we used CY 2017 home health claims data (as of March 2, 2018) with linked OASIS data. These data are the most current and complete data available at this time. We will use CY 2017 home health claims data (as of June 30, 2018 or later) with linked OASIS data to generate the CY 2019 HH PPS case-mix weights in the CY 2019 HH PPS final rule. The process we used to calculate the HH PPS case-mix weights are outlined below.

Step 1: Re-estimate the four-equation model to determine the clinical and functional points for an episode using wage-weighted minutes of care as our dependent variable for resource use. The wage-weighted minutes of care are determined using the CY 2016 Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the minutes per visit from the claim. The points for each of the variables for each leg of the model, updated with CY 2017 home health claims data, are shown in Table 5. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

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TABLE 5: CASE-MIX ADJUSTMENT VARIABLES AND SCORES

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
	CLINICAL DIMENSION				
1	Primary or Other Diagnosis = Blindness/Low Vision	.	.	.	.
2	Primary or Other Diagnosis = Blood disorders	.	2	.	.
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms	.	4	.	4
4	Primary Diagnosis = Diabetes	.	2	.	2
5	Other Diagnosis = Diabetes	.	.	.	.
6	Primary or Other Diagnosis = Dysphagia ***AND*** Primary or Other Diagnosis = Neuro 3 – Stroke	2	15	.	15
7	Primary or Other Diagnosis = Dysphagia ***AND*** M1030 (Therapy at home) = 3 (Enteral)	.	5	.	5
8	Primary or Other Diagnosis = Gastrointestinal disorders	.	1	.	2
9	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** M1630 (ostomy)= 1 or 2	.	5	.	.
10	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis, OR Neuro 2 - Peripheral neurological disorders, OR Neuro 3 - Stroke, OR Neuro 4 - Multiple Sclerosis	.	.	.	.
11	Primary or Other Diagnosis = Heart Disease OR Hypertension	2	3	.	2
12	Primary Diagnosis = Neuro 1 - Brain disorders and paralysis	2	7	4	7
13	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis ***AND*** M1840 (Toilet transfer) = 2 or more	.	2	.	.
14	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis ***OR*** Neuro 2 - Peripheral neurological disorders ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	3	5	2	3
15	Primary or Other Diagnosis = Neuro 3 - Stroke	3	6	2	.
16	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	.	3	.	.
17	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1860 (Ambulation) = 4 or more	.	.	.	.
18	Primary or Other Diagnosis = Neuro 4 - Multiple Sclerosis ***AND AT LEAST ONE OF THE FOLLOWING:*** M1830 (Bathing) = 2 or more ***OR*** M1840 (Toilet transfer) = 2 or more ***OR*** M1850 (Transferring) = 2 or more	2	7	3	7

	OR M1860 (Ambulation) = 4 or more				
19	Primary or Other Diagnosis = Ortho 1 - Leg Disorders or Gait Disorders ***AND*** M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4	7	2	7	.
20	Primary or Other Diagnosis = Ortho 1 - Leg OR Ortho 2 - Other orthopedic disorders ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	.	2	3	.
21	Primary or Other Diagnosis = Psych 1 – Affective and other psychoses, depression	.	.	.	.
22	Primary or Other Diagnosis = Psych 2 - Degenerative and other organic psychiatric disorders	.	.	.	.
23	Primary or Other Diagnosis = Pulmonary disorders	.	.	.	.
24	Primary or Other Diagnosis = Pulmonary disorders ***AND*** M1860 (Ambulation) = 1 or more	.	1	.	.
25	Primary Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications	2	14	6	14
26	Other Diagnosis = Skin 1 - Traumatic wounds, burns, post-operative complications	5	11	7	11
27	Primary or Other Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications ***OR*** Skin 2 – Ulcers and other skin conditions AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	.	.	.	.
28	Primary or Other Diagnosis = Skin 2 - Ulcers and other skin conditions	1	14	7	14
29	Primary or Other Diagnosis = Tracheostomy	1	10	.	10
30	Primary or Other Diagnosis = Urostomy/Cystostomy	.	17	.	10
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	.	10	1	10
32	M1030 (Therapy at home) = 3 (Enteral)	.	13	.	7
33	M1200 (Vision) = 1 or more	1	.	.	.
34	M1242 (Pain)= 3 or 4	3	.	2	.
35	M1308 = Two or more pressure ulcers at stage 3 or 4	2	4	2	.
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	3	16	6	15
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	5	27	8	22
38	M1334 (Stasis ulcer status)= 2	3	12	5	12
39	M1334 (Stasis ulcer status)= 3	5	15	7	15
40	M1342 (Surgical wound status)= 2	2	6	4	11
41	M1342 (Surgical wound status)= 3	.	5	4	8
42	M1400 (Dyspnea) = 2, 3, or 4	1	1	.	.
43	M1620 (Bowel Incontinence) = 2 to 5	.	4	.	3
44	M1630 (Ostomy)= 1 or 2	2	9	2	7
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3	.	.	.	.
	FUNCTIONAL DIMENSION				
46	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	1	2	.	.
47	M1830 (Bathing) = 2 or more	6	4	5	.
48	M1840 (Toilet transferring) = 2 or more	1	.	.	.
49	M1850 (Transferring) = 2 or more	2	1	2	.

50	M1860 (Ambulation) = 1, 2 or 3	6	.	4	.
51	M1860 (Ambulation) = 4 or more	7	7	6	7

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.

Note(s): Points are additive; however, points may not be given for the same line item in the table more than once. Please see Medicare Home Health Diagnosis Coding guidance at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.html for definitions of primary and secondary diagnoses.

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In updating the four-equation model for CY 2019, using 2017 home health claims data (the last update to the four-equation model for CY 2018 used CY 2016 home health claims data), there were few changes to the point values for the variables in the four-equation model. These relatively minor changes reflect the change in the relationship between the grouper variables and resource use between CY 2016 and CY 2017. The CY 2019 four-equation model resulted in 113 point-giving variables being used in the model (as compared to the 119 variables for the CY 2018 recalibration, which can be found in Table 2 of the CY 2018 HH PPS final rule (82 FR 51684)). There were 7 variables that were added to the model and 13 variables that were dropped from the model due to the absence of additional resources associated with the variable. Of the variables that were in both the four-equation model for CY 2019 and the four-equation model for CY 2018, the points for 10 variables increased in the CY 2019 four-equation model and the points for 67 variables decreased in the CY 2019 4-equation model. There were 29 variables with the same point values.

Step 2: Re-defining the clinical and functional thresholds so they are reflective of the new points associated with the CY 2019 four-equation model. After estimating the points for each of the variables and summing the clinical and functional points for each episode, we look at the distribution of the clinical score and functional score, breaking the episodes into different steps. The categorizations for the steps are as follows:

- Step 1: First and second episodes, 0–13 therapy visits.
- Step 2.1: First and second episodes, 14–19 therapy visits.
- Step 2.2: Third episodes and beyond, 14–19 therapy visits.
- Step 3: Third episodes and beyond, 0–13 therapy visits.
- Step 4: Episodes with 20+ therapy visits.

We then divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.[7] Also, we looked at the average resource use associated with each clinical and functional score and used that as a guide for setting our thresholds. We grouped scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off the CY 2019 four-equation model points are shown in Table 6.

TABLE 6—PROPOSED CY 2019 CLINICAL AND FUNCTIONAL THRESHOLDS

		1st and 2nd Episodes		3rd+ Episodes		All Episodes
		0 to 13 therapy visits	14 to 19 therapy visits	0 to 13 therapy visits	14 to 19 therapy visits	20+ therapy visits
Grouping Step		1	2	3	4	5
Equations used to calculate points (see Table 2)		1	2	3	4	(2&4)
Dimension	Severity Level	.....	.....	.....	.....	.....
Clinical	C1	0 to 1	0 to 1	0 to 1	0 to 1	0 to 3.
	C2	2 to 3	2 to 7	2	2 to 9	4 to 16.
	C3	4+	8+	3+	10+	17+.
Functional	F1	0 to 12	0 to 7	0 to 6	0 to 2	0 to 2.
	F2	13	8 to 12	7 to 10	3 to 7	3 to 6.
	F3	14+	13+	11+	8+	7+.

Step 3: Once the clinical and functional thresholds are determined and each episode is assigned a clinical and functional level, the payment regression is estimated with an episode's wage-weighted minutes of care as the dependent variable. Independent variables in the model are indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 7 shows the regression coefficients for the variables in the payment regression model updated with CY 2017 home

[7] For Step 1, 41% of episodes were in the medium functional level (All with score 13).

For Step 2.1, 86.7% of episodes were in the low functional level (Most with scores 6 to 7).

For Step 2.2, 81.5% of episodes were in the low functional level (Most with score 0).

For Step 3, 46.7% of episodes were in the medium functional level (Most with score 9).

For Step 4, 29.9% of episodes were in the medium functional level (Most with score 6).

health claims data. The R-squared value for the payment regression model is 0.5508 (an increase from 0.5095 for the CY 2018 recalibration).

TABLE 7—PAYMENT REGRESSION MODEL

	Payment regression from 4-equation model for CY 2019
Step 1, Clinical Score Medium	$21.81
Step 1, Clinical Score High	54.06
Step 1, Functional Score Medium	70.54
Step 1, Functional Score High	99.78
Step 2.1, Clinical Score Medium	50.90
Step 2.1, Clinical Score High	118.77
Step 2.1, Functional Score Medium	25.36
Step 2.1, Functional Score High	31.96
Step 2.2, Clinical Score Medium	48.03
Step 2.2, Clinical Score High	187.73
Step 2.2, Functional Score Medium	50.06
Step 2.2, Functional Score High	0.00
Step 3, Clinical Score Medium	18.05
Step 3, Clinical Score High	83.67
Step 3, Functional Score Medium	56.10
Step 3, Functional Score High	81.90
Step 4, Clinical Score Medium	70.97
Step 4, Clinical Score High	245.97
Step 4, Functional Score Medium	4.60
Step 4, Functional Score High	17.77
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	515.04
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	510.26
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	−60.34
Step 4, All Episodes, 20+ Therapy Visits	895.79
Intercept	375.32

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.

Step 4: We use the coefficients from the payment regression model to predict each episode's wage-weighted minutes of care (resource use). We then divide these predicted values by the mean of the dependent variable (that is, the average wage-weighted minutes of care across all episodes used in the payment regression). This division constructs the weight for each episode, which is simply the ratio of the episode's predicted wage-weighted minutes of care divided by the average wage-weighted minutes of care in the sample. Each episode is then aggregated into one of the 153 home health resource groups (HHRGs) and the ''raw'' weight for each HHRG was calculated as the average of the episode weights within the HHRG.

Step 5: The raw weights associated with 0 to 5 therapy visits are then increased by 3.75 percent, the weights associated with 14–15 therapy visits are decreased by 2.5 percent, and the weights associated with 20+ therapy visits are decreased by 5 percent. These adjustments to the case-mix weights were finalized in the CY 2012 HH PPS final rule (76 FR 68557) and were done to address MedPAC's concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes and to better align the case-mix weights with episode costs estimated from cost report data.[8]

Step 6: After the adjustments in step 5 are applied to the raw weights, the weights are further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy thresholds. Weights with the same clinical severity level, functional severity level, and early/later episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds are gradually increased. We do this by interpolating between the main thresholds on the model (from 0–5 to 14–15 therapy visits, and from 14–15 to 20+ therapy visits). We use a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0–5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) are constant. This interpolation is identical to the process finalized in the CY 2012 HH PPS final rule (76 FR 68555).

Step 7: The interpolated weights are then adjusted so that the average case-mix for the weights is equal to 1.0000.[9] This last step creates the proposed CY 2019 case-mix weights shown in Table 8.

[8] Medicare Payment Advisory Commission (MedPAC*), Report to the Congress: Medicare Payment Policy*. March 2011, P. 176.

[9] When computing the average, we compute a weighted average, assigning a value of one to each normal episode and a value equal to the episode length divided by 60 for PEPs.

TABLE 8—PROPOSED CY 2019 CASE-MIX PAYMENT WEIGHTS

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed weights for CY 2019
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5459
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.6801
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8143
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9485
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0828
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.6485
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.7691
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8897
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0104
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1310
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6910
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8049
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9189
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.0328
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1467
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.5776
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7194
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8612
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0030
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1448
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.6802
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8084
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9366
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0648
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1930
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.7227
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.8442
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9657
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.0872
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2087
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6245
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.7755
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9264
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.0774
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2284
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7271
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.8645
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0019
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.1392
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.2766
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7696
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9003
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0310
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.1617
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.2923
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2170
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3756
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5342
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2516
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4008
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5499
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2607
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4126
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.5646
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2866
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4535
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6204
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3212
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4786
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6361
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3302
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.4905
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.6508
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.3793
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.5930
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8067
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4140
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6182

TABLE 8—PROPOSED CY 2019 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed weights for CY 2019
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8224
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.4230
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.6300
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	1.8371
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2104
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3713
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5321
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2789
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4189
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5589
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2789
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4248
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.5706
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2761
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4465
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6169
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3445
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4942
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6438
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3445
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5000
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.6555
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4670
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6515
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8360
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5355
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6992
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8629
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5355
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.7050
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	1.8746
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4581
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6086
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7591
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9095
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0600
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5397
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.6876
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8354
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9832
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1310
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.5772
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7176
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.8579
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	0.9982
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1385
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4844
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6427
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8011
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	0.9594
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1178
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5660
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7217
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8774
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0331
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1888
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6035
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7517
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.8999
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.0481
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.1963
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.5798
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.7573
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9347
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1122
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2896
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.6614
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8362

TABLE 8—PROPOSED CY 2019 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed weights for CY 2019
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0110
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.1858
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3607
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.6989
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.8662
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0336
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.2009
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.3682
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.6929
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.6990
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.7165
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.7874
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.7935
40231	All Episodes, 20+ Therapy Visits	C2F3S1	1.8110
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.0204
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.0266
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.0441

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the proposed CY 2019 national, standardized 60-day episode payment rate (see section III.C.3. of this proposed rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when the CY 2019 HH PPS case-mix weights (developed using CY 2017 home health claims data) are applied to CY 2017 utilization (claims) data to total payments when CY 2018 HH PPS case-mix weights (developed using CY 2016 home health claims data) are applied to CY 2017 utilization data. This produces a case-mix budget neutrality factor for CY 2019 of 1.0163.

C. CY 2019 Home Health Payment Rate Update

1. Rebasing and Revising of the Home Health Market Basket

a. Background

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2019 be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. Effective for cost reporting periods beginning on or after July 1, 1980, we developed and adopted an HHA input price index (that is, the home health ''market basket''). Although ''market basket'' technically describes the mix of goods and services used to produce home health care, this term is also commonly used to denote the input price index derived from that market basket. Accordingly, the term ''home health market basket'' used in this document refers to the HHA input price index.

The percentage change in the home health market basket reflects the average change in the price of goods and services purchased by HHAs in providing an efficient level of home health care services. We first used the home health market basket to adjust HHA cost limits by an amount that reflected the average increase in the prices of the goods and services used to furnish reasonable cost home health care. This approach linked the increase in the cost limits to the efficient utilization of resources. For a greater discussion on the home health market basket, see the notice with comment period published in the February 15, 1980 **Federal Register** (45 FR 10450, 10451), the notice with comment period published in the February 14, 1995 **Federal Register** (60 FR 8389, 8392), and the notice with comment period published in the July 1, 1996 **Federal Register** (61 FR 34344, 34347). Beginning with the FY 2002 HHA PPS payments, we used the home health market basket to update payments under the HHA PPS. We last rebased the home health market basket effective with the CY 2013 update (77 FR 67081).

The home health market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use 2016 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted previously, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide HHA services. The effects on total expenditures resulting from changes in the mix of goods and services purchased

subsequent to the base period are not measured. For example, a HHA hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the HHA, but would not be factored into the price change measured by a fixed-weight home health market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that HHAs purchase (HHA inputs) to furnish inpatient care between base periods.

b. Rebasing and Revising the Home Health Market Basket

We believe that it is desirable to rebase the home health market basket periodically so that the cost category weights reflect changes in the mix of goods and services that HHAs purchase in furnishing home health care. We based the cost category weights in the current home health market basket on CY 2010 data. We are proposing to rebase and revise the home health market basket to reflect 2016 Medicare cost report (MCR) data, the latest available and most complete data on the actual structure of HHA costs.

The terms ''rebasing'' and ''revising,'' while often used interchangeably, denote different activities. The term ''rebasing'' means moving the base year for the structure of costs of an input price index (that is, in this exercise, we are proposing to move the base year cost structure from CY 2010 to CY 2016) without making any other major changes to the methodology. The term ''revising'' means changing data sources, cost categories, and/or price proxies used in the input price index.

For this proposed rebasing and revising, we are rebasing the detailed wages and salaries and benefits cost weights to reflect 2016 BLS Occupational Employment Statistics (OES) data on HHAs. The 2010-based home health market basket used 2010 BLS OES data on HHAs. We are also proposing to break out the All Other (residual) cost category weight into more detailed cost categories, based on the 2007 Benchmark U.S. Department of Commerce, Bureau of Economic Analysis (BEA) Input-Output (I–O) Table for HHAs. The 2010-based home health market basket used the 2002 I–O data. Finally, due to its small weight, we are proposing to eliminate the cost category 'Postage' and include these expenses in the 'All Other Services' cost weight.

c. Derivation of the Proposed 2016-Based Home Health Market Basket Cost Weights

The major cost weights for this proposed revised and rebased home health market basket are derived from the Medicare Cost Reports (MCR; CMS Form 1728–94) data for freestanding HHAs whose cost reporting period began on or after October 1, 2015 and before October 1, 2016. Of the 2016 Medicare cost reports for freestanding HHAs, approximately 84 percent of the reports had a begin date on January 1, 2016, approximately 6 percent had a begin date on July 1, 2016, and approximately 4 percent had a begin date on October 1, 2015. Using this methodology allowed our sample to include HHAs with varying cost report years including, but not limited to, the Federal fiscal or calendar year. We refer to the market basket as a calendar year market basket because the base period for all price proxies and weights are set to CY 2016.

We propose to maintain our policy of using data from freestanding HHAs, which account for over 90 percent of HHAs (82 FR 35383), because we have determined that they better reflect HHAs' actual cost structure. Expense data for hospital-based HHAs can be affected by the allocation of overhead costs over the entire institution.

We are proposing to derive eight major expense categories (Wages and Salaries, Benefits, Contract Labor, Transportation, Professional Liability Insurance (PLI), Fixed Capital, Movable Capital, and a residual ''All Other'') from the 2016 Medicare HHA cost reports. Due to its small weight, we are proposing to eliminate the cost category 'Postage' and include these expenses in the ''All Other (residual)'' cost weight. These major expense categories are based on those cost centers that are reimbursable under the HHA PPS, specifically Skilled Nursing Care, Physical Therapy, Occupational Therapy, Speech Pathology, Medical Social Services, Home Health Aide, and Supplies. These are the same cost centers that were used in the 2014 base payment rebasing (78 FR 72276), which are described in the Abt Associates Inc. June 2013, Technical Paper, ''Analyses In Support of Rebasing and Updating Medicare Home Health Payment Rates'' (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Analyses-in-Support-of-Rebasing-and-Updating-the-Medicare-Home-Health-Payment-Rates-Technical-Report.pdf*). Total costs for the HHA PPS reimbursable services reflect overhead allocation. We provide detail on the calculations for each major expense category.

(1) Wages and Salaries: Wages and Salaries costs reflect direct patient care wages and salaries costs as well as wages and salaries costs associated with Plant Operations and Maintenance, Transportation, and Administrative and General. Specifically, we are proposing to calculate Wages and Salaries by summing costs from Worksheet A, column 1, lines 3 through 12 and subtracting line 5.03 (A&G Nonreimbursable costs).

(2) Benefits: Benefits costs reflect direct patient care benefit costs as well as benefit costs associated with Plant Operations and Maintenance, Transportation, and Administrative and General. Specifically, we are proposing to calculate Benefits by summing costs from Worksheet A, column 2, lines 3 through 12 and subtracting line 5.03 (A&G Nonreimbursable costs).

(3) Direct Patient Care Contract Labor: Contract Labor costs reflect direct patient care contract labor. Specifically, we are proposing to calculate Contract Labor by summing costs from Worksheet A, column 4, lines 6 through 11.

(4) Transportation: Transportation costs reflect direct patient care costs as well as transportation costs associated with Capital Expenses, Plant Operations and Maintenance, and Administrative and General. Specifically, we are proposing to calculate Transportation by summing costs from Worksheet A, column 3, lines 1 through 12 and subtracting line 5.03 (A&G Nonreimbursable costs).

(5) Professional Liability Insurance: Professional Liability Insurance reflects premiums, paid losses, and self-insurance costs. Specifically we are proposing to calculate Professional Liability Insurance by summing costs from Worksheet S2, lines 27.01, 27.02 and 27.03.

(6) Fixed Capital: Fixed Capital-related costs reflect the portion of Medicare-allowable costs reported in ''Capital Related Buildings and Fixtures'' (Worksheet A, column 5, line 1). We calculate this Medicare allowable portion by first calculating a ratio for each provider that reflects fixed capital costs as a percentage of HHA reimbursable services. Specifically this ratio is calculated as the sum of costs from Worksheet B, column 1, lines 6 through 12 divided by the sum of costs from Worksheet B, column 1, line 1 minus lines 3 through 5. This percentage is then applied to the sum of the costs from Worksheet A, column 5, line 1.

(7) Movable Capital: Movable Capital-related costs reflect the portion of Medicare-allowable costs reported in ''Capital Related Moveable Equipment'' (Worksheet A, column 5, line 2). We calculate this Medicare allowable portion by first calculating a ratio for each provider that reflects movable capital costs as a percentage of HHA reimbursable services. Specifically this ratio is calculated as the sum of costs from Worksheet B, column 2, lines 6 through 12 divided by the sum of costs from Worksheet B, column 2, line 2 minus lines 3 through 5. This percentage is then applied to the sum of the costs from Worksheet A, column 5, line 2.

(8) All Other (residual): The ''All Other'' cost weight is a residual, calculated by subtracting the major cost weight percentages (Wages and Salaries, Benefits, Direct Patient Care Contract Labor, Transportation, Professional Liability Insurance, Fixed Capital, and Movable Capital) from 1.

As prescription drugs and DME are not payable under the HH PPS, we continue to exclude those items from the home health market basket. Totals within each of the major cost categories were edited to remove reports where the data were deemed unreasonable (for example, when total costs were not greater than zero). We then determined the proportion of total Medicare allowable costs that each category represents. For all of the major cost categories except the ''residual'' All Other cost weight, we then removed those providers whose derived cost weights fall in the top and bottom five percent of provider-specific cost weights to ensure the removal of outliers. After the outliers were removed, we summed the costs for each category across all remaining providers. We then divided this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2016-based home health market basket for the given category.

Table 9 shows the major cost categories and their respective cost weights as derived from the Medicare cost reports for this proposed rule.

TABLE 9—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major cost categories	2010 based	Proposed 2016 based
Wages and Salaries (including allocated direct patient care contract labor)	66.3	65.1
Benefits (including allocated direct patient care contract labor)	12.2	10.9
Transportation	2.5	2.6
Professional Liability Insurance (Malpractice)	0.4	0.3
Fixed Capital	1.5	1.4
Moveable Capital	0.6	0.6
''All Other'' residual	16.5	19.0

* Figures may not sum to 100.0 due to rounding.

The decrease in the wages and salaries cost weight of 1.2 percentage points and the decrease in the benefits cost weight of 1.3 percentage points is attributable to both employed compensation and direct patient care contract labor costs as reported on the MCR data. Our analysis of the MCR data shows that the decrease in the compensation cost weight of 2.4 percentage points (calculated by combining wages and salaries and benefits) from 2010 to 2016 occurred among for-profit, nonprofit, and government providers and among providers serving only rural beneficiaries, only urban beneficiaries, or both rural and urban beneficiaries.

Over the 2010 to 2016 time period, the average number of FTEs per provider decreased considerably. This corresponds with the HHA claims analysis published on page 35279 of the CY 2018 proposed rule (*https://www.gpo.gov/fdsys/pkg/FR-2017-07-28/pdf/2017-15825.pdf*), which shows that the number of visits per 60-day episode has decreased from 19.8 visits in 2010 to 17.9 visits in 2016 for Medicare PPS. Medicare visits account for approximately 60 percent of total visits.

The direct patient care contract labor costs are contract labor costs for skilled nursing, physical therapy, occupational therapy, speech therapy, and home health aide cost centers. We allocated these direct patient care contract labor costs to the Wages and Salaries and Benefits cost categories based on each provider's relative proportions of both employee wages and salaries and employee benefits costs. For example, the direct patient care contract labor costs that are allocated to wages and salaries is equal to: (A) The employee wages and salaries costs as a percent of the sum of employee wages and salaries costs and employee benefits costs times; and (B) direct patient care contract labor costs. Nondirect patient care contract labor costs (such as contract labor costs reported in the Administrative and General cost center of the MCR) are captured in the ''All Other'' residual cost weight and later disaggregated into more detail as described below. This is a similar methodology that was implemented for the 2010-based home health market basket.

We further divide the ''All Other'' residual cost weight estimated from the 2016 Medicare cost report data into more detailed cost categories. To divide this cost weight we are proposing to use the 2007 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 621600, Home Health Agencies, published by the BEA. These data are publicly available at *http://www.bea.gov/industry/io_annual.htm.* The BEA Benchmark I–O data are generally scheduled for publication every five years. The most recent data available at the time of rebasing was for 2007. The 2007 Benchmark I–O data are derived from the 2007 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[10] Besides Benchmark I–O estimates, BEA also produces Annual I–O estimates. While based on a similar methodology, the Annual I–O estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we are proposing to inflate the detailed 2007 Benchmark I–O data forward to 2016 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2007 Benchmark I–O data. We repeated this practice for each year. We then calculated the cost shares that each cost

[10] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

category represents of the 2007 data inflated to 2016. These resulting 2016 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2016-based home health market basket. For example, the cost for Operations and Maintenance represents 8.0 percent of the sum of the ''All Other'' 2007 Benchmark I–O HHA Expenditures inflated to 2016. Therefore, the Operations and Maintenance cost weight represents 8.0 percent of the proposed 2016-based home health market basket's ''All Other'' cost category (19.0 percent), yielding an Operations and Maintenance proposed cost weight of 1.5 percent in the proposed 2016-based home health market basket (0.080 × 19.0 percent = 1.5 percent). For the 2010-based home health market basket, we used the same methodology utilizing the 2002 Benchmark I–O data (aged to 2010).

Using this methodology, we are proposing to derive nine detailed cost categories from the proposed 2016-based home health market basket ''All Other'' residual cost weight (19.0 percent). These categories are: (1) Operations and Maintenance; (2) Administrative Support; (3) Financial Services; (4) Medical Supplies; (5) Rubber and Plastics; (6) Telephone; (7) Professional Fees; (8) Other Products; and (9) Other Services. The 2010-based home health market basket included a separate cost category for Postage; however, due to its small weight for the 2016-based home health market basket, we propose to eliminate the stand-alone cost category for Postage and include these expenses in the Other Services cost category.

Table 10 lists the proposed 2016-based home health market basket cost categories, cost weights, and price proxies.

TABLE 10—COST CATEGORIES, WEIGHTS, AND PRICE PROXIES IN PROPOSED 2016-BASED HOME HEALTH MARKET BASKET

Cost categories	Weight	Price proxy
Compensation, including allocated contract services' labor.	76.1	
Wages and Salaries, including allocated contract services' labor.	65.1	Proposed Home Health Blended Wages and Salaries Index (2016).
Benefits, including allocated contract services' labor.	10.9	Proposed Home Health Blended Benefits Index (2016).
Operations & Maintenance	1.5	CPI–U for Fuel and utilities.
Professional Liability Insurance	0.3	CMS Physician Professional Liability Insurance Index.
Administrative & General & Other Expenses including allocated contract services' labor.	17.4	
Administrative Support	1.0	ECI for Total compensation for Private industry workers in Office and administrative support.
Financial Services	1.9	ECI for Total compensation for Private industry workers in Financial activities.
Medical Supplies	0.9	PPI Commodity data for Medical, surgical & personal aid devices.
Rubber & Plastics	1.6	PPI Commodity data for Rubber and plastic products.
Telephone	0.7	CPI–U for Telephone services.
Professional Fees	5.3	ECI for Total compensation for Private industry workers in Professional and related.
Other Products	2.8	PPI Commodity data for Finished goods less foods and energy.
Other Services	3.2	ECI for Total compensation for Private industry workers in Service occupations.
Transportation	2.6	CPI–U for Transportation.
Capital-Related	2.1	
Fixed Capital	1.4	CPI–U for Owners' equivalent rent of residences.
Movable Capital	0.6	PPI Commodity data for Machinery and equipment.
Total	*100.0	

*Figures may not sum due to rounding.

d. Proposed 2016-Based Home Health Market Basket Price Proxies

After we computed the CY 2016 cost category weights for the proposed rebased home health market basket, we selected the most appropriate wage and price indexes to proxy the rate of change for each expenditure category. With the exception of the price index for Professional Liability Insurance costs, the proposed price proxies are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

• *Employment Cost Indexes*—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. They are not affected by shifts in skill mix. ECIs are superior to average hourly earnings as price proxies for input price indexes for two reasons: (a) They measure pure price change; and (b) they are available by occupational groups, not just by industry.

• *Consumer Price Indexes*—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Consumer price indexes are used when the expenditure is more similar to that of a purchase at the retail level rather than at the wholesale level, or if no appropriate Producer Price Indexes (PPIs) were available.

• *Producer Price Indexes*—PPIs measures average changes in prices received by domestic producers for their goods and services. PPIs are used to measure price changes for goods sold in other than retail markets. For example, a PPI for movable equipment is used rather than a CPI for equipment. PPIs in some cases are preferable price proxies for goods that HHAs purchase at wholesale levels. These fixed-weight indexes are a measure of price change

at the producer or at the intermediate stage of production.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in way that can be replicated. Low sampling variability is desirable because it indicates that sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because a sample was surveyed rather than the entire population.) Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly and therefore it is important the underlying price proxies be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly helps ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently because we believe that this is an optimal way to stay abreast of the most current data available. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs selected by us to be proposed in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

As part of the revising and rebasing of the home health market basket, we are proposing to rebase the home health blended Wages and Salaries index and the home health blended Benefits index. We propose to use these blended indexes as price proxies for the Wages and Salaries and the Benefits portions of the proposed 2016-based home health market basket, as we did in the 2010-based home health market basket. A more detailed discussion is provided below.

- *Wages and Salaries:* For measuring price growth in the 2016-based home health market basket, we are proposing to apply six price proxies to six occupational subcategories within the Wages and Salaries component, which would reflect the HHA occupational mix. This is the same approach used for the 2010-based index. We use a blended wage proxy because there is not a published wage proxy specific to the home health industry.

We are proposing to continue to use the National Industry-Specific Occupational Employment and Wage estimates for North American Industrial Classification System (NAICS) 621600, Home Health Care Services, published by the BLS Office of Occupational Employment Statistics (OES) as the data source for the cost shares of the home health blended wage and benefits proxy. This is the same data source that was used for the 2010-based HHA blended wage and benefit proxies; however, we are proposing to use the May 2016 estimates in place of the May 2010 estimates. Detailed information on the methodology for the national industry-specific occupational employment and wage estimates survey can be found at *http://www.bls.gov/oes/current/oes_tec.htm.*

The needed data on HHA expenditures for the six occupational subcategories (Health-Related Professional and Technical, Non Health-Related Professional and Technical, Management, Administrative, Health and Social Assistance Service, and Other Service Workers) for the wages and salaries component were tabulated from the May 2016 OES data for NAICS 621600, Home Health Care Services. Table 11 compares the proposed 2016 occupational assignments to the 2010 occupational assignments of the six CMS designated subcategories. If an OES occupational classification does not exist in the 2010 or 2016 data we use ''n/a.''

TABLE 11—PROPOSED 2016 OCCUPATIONAL ASSIGNMENTS COMPARED TO 2010 OCCUPATIONAL ASSIGNMENTS FOR CMS HOME HEALTH WAGES AND SALARIES BLEND

2016 proposed occupational groupings		2010 occupational groupings	
Group 1	Health-related professional and technical	Group 1	Health-related professional and technical
n/a	n/a	29–1021	Dentists, General.
29–1031	Dietitians and Nutritionists	29–1031	Dietitians and Nutritionists.
29–1051	Pharmacists	29–1051	Pharmacists.
29–1062	Family and General Practitioners	29–1062	Family and General Practitioners.
29–1063	Internists, General	29–1063	Internists, General.
29–1065	Pediatricians, General	n/a	n/a.
29–1066	Psychiatrists	n/a	n/a.
29–1069	Physicians and Surgeons, All Other	29–1069	Physicians and Surgeons, All Other.
29–1071	Physician Assistants	29–1071	Physician Assistants.
n/a	n/a	29–1111	Registered Nurses.
29–1122	Occupational Therapists	29–1122	Occupational Therapists.
29–1123	Physical Therapists	29–1123	Physical Therapists.
29–1125	Recreational Therapists	29–1125	Recreational Therapists.
29–1126	Respiratory Therapists	29–1126	Respiratory Therapists.
29–1127	Speech-Language Pathologists	29–1127	Speech-Language Pathologists.
29–1129	Therapists, All Other	29–1129	Therapists, All Other.
29–1141	Registered Nurses	n/a	n/a.
29–1171	Nurse Practitioners	n/a	n/a.
29–1199	Health Diagnosing and Treating Practitioners, All Other.	29–1199	Health Diagnosing and Treating Practitioners, All Other.

2016 proposed occupational groups		2010 occupational groupings	
Group 2	Non health related professional & technical	Group 2	Non health related professional & technical
13–0000	Business and Financial Operations Occupations	13–0000	Business and Financial Operations Occupations.
15–0000	Computer and Mathematical Occupations	15–0000	Computer and Mathematical Science Occupations.
n/a	n/a	17–0000	Architecture and Engineering Occupations.
19–0000	Life, Physical, and Social Science Occupations	19–0000	Life, Physical, and Social Science Occupations.
n/a	n/a	23–0000	Legal Occupations.
25–0000	Education, Training, and Library Occupations	25–0000	Education, Training, and Library Occupations.
27–0000	Arts, Design, Entertainment, Sports, and Media Occupations.	27–0000	Arts, Design, Entertainment, Sports, and Media Occupations.
Group 3	Management	Group 3	Management
11–0000	Management Occupations	11–0000	Management Occupations.
Group 4	Administrative	Group 4	Administrative
43–0000	Office and Administrative Support Occupations	43–0000	Office and Administrative Support Occupations.
Group 5	Health and social assistance services	Group 5	Health and social assistance services
21–0000	Community and Social Service Occupations	21–0000	Community and Social Services Occupations.
29–2011	Medical and Clinical Laboratory Technologists	29–2011	Medical and Clinical Laboratory Technologists.
29–2012	Medical and Clinical Laboratory Technicians	29–2012	Medical and Clinical Laboratory Technicians.
29–2021	Dental Hygienists	29–2021	Dental Hygienists.
29–2032	Diagnostic Medical Sonographers	29–2032	Diagnostic Medical Sonographers.
29–2034	Radiologic Technologists	29–2034	Radiologic Technologists and Technicians.
29–2041	Emergency Medical Technicians and Paramedics	29–2041	Emergency Medical Technicians and Paramedics.
29–2051	Dietetic Technicians	29–2051	Dietetic Technicians.
29–2052	Pharmacy Technicians	29–2052	Pharmacy Technicians.
29–2053	Psychiatric Technicians	n/a	n/a.
29–2054	Respiratory Therapy Technicians	29–2054	Respiratory Therapy Technicians.
29–2055	Surgical Technologists	n/a	n/a.
29–2061	Licensed Practical and Licensed Vocational Nurses	29–2061	Licensed Practical and Licensed Vocational Nurses.
29–2071	Medical Records and Health Information Technicians	29–2071	Medical Records and Health Information Technicians.
29–2099	Health Technologists and Technicians, All Other	29–2099	Health Technologists and Technicians, All Other.
n/a	n/a	29–9012	Occupational Health and Safety Technicians.
29–9099	Healthcare Practitioners and Technical Workers, All Other.	29–9099	Healthcare Practitioner and Technical Workers, All Other.
31–0000	Healthcare Support Occupations	31–0000	Healthcare Support Occupations.
Group 6	Other service workers	Group 6	Other service workers
33–0000	Protective Service Occupations	33–0000	Protective Service Occupations.
35–0000	Food Preparation and Serving Related Occupations	35–0000	Food Preparation and Serving Related Occupations.
37–0000	Building and Grounds Cleaning and Maintenance Occupations.	37–0000	Building and Grounds Cleaning and Maintenance Occupations.
39–0000	Personal Care and Service Occupations	39–0000	Personal Care and Service Occupations.
41–0000	Sales and Related Occupations	41–0000	Sales and Related Occupations.
47–0000	Construction and Extraction Occupations	n/a	n/a.
49–0000	Installation, Maintenance, and Repair Occupations	49–0000	Installation, Maintenance, and Repair Occupations.
51–0000	Production Occupations	51–0000	Production Occupations.
53–0000	Transportation and Material Moving Occupations	53–0000	Transportation and Material Moving Occupations.

Total expenditures by occupation were calculated by taking the OES number of employees multiplied by the OES annual average salary for each subcategory, and then calculating the proportion of total wage costs that each subcategory represents. The proportions listed in Table 12 represent the Wages and Salaries blend weights.

TABLE 12—COMPARISON OF THE PROPOSED 2016-BASED HOME HEALTH WAGES AND SALARIES BLEND AND THE 2010-BASED HOME HEALTH WAGES AND SALARIES BLEND

Cost subcategory	Proposed 2016 weight	2010 weight	Price proxy	BLS series ID
Health-Related Professional and Technical.	33.7	33.4	ECI for Wages and salaries for All Civilian workers in Hospitals.	CIU10262200000000I.
Non Health-Related Professional and Technical.	2.3	2.3	ECI for Wages and salaries for Private industry workers in Professional, scientific, and technical services.	CIU20254000000000I.
Management	7.6	8.3	ECI for Wages and salaries for Private industry workers in Management, business, and financial.	CIU20200001100000I.

TABLE 12—COMPARISON OF THE PROPOSED 2016-BASED HOME HEALTH WAGES AND SALARIES BLEND AND THE 2010-BASED HOME HEALTH WAGES AND SALARIES BLEND—Continued

Cost subcategory	Proposed 2016 weight	2010 weight	Price proxy	BLS series ID
Administrative	6.7	7.7	ECI for Wages and salaries for Private industry workers in Office and administrative support.	CIU20200002200001.
Health and Social Assistance Services.	35.3	35.8	ECI for Wages and salaries for All Civilian workers in Health care and social assistance.	CIU10262000000001.
Other Service Occupations	14.4	12.6	ECI for Wages and salaries for Private industry workers in Service occupations.	CIU20200003000001.
Total *	100.0	100.0		

* Totals may not sum due to rounding.

A comparison of the yearly changes from CY 2016 to CY 2019 for the 2010-based home health Wages and Salaries blend and the proposed 2016-based home health Wages and Salaries blend is shown in Table 13. The annual increases in the two price proxies are the same when rounded to one decimal place.

TABLE 13—ANNUAL GROWTH IN PROPOSED 2016 AND 2010 HOME HEALTH WAGES AND SALARIES BLEND

	2016	2017	2018	2019
Wage Blend 2016	2.3	2.5	2.6	3.0
Wage Blend 2010	2.3	2.5	2.6	3.0

Source: IHS Global Insight Inc. 1st Quarter 2018 forecast with historical data through 4th Quarter 2017.

• *Benefits:* For measuring Benefits price growth in the proposed 2016-based home health market basket, we are proposing to apply applicable price proxies to the six occupational subcategories that are used for the Wages and Salaries blend. The proposed six categories in Table 14 are the same as those in the 2010-based home health market basket and include the same occupational mix as listed in Table 14.

TABLE 14—COMPARISON OF THE PROPOSED 2016-BASED HOME HEALTH BENEFITS BLEND AND 2010-BASED HOME HEALTH BENEFITS BLEND

Cost category	Proposed 2016 weight	2010 weight	Price proxy
Health-Related Professional and Technical	33.9	33.5	ECI for Benefits for All Civilian workers in Hospitals.
Non Health-Related Professional and Technical.	2.3	2.2	ECI for Benefits for Private industry workers in Professional, scientific, and technical services.
Management	7.3	8.0	ECI for Benefits for Private industry workers in Management, business, and financial.
Administrative	6.7	7.8	ECI for Benefits for Private industry workers in Office and administrative support.
Health and Social Assistance Services	35.5	35.9	ECI for Benefits for All Civilian workers in Health care and social assistance.
Other Service Workers	14.2	12.5	ECI for Benefits for Private industry workers in Service occupations.
Total *	100.0	100.0	

* Totals may not sum due to rounding.

There is no available data source that exists for benefit expenditures by occupation for the home health industry. Thus, to construct weights for the home health benefits blend we calculated the ratio of benefits to wages and salaries for CY 2016 for the six ECI series we are proposing to use in the blended 'wages and salaries' and 'benefits' indexes. To derive the relevant benefits weight, we applied the benefit-to-wage ratios to each of the six occupational subcategories from the 2016 OES wage and salary weights, and normalized. For example, the ratio of benefits to wages from the 2016 home health wages and salaries blend and the benefits blend for the management category is 0.984. We apply this ratio to the 2016 OES weight for wages and salaries for management, 7.6 percent, and then normalize those weights relative to the other five benefit occupational categories to obtain a benefit weight for management of 7.3 percent.

A comparison of the yearly changes from CY 2016 to CY 2019 for the 2010-based home health Benefits blend and the proposed 2016-based home health Benefits blend is shown in Table 15. With the exception of a 0.1 percentage point difference in 2019, the annual increases in the two price proxies are the same when rounded to one decimal place.

TABLE 15—ANNUAL GROWTH IN THE PROPOSED 2016 HOME HEALTH BENEFITS BLEND AND THE 2010 HOME HEALTH BENEFITS BLEND

	2016	2017	2018	2019
Benefits Blend 2016	1.7	1.9	2.4	3.0
Benefits Blend 2010	1.7	1.9	2.4	2.9

Source: IHS Global Insight Inc. 1st Quarter 2018 forecast with historical data through 4th Quarter 2017.

• *Operations and Maintenance:* We are proposing to use CPI U.S. city average for Fuel and utilities (BLS series code #CUUR0000SAH2) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

• *Professional Liability Insurance:* We are proposing to use the CMS Physician Professional Liability Insurance price index to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

To accurately reflect the price changes associated with physician PLI, each year we collect PLI premium data for physicians from a representative sample of commercial carriers and publically available rate filings as maintained by each State's Association of Insurance Commissioners. As we require for our other price proxies, the PLI price proxy is intended to reflect the pure price change associated with this particular cost category. Thus, the level of liability coverage is held constant from year to year. To accomplish this, we obtain premium information from a sample of commercial carriers for a fixed level of coverage, currently $1 million per occurrence and a $3 million annual limit. This information is collected for every State by physician specialty and risk class. Finally, the State-level, physician-specialty data are aggregated to compute a national total, using counts of physicians by State and specialty as provided in the AMA publication, *Physician Characteristics and Distribution in the U.S.*

• *Administrative and Support:* We are proposing to use the ECI for Total compensation for Private industry workers in Office and administrative support (BLS series code #CIU2010000220000I) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

• *Financial Services:* We are proposing to use the ECI for Total compensation for Private industry workers in Financial activities (BLS series code #CIU201520A000000I) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

• *Medical Supplies:* We are proposing to use the PPI Commodity data for Miscellaneous products-Medical, surgical & personal aid devices (BLS series code #WPU156) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

• *Rubber and Plastics:* We are proposing to use the PPI Commodity data for Rubber and plastic products (BLS series code #WPU07) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

• *Telephone:* We are proposing to use CPI U.S. city average for Telephone services (BLS series code #CUUR0000SEED) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

• *Professional Fees:* We are proposing to use the ECI for Total compensation for Private industry workers in Professional and related (BLS series code #CIS2010000120000I) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

• *Other Products:* We are proposing to use the PPI Commodity data for Final demand-Finished goods less foods and energy (BLS series code #WPUFD4131) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

• *Other Services:* We are proposing to use the ECI for Total compensation for Private industry workers in Service occupations (BLS series code #CIU2010000300000I) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

• *Transportation:* We are proposing to use the CPI U.S. city average for Transportation (BLS series code #CUUR0000SAT) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

• *Fixed capital:* We are proposing to use the CPI U.S. city average for Owners' equivalent rent of residences (BLS series code #CUUS0000SEHC) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

• *Movable Capital:* We are proposing to use the PPI Commodity data for Machinery and equipment (BLS series code #WPU11) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

e. Rebasing Results

A comparison of the yearly changes from CY 2014 to CY 2021 for the 2010-based home health market basket and the proposed 2016-based home health market basket is shown in Table 16.

TABLE 16—COMPARISON OF THE 2010-BASED HOME HEALTH MARKET BASKET AND THE PROPOSED 2016-BASED HOME HEALTH MARKET BASKET, PERCENT CHANGE, 2014–2021

	Home health market basket, 2010-based	Proposed home health market basket, 2016-based	Difference (proposed 2016-based less 2010-based)
Historical data:			
CY 2014	1.6	1.6	0.0
CY 2015	1.6	1.5	−0.1
CY 2016	2.0	2.0	0.0
CY 2017	2.3	2.3	0.0

TABLE 16—COMPARISON OF THE 2010-BASED HOME HEALTH MARKET BASKET AND THE PROPOSED 2016-BASED HOME HEALTH MARKET BASKET, PERCENT CHANGE, 2014–2021—Continued

	Home health market basket, 2010-based	Proposed home health market basket, 2016-based	Difference (proposed 2016-based less 2010-based)
Average CYs 2014–2017	1.9	1.9	0.0
Forecast:			
CY 2018	2.5	2.5	0.0
CY 2019	2.8	2.8	0.0
CY 2020	3.0	3.0	0.0
CY 2021	3.0	3.0	0.0
Average CYs 2018–2021	2.8	2.8	0.0

Source: IHS Global Inc. 1st Quarter 2018 forecast with historical data through 4th Quarter 2017.

Table 16 shows that the forecasted rate of growth for CY 2019 for the proposed 2016-based home health market basket is 2.8 percent, the same rate of growth as estimated using the 2010-based home health market basket; other forecasted years also show a similar increase. Similarly, the historical estimates of the growth in the 2016-based and 2010-based home health market basket are the same except for CY 2015 where the 2010-based home health market basket is 0.1 percentage point higher. We note that if more recent data are subsequently available (for example, a more recent estimate of the market basket), we would use such data to determine the market basket increases in the final rule.

f. Labor-Related Share

Effective for CY 2019, we are proposing to revise the labor-related share to reflect the proposed 2016-based home health market basket Compensation (Wages and Salaries plus Benefits) cost weight. The current labor-related share is based on the Compensation cost weight of the 2010-based home health market basket. Based on the proposed 2016-based home health market basket, the labor-related share would be 76.1 percent and the proposed non-labor-related share would be 23.9 percent. The labor-related share for the 2010-based home health market basket was 78.5 percent and the non-labor-related share was 21.5 percent. As explained earlier, the decrease in the compensation cost weight of 2.4 percentage points is attributable to both employed compensation (wages and salaries and benefits for employees) and direct patient care contract labor costs as reported in the MCR data. Table 17 details the components of the labor-related share for the 2010-based and proposed 2016-based home health market baskets.

TABLE 17—LABOR–RELATED SHARE OF CURRENT AND PROPOSED HOME HEALTH MARKET BASKETS

Cost category	2010-based market basket weight	Proposed 2016-based market basket weight
Wages and Salaries	66.3	65.1
Employee Benefits	12.2	11.0
Total Labor-Related	78.5	76.1
Total Non Labor-Related	21.5	23.9

We propose to implement the proposed revision to the labor-related share of 76.1 percent in a budget neutral manner. This proposal would be consistent with our policy of implementing the annual recalibration of the case-mix weights and update of the home health wage index in a budget neutral manner.

g. Multifactor Productivity

In the CY 2015 HHA PPS final rule (79 FR 38384 through 38384), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1895(b)(3)(B)(vi) of the Act, requires that, in CY 2015 (and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)), the market basket percentage under the HHA prospective payment system as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp,* to obtain the BLS historical published MFP data.

Based on IHS Global Inc.'s (IGI's) first quarter 2018 forecast with history through the fourth quarter of 2017, the projected MFP adjustment (the 10-year moving average of MFP for the period ending December 31, 2019) for CY 2019 is 0.7 percent. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. We note that if more recent data are subsequently available (for example, a more recent estimate of the MFP adjustment), we would use such data to determine the MFP adjustment in the final rule.

2. Proposed CY 2019 Market Basket Update for HHAs

Using IGI's first quarter 2018 forecast, the MFP adjustment for CY 2019 is projected to be 0.7 percent. In accordance with section 1895(b)(3)(B)(iii) of the Act, we propose to base the CY 2019 market basket update, which is used to determine the applicable percentage increase for HHA payments, on the most recent estimate of the proposed 2016-based home health market basket. Based on IGI's first quarter 2018 forecast with history through the fourth quarter of 2017, the projected increase of the proposed 2016-based home health market basket for CY 2019 is 2.8 percent. We propose to then reduce this percentage increase by the current estimate of the MFP adjustment for CY 2019 of 0.7 percentage point in accordance with 1895(b)(3)(B)(vi) of the Act. Therefore, the current estimate of the CY 2019 HHA payment update is 2.1 percent (2.8 percent market basket update, less 0.7 percentage point MFP adjustment). Furthermore, we note that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data to determine the CY 2019 market basket update and MFP adjustment in the final rule.

Section 1895(b)(3)(B)(v) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2019, the home health payment update will be 0.1 percent (2.1 percent minus 2 percentage points).

3. CY 2019 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We propose to continue this practice for CY 2019, as we continue to believe that, in the absence of HH-specific wage data that accounts for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. Specifically, we propose to continue to use the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2019, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2014, and before October 1, 2015 (FY 2015 cost report data). We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2019 HH PPS wage index, we propose to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we propose to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we propose to continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2019, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980).

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted the OMB's new area delineations using a 1-year transition.

On August 15, 2017, OMB issued Bulletin No. 17–01 in which it announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area. The new CBSA (46300) comprises the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. The CY 2019 HH PPS wage index value for CBSA 46300, Twin Falls, Idaho, will be 0.8335. Bulletin No. 17–01 is available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*.[11]

The most recent OMB Bulletin (No. 18–03) was published on April 10, 2018 and is available at *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf*.[12] The revisions contained in OMB Bulletin No. 18–03 have no impact on the geographic area delineations that are used to wage adjust HH PPS payments.

The CY 2019 wage index is available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html*.

4. CY 2019 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS is a national, standardized 60-day episode payment rate. As set forth in § 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary.

To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. As discussed in section III.C.1 of this proposed rule, based on the proposed 2016-based home health market basket, the proposed labor-related share would be 76.1 percent and the proposed non-labor-related share would be 23.9 percent for CY 2019. The CY 2019 HH PPS rates use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and will be adjusted as described in section III.B of this proposed rule. The following are the steps we take to compute the case-mix

[11] ''Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas''. OMB BULLETIN NO. 17–01. August 15, 2017. *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*.

[12] ''Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas''. OMB BULLETIN NO. 18–03. April 10, 2018. *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf*.

and wage-adjusted 60-day episode rate for CY 2019:

- Multiply the national 60-day episode rate by the patient's applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (76.1 percent) and a non-labor portion (23.9 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments.

In accordance with section 1895(b)(3)(B) of the Act, we propose the annual update of the HH PPS rates. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare will use to pay the claim.

We may also adjust the 60-day case-mix and wage-adjusted episode payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in §§ 484.205(c) and 484.230.
- A partial episode payment (PEP) adjustment as set forth in §§ 484.205(d) and 484.235.
- An outlier payment as set forth in §§ 484.205(e) and 484.240.

b. CY 2019 National, Standardized 60-Day Episode Payment Rate

Section 1895(b)(3)(A)(i) of the Act requires that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2019 national, standardized 60-day episode payment rate, we apply a wage index budget neutrality factor and a case-mix budget neutrality factor described in section III.B of this proposed rule; and the home health payment update percentage discussed in section III.C.2 of this proposed rule.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the CY 2019 wage index (including the application of the proposed labor-related share of 76.1 percent and the proposed non-labor-related share of 23.9 percent) and compared it to our simulation of total payments for non-LUPA episodes using the CY 2018 wage index and CY 2018 (including the application of the current labor-related share of 78.535 percent and the non-labor-related of 21.465). By dividing the total payments for non-LUPA episodes using the CY 2019 wage index by the total payments for non-LUPA episodes using the CY 2018 wage index, we obtain a wage index budget neutrality factor of 0.9991. We would apply the wage index budget neutrality factor of 0.9991 to the calculation of the CY 2019 national, standardized 60-day episode payment rate.

As discussed in section III.B of this proposed rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we propose to apply a case-mix weight budget neutrality factor to the CY 2019 national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2019 case-mix weights are applied to CY 2017 utilization (claims) data to total payments when CY 2018 case-mix weights are applied to CY 2017 utilization data. The case-mix budget neutrality factor for CY 2019 is 1.0163 as described in section III.B of this proposed rule.

Next, we would update the payment rates by the CY 2019 home health payment update percentage of 2.1 percent as described in section III.C.2 of this proposed rule. The CY 2019 national, standardized 60-day episode payment rate is calculated in Table 18.

TABLE 18—CY 2019 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2018 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	CY 2019 HH payment update	CY 2019 National, standardized 60-day episode payment
$3,039.64	× 0.9991	× 1.0163	× 1.021	$3,151.22

The CY 2019 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2019 home health payment update of 2.1 percent minus 2 percentage points and is shown in Table 19.

TABLE 19—CY 2019 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2018 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	CY 2019 HH payment update minus 2 percentage points	CY 2019 National, standardized 60-day episode payment
$3,039.64	× 0.9991	× 1.0163	× 1.001	$3,089.49

c. CY 2019 National Per-Visit Rates

The national per-visit rates are used to pay LUPAs (episodes with four or fewer visits) and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the CY 2019 national per-visit rates, we started with the CY 2018 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA episodes using the CY 2019 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2018 wage index. By dividing the total payments for LUPA episodes using the CY 2019 wage index by the total payments for LUPA episodes using the CY 2018 wage index, we obtained a wage index budget neutrality factor of 1.0000. We apply the wage index budget neutrality factor of 1.0000 in order to calculate the CY 2019 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weights budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the CY 2019 home health payment update percentage of 2.1 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2019 national per-visit rates for HHAs that submit the required quality data are updated by the CY 2019 HH payment update percentage of 2.1 percent and are shown in Table 20.

TABLE 20—CY 2019 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2018 per-visit payment	Wage index budget neutrality factor	CY 2019 HH payment update	CY 2019 per-visit payment
Home Health Aide	$64.94	× 1.0000	× 1.021	$66.30
Medical Social Services	229.86	× 1.0000	× 1.021	234.69
Occupational Therapy	157.83	× 1.0000	× 1.021	161.14
Physical Therapy	156.76	× 1.0000	× 1.021	160.05
Skilled Nursing	143.40	× 1.0000	× 1.021	146.41
Speech-Language Pathology	170.38	× 1.0000	× 1.021	173.96

The CY 2019 per-visit payment rates for HHAs that do not submit the required quality data are updated by the CY 2019 HH payment update percentage of 2.1 percent minus 2 percentage points and are shown in Table 21.

TABLE 21—CY 2019 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2018 per-visit rates	Wage index budget neutrality factor	CY 2019 HH payment update minus 2 percentage points	CY 2019 per-visit rates
Home Health Aide	$64.94	× 1.0000	× 1.001	$65.00
Medical Social Services	229.86	× 1.0000	× 1.001	230.09
Occupational Therapy	157.83	× 1.0000	× 1.001	157.99
Physical Therapy	156.76	× 1.0000	× 1.001	156.92
Skilled Nursing	143.40	× 1.0000	× 1.001	143.54
Speech-Language Pathology	170.38	× 1.0000	× 1.001	170.55

d. Low-Utilization Payment Adjustment (LUPA) Add-On Factors

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. In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. 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 to determine the LUPA add-on payment amount. For example, in the case of HHAs that do submit the required quality data, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit will be $270.14 (1.8451 multiplied by $146.41), subject to area wage adjustment.

e. CY 2019 Non-Routine Medical Supply (NRS) Payment Rates

All medical supplies (routine and nonroutine) must be provided by the HHA while the patient is under a home health plan of care. Examples of supplies that can be considered non-routine include dressings for wound care, I.V. supplies, ostomy supplies, catheters, and catheter supplies. Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the CY 2019 NRS conversion factor, we updated the CY 2018 NRS conversion factor ($53.03) by the CY 2019 home health payment update percentage of 2.1 percent. We did not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The proposed NRS conversion factor for CY 2019 is shown in Table 22.

TABLE 22—CY 2019 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2018 NRS conversion factor	CY 2019 HH payment update	CY 2019 NRS conversion factor
$53.03	× 1.021	$54.14

Using the CY 2019 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 23.

TABLE 23—CY 2019 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2019 NRS payment amounts
1	0	0.2698	$ 14.61
2	1 to 14	0.9742	52.74
3	15 to 27	2.6712	144.62
4	28 to 48	3.9686	214.86
5	49 to 98	6.1198	331.33
6	99+	10.5254	569.85

For HHAs that do not submit the required quality data, we updated the CY 2018 NRS conversion factor ($53.03) by the CY 2019 home health payment update percentage of 2.1 percent minus 2 percentage points. The proposed CY 2019 NRS conversion factor for HHAs that do not submit quality data is shown in Table 24.

TABLE 24—CY 2019 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2018 NRS conversion factor	CY 2019 HH payment update percentage minus 2 percentage points	CY 2019 NRS conversion factor
$53.03	× 1.001	$53.08

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not submit quality data are calculated in Table 25.

TABLE 25—CY 2019 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2019 NRS payment amounts
1	0	0.2698	$ 14.32
2	1 to 14	0.9742	51.71
3	15 to 27	2.6712	141.79
4	28 to 48	3.9686	210.65
5	49 to 98	6.1198	324.84
6	99+	10.5254	558.69

D. Proposed Rural Add-On Payments for CYs 2019 Through 2022

1. Background

Section 421(a) of the MMA required, for HH services furnished in a rural areas (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent.

Section 5201 of the DRA amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006, and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018.

Section 50208(a) of the Bipartisan Budget Act of 2018 amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2019. This extension of the rural add-on payments was implemented as described in CMS Transmittal 2047 published on March 20, 2018.

2. Proposed Rural Add-On Payments for CYs 2019 Through 2022

Section 50208(a)(1)(D) of the BBA of 2018 adds a new subsection (b) to section 421 of the MMA to provide rural add-on payments for episodes and visits ending during CYs 2019 through 2022 . It also mandates implementation of a new methodology for applying those payments. Unlike previous rural add-ons, which were applied to all rural areas uniformly, the extension provides varying add-on amounts depending on the rural county (or equivalent area) classification by classifying each rural county (or equivalent area) into one of three distinct categories.

Specifically, section 421(b)(1) of the MMA, as amended by section 50208 of the BBA of 2018, provides that rural counties (or equivalent areas) would be placed into one of three categories for purposes of HH rural add-on payments: (1) Rural counties and equivalent areas in the highest quartile of all counties and equivalent areas based on the number of Medicare home health episodes furnished per 100 individuals who are entitled to, or enrolled for, benefits under part A of Medicare or enrolled for benefits under part B of Medicare only, but not enrolled in a Medicare Advantage plan under part C of Medicare, as provided in section 421(b)(1)(A) of the MMA (the ''High utilization'' category); (2) rural counties and equivalent areas with a population density of 6 individuals or fewer per square mile of land area and are not included in the category provided in section 421(b)(1)(A) of the MMA, as provided in section 421(b)(1)(B) of the MMA (the Low population density'' category); and (3) rural counties and equivalent areas not in the categories provided in either sections 421(b)(1)(A) or 421(b)(1)(B) of the MMA, as provided in section 421(b)(1)(C) of the MMA (the ''All other'' category). The list of counties and equivalent areas used in our analysis is based on the CY 2015 HH PPS wage index file, which includes the names of the constituent counties for each rural and urban area designation. We used the 2015 HH PPS wage index file as the basis for our analysis because the 2015 HH PPS wage index file already included SSA state and county codes not normally included on the HH PPS wage index files, but were included in the 2015 HH PPS wage index file due to the transition to new OMB geographic area delineations that year. The CY 2015 HH PPS wage index file is available for download at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices-Items/CMS-1611-F.html.* This file includes 3,246 counties and equivalent areas and their urban and rural status and uses the OMB's geographic area delineations, as described in section III.C.3 of this proposed rule. We updated the information contained in this file to include any revisions to the geographic area delineations as published by the OMB in their publicly available bulletins that would reflect a change in urban and rural status. The states, the District of Columbia, and the U.S. territories of Guam, Puerto Rico, and the U.S. Virgin Islands are included in the analysis file containing 3,246 counties and equivalent areas. Of the 3,246 total counties and equivalent areas that were used in our analysis, 2,006 of these are considered rural for purposes of determining HH rural add-on payments. We identify equivalent areas based on the definition of equivalent entities as defined by the OMB in their most recent bulletin (No. 18–03) available at *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf.*[13] We consider boroughs and a municipality in Alaska, parishes in Louisiana, municipios in Puerto Rico, and independent cities in

[13] ''Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas''. OMB BULLETIN NO. 18–03. April 10, 2018. *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf.*

Maryland, Missouri, Nevada, and Virginia as equivalent areas.

Under section 421(b)(1)(A) of the MMA, one category of rural counties and equivalent areas for purposes of the HH rural add-on payment is a category comprised of rural counties or equivalent areas that are in the highest quartile of all counties or equivalent areas based on the number of Medicare home health episodes furnished per 100 Medicare beneficiaries. Section 421(b)(2)(B)(i) of the MMA requires the use of data from 2015 to determine which counties or equivalent areas are in the highest quartile of home health utilization for the category described under section 421(b)(1)(A) of the MMA, that is, the ''High utilization'' category. Section 421(b)(2)(B)(ii) of the MMA requires that data from the territories are to be excluded in determining which counties or equivalent areas are in the highest quartile of home health utilization and requires that the territories be excluded from the category described by section 421(b)(1)(A) of the MMA. Under section 421(b)(2)(B)(iii) of the MMA, the Secretary may exclude data from counties or equivalent areas in rural areas with a low volume of home health episodes in determining which counties or equivalent areas are in the highest quartile of home health utilization. If data is excluded for a county or equivalent area, section 421(b)(2)(B)(iii) of the MMA requires that the county or equivalent area be excluded from the category described by section 421(b)(1)(A) of the MMA (the ''High utilization'' category).

We used CY 2015 claims data and 2015 data from the Medicare Beneficiary Summary File to classify rural counties and equivalent areas into the ''High utilization'' category. We propose to classify a rural county or equivalent area into this category if the county or equivalent area is in the highest quartile (top 25th percentile) of all (urban and rural) counties and equivalent areas based on the ratio of Medicare home health episodes furnished per 100 Medicare enrollees. The Medicare Beneficiary Summary File contained information on the Social Security Administration (SSA) state and county code of the beneficiary's mailing address and information on enrollment in Medicare Part A, B, and C during 2015. The claims data and information from the Medicare Beneficiary Summary File were pulled from the Chronic Condition Warehouse Virtual Research Data Center during December 2017. We used the claims data to determine how many home health episodes (excluding Requests for Anticipated Payments (RAPs) and zero payment episodes) occurred in each state and county or equivalent area. We assigned each home health episode to the state and county code of the beneficiary's mailing address. As stipulated by section 421(b)(2)(B)(ii) of the MMA, we excluded any data from the territories of Guam, Puerto Rico, and the U.S. Virgin Islands for determining which rural counties and equivalent areas belong in the ''High utilization'' category. We note that the territories of American Samoa and the Northern Mariana Islands were not included in the CY 2015 HH PPS wage index file to identify counties or equivalent areas for these territories so no data from these territories were included in determining the ''High utilization'' category. As we are not aware of any Medicare home health services being furnished in these two territories in recent years, we will address any application of home health rural add-on payments for these territories in the future should Medicare home health services be furnished in them. Therefore, counties and equivalent areas in the territories of American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands are not included in the ''High utilization'' category, as required by section 421(b)(2)(B)(ii) of the MMA. In addition, under the authority granted to the Secretary (by section 421(b)(2)(B)(iii) of the MMA) to exclude data from counties or equivalent areas in rural areas with a low volume of home health episodes, we excluded data from rural counties and equivalent areas that had 10 or fewer episodes during 2015 for determining which counties and equivalent areas belong in the ''High utilization'' category. We believe that using a threshold of 10 or fewer episodes is a reasonable threshold for defining low volume, in accordance with section 421(b)(2)(B)(iii) of the MMA. After excluding data from (1) the territories of Guam, Puerto Rico, and the U.S. Virgin Islands and (2) counties and equivalent areas that had 10 or fewer episodes during 2015, we determined the number of home health episodes furnished per 100 enrollees for the remaining counties and equivalent areas. We determined that the counties or equivalent areas in the highest quartile have a ratio of episodes to beneficiaries that is at or above 17.72487. The highest quartile consisted of 778 counties or equivalent areas. Of those 778 counties or equivalent areas, 510 are rural and, therefore, we propose to classify these 510 rural counties or equivalent areas into the ''High utilization'' category.

Under section 421(b)(1)(B) of the MMA, another category of rural counties and equivalent areas for purposes of the HH rural add-on payment is a category comprised of rural counties or equivalent areas with a population density of 6 individuals or fewer per square mile of land area and that are not included in the ''High utilization'' category. Section 421(b)(2)(C) of the MMA requires that data from the 2010 decennial Census be used for purposes of determining population density with respect to the category provided under section 421(b)(1)(B) of the MMA, that is, the ''Low population density'' category.

We used 2010 Census data gathered from the tables provided at: *https://factfinder.census.gov/bkmk/table/1.0/en/DEC/10_SF1/GCTPH1.US05PR* and *https://www.census.gov/data/tables/time-series/dec/cph-series/cph-t/cph-t-8.html* to determine which counties and equivalent areas have a population density of six individuals or fewer per square mile of land area.[14] [15] In examining the rural counties and equivalent areas that were not already classified into the ''High utilization'' category, we identified each rural county or equivalent area that had a population density of six individuals or fewer per square mile of land area. As a result of that analysis, we determined there are 334 rural counties or equivalent areas that have a population density of six individuals or fewer per square mile of land area and that are not already classified into the ''High utilization'' category. We propose to classify 334 rural counties or equivalent areas into the ''Low population density'' category.

Lastly, section 421(b)(1)(C) of the MMA provides for a category comprised of rural counties or equivalent areas that are not included in either the ''High utilization'' or the ''Low population density'' category. After determining which rural counties and equivalent areas should be classified into the ''High utilization'' and ''Low population density'' categories, we have determined that there are 1,162 remaining rural counties and equivalent areas that do not meet the criteria for inclusion in the ''High utilization'' or ''Low population density'' categories. We propose to classify these 1,162 rural counties and

[14] ''Population, Housing Units, Area, and Density: 2010—United States—County by State; and for Puerto Rico 2010 Census Summary File 1''. *https://factfinder.census.gov/bkmk/table/1.0/en/DEC/10_SF1/GCTPH1.US05PR.*

[15] ''Population, Housing Units, Land Area, and Density for U.S. Island Areas: 2010 (CPH–T–8)''. 10/28/2013. *https://www.census.gov/data/tables/time-series/dec/cph-series/cph-t/cph-t-8.html.*

equivalent areas into the ''All other'' category.

Section 421(b)(1) of the MMA specifies varying rural add-on payment percentages and varying durations of rural add-on payments for home health services furnished in a rural county or equivalent area according to which category described in section 421(b)(1)(A), 421(b)(1)(B), or 421(b)(1)(C) of the MMA that the rural county or equivalent area is classified into. The rural add-on payment percentages and duration of rural add-on payments are shown in Table 26. The national standardized 60-day episode payment rate, the national per-visit rates, and the NRS conversion factor will be increased by the rural add-on payment percentages as noted in Table 26 when services are provided in rural areas. The HH Pricer module, located within CMS' claims processing system, will increase the base payment rates provided in Tables 18 through 25 by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments.

TABLE 26—HH PPS RURAL ADD-ON PERCENTAGES, CYS 2019–2022

Category	CY 2019 (%)	CY 2020 (%)	CY 2021 (%)	CY 2022 (%)
High utilization	1.5	0.5	.....	.....
Low population density	4.0	3.0	2.0	1.0
All other	3.0	2.0	1.0	.....

Section 421(b)(2)(A) of the MMA provides that the Secretary shall make a determination only for a single time as to which category under sections 421(b)(1)(A), 421(b)(1)(B), or 421(b)(1)(C) of the MMA that a rural county or equivalent area is classified into, and that the determination applies for the entire duration of the period for which rural add-on payments are in place under section 421(b) of the MMA. We propose that our proposed classifications of rural counties and equivalent areas in the ''High utilization'', ''Low population density'', and ''All other'' categories would be applicable throughout the period of rural add-on payments established under section 421(b) of the MMA and there would be no changes in classifications. This would mean that a rural county or equivalent area classified into the ''High utilization'' category would remain in that category through CY 2022 even after rural add-on payments for that category ends after CY 2020. Similarly, a rural county or equivalent area classified into the ''All other'' category would remain in that category through CY 2022 even after rural add-on payments for that category ends after CY 2021. A rural county or equivalent area classified into the ''Low population density'' category would remain in that category through CY 2022.

Section 421(b)(3) of the MMA provides that there shall be no administrative or judicial review of the classification determinations made for the rural add-on payments under section 421(b)(1) of the MMA.

Section 50208(a)(2) of the Bipartisan Budget Act of 2018 amended section 1895(c) of the Act by adding a new requirement set out at section 1895(c)(3) of the Act. This requirement states that no claim for home health services may be paid unless ''in the case of home health services furnished on or after January 1, 2019, the claim contains the code for the county (or equivalent area) in which the home health service was furnished.'' This information will be necessary in order to calculate the rural add-on payments. We are proposing that HHAs enter the FIPS state and county code, rather than the SSA state and county code, on the claim. Many HHAs are more familiar with using FIPS state and county codes since HHAs in a number of States are already using FIPS state and county codes for State-mandated reporting programs. Our analysis is based entirely on the SSA state and county codes as these are the codes that are included in the Medicare Beneficiary Summary File. We cross-walked the SSA state and county codes used in our analysis to the FIPS state and county codes in order to provide HHAs with the corresponding FIPS state and county codes that should be reported on their claims.

The data used to categorize each county or equivalent area is available in the Downloads section associated with the publication of this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices-Items/CMS-1689-P.html.* In addition, an Excel file containing the rural county or equivalent area names, their FIPS state and county codes, and their designation into one of the three rural add-on categories is available for download.

We are soliciting comments regarding our application of the methodology specified by section 50208 of the Bipartisan Budget Act of 2018.

E. Proposed Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or Partial Episode Payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the HH FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost beyond the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act, and required the Secretary to reduce the HH PPS payment rates such that aggregate HH PPS payments were

reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act, and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act which capped outlier payments as a percent of total payments for each HHA at 10 percent.

As such, beginning in CY 2011, we reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we target up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10 percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted that the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care in order to surpass the outlier threshold; and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

We plan to publish the cost-per-unit amounts for CY 2019 in the rate update change request, which is issued after the publication of the CY 2019 HH PPS final rule. We note that in the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, we noted that the per-unit rates used to estimate an episode's cost will be updated by the home health update percentage each year, meaning we would start with the national per-visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We note that we will continue to monitor the visit length by discipline as more recent data become available, and we may propose to update the rates as needed in the future.

2. Proposed Fixed Dollar Loss (FDL) Ratio

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount.

Simulations based on CY 2015 claims data (as of June 30, 2016) completed for the CY 2017 HH PPS final rule showed that outlier payments were estimated to represent approximately 2.84 percent of total HH PPS payments in CY 2017, and as such, we raised the FDL ratio from 0.45 to 0.55. We stated that raising the FDL ratio to 0.55, while maintaining a loss-sharing ratio of 0.80, struck an effective balance of compensating for high-cost episodes while still meeting the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments (81 FR 76726). The national, standardized 60-day episode payment amount is multiplied by the FDL ratio. That amount is wage-adjusted to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

For this proposed rule, simulating payments using preliminary CY 2017 claims data (as of March 2, 2018) and the CY 2018 HH PPS payment rates (82 FR 51676), we estimate that outlier payments in CY 2018 would comprise 2.30 percent of total payments. Based on simulations using CY 2017 claims data (as of March 2, 2018) and the proposed CY 2019 payment rates presented in section III.C.4 of this proposed rule, we estimate that outlier payments would constitute approximately 2.32 percent of total HH PPS payments in CY 2019. Our simulations show that the FDL ratio would need to be changed from 0.55 to 0.51 to pay up to, but no more than, 2.5 percent of total payments as outlier payments in CY 2019.

Given the statutory requirement that total outlier payments not exceed 2.5 percent of the total payments estimated to be made based under the HH PPS, we are proposing to lower the FDL ratio for CY 2019 from 0.55 to 0.51 to better approximate the 2.5 percent statutory maximum. However, we note that we are not proposing a change to the loss-sharing ratio (0.80) for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.). We note that in the final rule, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete year of HH PPS data (CY 2017 claims data as of June 30, 2018 or later) and therefore, we may adjust the final FDL ratio accordingly. We invite public comments on the

proposed change to the FDL ratio for CY 2019.

3. Home Health Outlier Payments: Clinical Example

In recent months, concerns regarding the provision of home health care for Medicare patients with chronic, complex conditions have been raised by stakeholders as well as the press.[16] [17] [18] [19] News stories and anecdotal reports indicate that Medicare patients with chronic conditions may be encountering difficulty in accessing home health care if the goal of home health care is to maintain or prevent further decline of the patient's condition rather than improvement of the patient's condition. While patients must require skilled care to be eligible to receive services under the Medicare home health benefit, as outlined in regulation at 42 CFR 409.42(c), we note that coverage does not turn on the presence or absence of an individual's potential for improvement, but rather on the beneficiary's need for skilled care. Skilled care is covered where such services are necessary to maintain the patient's current condition or prevent or slow further deterioration so long as the beneficiary requires skilled care for the services to be safely and effectively provided. Additionally, there appears to be confusion among the HHA provider community regarding possible Medicare payment through the HH PPS, as it appears that some perceive that payment is somewhat fixed and not able to account for home health stays with higher costs.

The news stories referenced an individual with amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, and the difficulties encountered in finding Medicare home health care. Below we describe a clinical example of how care for a patient with ALS could qualify for an additional outlier payment, which would serve to offset unusually high costs associated with providing home health to a patient with unusual variations in the amount of medically necessary care. This example, using payment policies in place for CY 2018, is provided for illustrative purposes only. We hope that in providing the example below, which illustrates how HHAs could be paid by Medicare for providing care to patients with higher resource use in their homes, and by reiterating that the patient's condition does not need to improve for home health services to be covered by Medicare, that there will be a better understanding of Medicare coverage policies and how outlier payments promote access to home health services for such patients under the HH PPS.

a. Clinical Scenario

Amyotrophic Lateral Sclerosis (ALS) is a progressive neuromuscular degenerative disease. The incidence rates of ALS have been increasing over the last few decades, and the peak incidence rate occurs at age 75.[20] The prevalence rate of ALS in the United States is 4.3 per 100,000 population.[21] Half of all people affected with ALS live at least 3 or more years after diagnosis. Twenty percent live 5 years or more; up to 10 percent will live more than 10 years.[22] Because of the progressive nature of this disease, care needs change and generally intensify as different body systems are affected. As such, patients with ALS often require a multidisciplinary approach to meet their care needs.

The clinical care of a beneficiary with ALS typically includes the ongoing assessment of and treatment for many impacts to the body systems. As a part of a home health episode, a skilled nurse could assess the patient for shortness of breath, mucus secretions, sialorrhea, pressure sores, and pain. From these assessments, the nurse could speak with the doctor about changes to the care plan. A nurse's aide could provide assistance with bathing, dressing, toileting, and transferring. Physical therapy services could also help the patient with range of motion exercises, adaptive transfer techniques, and assistive devices in order to maintain a level of function.

The following is a description of how the provision of services per the home health plan of care could emerge for a beneficiary with ALS who qualifies for the Medicare home health benefit. We note that this example is provided for illustrative purposes only and does not constitute a specific Medicare payment scenario.

b. Example One: Home Health Episodes 1 and 2

A beneficiary with ALS may be assessed by a physician in the community and subsequently be deemed to require home health services for skilled nursing, physical therapy, occupational therapy, and a home health aide. The beneficiary could receive skilled nursing twice a week for 45 minutes to assess dyspnea when transferring to a bedside commode, stage two pressure ulcer at the sacrum, and pain status. In addition, a home health aide could provide services for three hours in the morning and three hours in the afternoon on Monday, Wednesday, and Friday and two and a half hours in the morning and 2.5 hours in the afternoon on Tuesday and Thursdays to assist with bathing, dressing, and transferring. Physical therapy services twice a week for 45 minutes could be provided for adaptive transfer techniques, and occupational therapy services could be supplied twice a week for 45 minutes for assessment and teaching of assistive devices for activities of daily living to prevent or slow deterioration of the patient's condition. Given the patient's clinical presentation, for the purpose of this specific example, we will assign the patient payment group 40331 (C3F3S1 with 20+ therapy visits).

For the purposes of this example, we assume that services are rendered per week for a total of 8 weeks per home health episode. For both the first and second home health episodes of care, the calculation to determine outlier payment utilizing payment amounts and case mix weights for CY 2018, as described in the CY 2018 HH PPS final rule (82 FR 51676), would be as follows, per 60-day episode:

TABLE 27—CLINICAL SCENARIO CALCULATION TABLE: EPISODES 1 AND 2

HH outlier—CY 2018 illustrative values	Value	Operation	Adjuster	Equals	Output
National, Standardized 60-day Episode Payment Rate	$3,039.64				

[16] *https://www.npr.org/sections/health-shots/2018/01/17/578423012/home-care-agencies-often-wrongly-deny-medicare-help-to-the-chronically-ill.*

[17] *http://www.alsa.org/als-care/resources/fyi/medicare-and-home-health-care.html.*

[18] *https://patientworthy.com/2018/01/31/chronically-ill-are-being-denied-medicare-coverage-by-home-care-agencies/.*

[19] *https://alsnewstoday.com/2018/05/09/als-medicare-cover-home-healthcare/.*

[20] Worms PM, The epidemiology of motor neuron diseases: A review of recent studies. J Neurol Sci. 2001;191(1–2):3.

[21] Mehta P, Prevalence of Amyotrophic Lateral Sclerosis—United States, 2012–2013. MMWR Surveill Summ. 2016;65(8):1. Epub 2016 Aug 5.

[22] *http://www.alsa.org.*

TABLE 27—CLINICAL SCENARIO CALCULATION TABLE: EPISODES 1 AND 2—Continued

HH outlier—CY 2018 illustrative values	Value	Operation	Adjuster	Equals	Output
Case-Mix Weight for Payment Group 4.0331 (for C3F3S1 for 20+ therapy) ..	2.1359	.....	.....	.....	.....
Case-Mix Adjusted Episode Payment Amount	3,039.64	*	2.1359	=	6,492.37
Labor Portion of the Case-Mix Adjusted Episode Payment Amount	6,492.37	*	0.78535	–	5,098.78
Non-Labor Portion of the Case-Mix Adjusted Episode Payment Amount	6,492.37	*	0.21465	=	1,393.59
Wage Index Value (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.2781	.....	.....	.....	.....
Wage-Adjusted Labor Portion of the Case-Mix Adjusted Episode Payment Amount	5,098.78	*	1.2781	=	6,516.75
NRS Payment Amount (Severity Level 2)	51.66	.....	.....	=	51.66
Total Case-Mix and Wage-Adjusted Episode Payment Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Episode Payment Amount plus the NRS Amount)	.....	.....	.....	=	7,962.00
Total Wage-Adjusted Fixed Dollar Loss Amount:					
Fixed Dollar Loss Amount (National, Standardized 60-day Episode Payment Rate * FDL Ratio)	3,039.64	*	0.55	=	1,671.80
Labor Portion of the Fixed Dollar Loss Amount	1,671.80	*	0.78535	=	1,312.95
Non-Labor Amount of the Fixed Dollar Loss Amount	1,671.80	*	0.21465	=	358.85
Wage-Adjusted Fixed Dollar Loss Amount	1,312.95	*	1.2781	=	1,678.08
Total Wage-Adjusted Fixed Dollar Loss Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Fixed Dollar Loss Amount)	1,678.08	+	358.85	=	2,036.93
Total Wage-Adjusted Imputed Cost Amount:					
National Per-Unit Payment Amount—Skilled Nursing	48.01	.....	.....	.....	.....
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48	.....	.....	.....	.....
Imputed Skilled Nursing Visit Costs (National Per-Unit Payment Amount * Number of Units)	48.01	*	48	=	2,304.48
National Per-Unit Payment Amount—Home Health Aide	15.46	.....	.....	.....	.....
Number of 15-minute units (28 hours per week = 112 units per week for 8 weeks)	896	.....	.....	.....	.....
Imputed Home Health Aide Costs (National Per-Unit Payment Amount * Number of Units)	15.46	*	896	=	13,852.16
National Per-Unit Payment Amount—Occupational Therapy (OT)	50.26	.....	.....	.....	.....
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48	.....	.....	.....	.....
Imputed OT Visit Costs (National Per-Unit Payment Amount * Number of Units)	50.26	*	48	=	2,412.48
National Per-Unit Payment Amount—Physical Therapy (PT)	50.46	.....	.....	.....	.....
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48	.....	.....	.....	.....
Imputed PT Visit Costs (National Per-Unit Payment Amount * Number of Units)	50.46	*	48	=	2,422.08
Total Imputed Cost Amount for all Disciplines	.....	.....	.....	=	20,991.20
Labor Portion of the Imputed Costs for All Disciplines	20,991.20	*	0.78535	=	16,485.44
Non-Labor Portion of Imputed Cost Amount for All Disciplines	20,991.20	*	0.21465	=	4,505.76
CBSA Wage Index (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.2781	.....	.....	.....	.....
Wage-Adjusted Labor Portion of the Imputed Cost Amount for All Disciplines	16,485.44	*	1.2781	=	21,070.04
Total Wage-Adjusted Imputed Cost Amount (Wage-Adjusted Labor Portion of the Imputed Cost Amount plus Non-Labor Portion of the Imputed Cost Amount)	21,070.04	+	4,505.76	=	25,575.80
Total Payment Per 60-Day Episode:					
Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Episode Payment Amount)	2,036.93	+	7,962.00	=	9,998.93
Total Wage-Adjusted Imputed Cost Amount—Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Episode Payment Amount)	25,575.80	–	9,998.93	=	15,576.87
Outlier Payment = Imputed Costs Greater Than the Outlier Threshold * Loss-Sharing Ratio (0.80)	15,576.87	*	0.80	=	12,461.50
Total Payment Per 60-Day Episode = Total Case-Mix and Wage-Adjusted Episode Payment Amount + Outlier Payment	7,962.00	+	12,461.50	=	20,423.49

For Episodes 1 and 2 of this clinical scenario, the preceding calculation illustrates how HHAs are paid by Medicare for providing care to patients with higher resource use in their homes.

c. Example Two: Home Health Episodes 3 and 4

ALS is a progressive disease such that the patient would most likely need care beyond a second 60-day HH episode. A beneficiary's condition could become more complex, such that the patient could require a gastrostomy tube, which could be placed during a hospital stay. The patient could be discharged to home for enteral nutrition to maintain weight and continuing care for his/her stage two pressure ulcer. Given the complexity of the beneficiary's condition in this example, the episode could remain at the highest level of care C3F3S1 and would now fit into equation 4.

For the purposes of this example, we assume that services are rendered per week for a total of 8 weeks per home health episode. For both the third and fourth home health episodes of care, the calculation to determine outlier payment utilizing payment amounts and case mix weights for CY 2018 as described in as described in the CY 2018 HH PPS final rule (82 FR 51676) would be as follows, per 60-day episode:

TABLE 28—CLINICAL SCENARIO CALCULATION: EPISODES 3 AND 4

HH outlier—CY 2018 illustrative values	Value	Operation	Adjuster	Equals	Output
National, Standardized 60-day Episode Payment Rate	$3,039.64				
Case-Mix Weight for Payment Group 4.0331 (for C3F3S1 for 20+ therapy)	2.1359				
Case-Mix Adjusted Episode Payment Amount	3,039.64	*	2.1359	=	$6,492.37
Labor Portion of the Case-Mix Adjusted Episode Payment Amount	6,492.37	*	0.78535	=	5,098.78
Non-Labor Portion of the Case-Mix Adjusted Episode Payment Amount	6,492.37	*	0.21465	=	1,393.59
Wage Index Value (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.2781				
Wage-Adjusted Labor Portion of the Case-Mix Adjusted Episode Payment Amount	5,098.78	*	1.2781	=	6,516.75
NRS Payment Amount (Severity Level 2)	324.53			=	324.53
Total Case-Mix and Wage-Adjusted Episode Payment Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Episode Payment Amount plus the NRS Amount)				=	8,234.87
Total Wage-Adjusted Fixed Dollar Loss Amount:					
Fixed Dollar Loss Amount (National, Standardized 60-day Episode Payment Rate * FDL Ratio)	3,039.64	*	0.55	=	1,671.80
Labor Portion of the Fixed Dollar Loss Amount	1,671.80	*	0.78535	=	1,312.95
Non-Labor Amount of the Fixed Dollar Loss Amount	1,671.80	*	0.21465	=	358.85
Wage-Adjusted Fixed Dollar Loss Amount	1,312.95	*	1.2781	=	1,678.08
Total Wage-Adjusted Fixed Dollar Loss Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Fixed Dollar Loss Amount)	1,678.08	+	358.85	=	2,036.93
Total Wage-Adjusted Imputed Cost Amount:					
National Per-Unit Payment Amount—Skilled Nursing	48.01				
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48				
Imputed Skilled Nursing Visit Costs (National Per-Unit Payment Amount * Number of Units)	48.01	*	48	=	2,304.48
National Per-Unit Payment Amount—Home Health Aide	15.46				
Number of 15-minute units (28 hours per week = 112 units per week for 8 weeks)	896				
Imputed Home Health Aide Costs (National Per-Unit Payment Amount * Number of Units)	15.46	*	896	=	13,852.16
National Per-Unit Payment Amount—Occupational Therapy (OT)	50.26				
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48				
Imputed OT Visit Costs (National Per-Unit Payment Amount * Number of Units)	50.26	*	48	=	2,412.48
National Per-Unit Payment Amount—Physical Therapy (PT)	50.46				
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48				
Imputed PT Visit Costs (National Per-Unit Payment Amount * Number of Units)	50.46	*	48	=	2,422.08
Total Imputed Cost Amount for all Disciplines				=	20,991.20
Labor Portion of the Imputed Costs for All Disciplines	20,991.20	*	0.78535	=	16,485.44
Non-Labor Portion of Imputed Cost Amount for All Disciplines	20,991.20	*	0.21465	=	4,505.76
CBSA Wage Index (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.2781				
Wage-Adjusted Labor Portion of the Imputed Cost Amount for All Disciplines	16,485.44	*	1.2781	=	21,070.04
Total Wage-Adjusted Imputed Cost Amount (Wage-Adjusted Labor Portion of the Imputed Cost Amount plus Non-Labor Portion of the Imputed Cost Amount)	21,070.04	+	4,505.76	=	25,575.80
Total Payment Per 60-Day Episode:					

TABLE 28—CLINICAL SCENARIO CALCULATION: EPISODES 3 AND 4—Continued

HH outlier—CY 2018 illustrative values	Value	Operation	Adjuster	Equals	Output
Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Episode Payment Amount)	2,036.93	+	8,234.87	=	10,271.80
Total Wage-Adjusted Imputed Cost Amount − Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Episode Payment Amount)	25,575.80	−	10,271.80	=	15,304.00
Outlier Payment = Imputed Costs Greater Than the Outlier Threshold * Loss-Sharing Ratio (0.80)	15,304.00	*	0.80	=	12,243.20
Total Payment Per 60-Day Episode = Total Case-Mix and Wage-Adjusted Episode Payment Amount + Outlier Payment	12,243.20	+	8,234.87	=	20,478.07

For Episodes 3 and 4 of this clinical scenario, the above calculation demonstrates how outlier payments could be made for patients with chronic, complex conditions under the HH PPS. We reiterate that outlier payments could provide payment to HHAs for those patients with higher resource use and that the patient's condition does not need to improve for home health services to be covered by Medicare. We appreciate the feedback we have received from the public on the outlier policy under the HH PPS and look forward to ongoing collaboration with stakeholders on any further refinements that may be warranted. We note that this example is presented for illustrative purposes only, and is not intended to suggest that all diagnoses of ALS should receive the grouping assignment or number of episodes described here. The CMS Grouper assigns these groups based on information in the OASIS.

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

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

a. Background and Legislation

In the CY 2018 HH PPS proposed rule, we proposed an alternative case mix-adjustment methodology (known as the Home Health Groupings Model or HHGM), to be implemented for home health periods of care beginning on or after January 1, 2019. Ultimately this proposed alternative case-mix adjustment methodology, including a proposed change in the unit of payment from 60 days to 30 days, was not finalized in the CY 2018 HH PPS final rule in order to allow us additional time to consider public comments for potential refinements to the methodology (82 FR 51676).

On February 9, 2018, the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) was signed into law. Section 51001(a)(1) of the BBA of 2018 amended section 1895(b)(2) of the Act by adding a new subparagraph (B) to require the Secretary to apply a 30-day unit of service for purposes of implementing the HH PPS, effective January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service that end during the 12-month period beginning January 1, 2020 in a budget neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before, and not affect the application of, the provisions of section 1895(b)(3)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act additionally requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavioral changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavioral assumptions made in notice and comment rulemaking.

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary to annually determine the impact of differences between assumed behavior changes as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year.

Section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for 2020 and subsequent years. Lastly, section 51001(b)(4) of the BBA of 2018 requires the Secretary to pursue notice and comment rulemaking no later than December 31, 2019 on a revised case-mix system for payment of home health services under the HH PPS

b. Overview

To meet the requirement under section 51001(b)(4) of the BBA of 2018 to engage in notice and comment rulemaking on a HH PPS case-mix system and to better align payment with

patient care needs and better ensure that clinically complex and ill beneficiaries have adequate access to home health care, we are proposing case-mix methodology refinements through the implementation of the Patient-Driven Groupings Model (PDGM). The proposed PDGM shares many of the features included in the alternative case mix-adjustment methodology proposed in the CY 2018 HH PPS proposed rule. We propose to implement the PDGM for home health periods of care beginning on or after January 1, 2020. The implementation of the PDGM will require provider education and training, updating and revising relevant manuals, and changing claims processing systems. Implementation starting in CY 2020 would provide opportunity for CMS, its contractors, and the agencies themselves to prepare. This patient-centered model groups periods of care in a manner consistent with how clinicians differentiate between patients and the primary reason for needing home health care. As required by section 1895(b)(2)(B) of the Act, we propose to use 30-day periods rather than the 60-day episode used in the current payment system. In addition, section 1895(b)(4)(B)(ii) of the Act eliminates the use of therapy thresholds in the case-mix adjustment for determining payment. The proposed PDGM does not use the number of therapy visits in determining payment. The change from the current case-mix adjustment methodology for the HH PPS, which relies heavily on therapy thresholds as a major determinant for payment and thus provides a higher payment for a higher volume of therapy provided, to the PDGM would remove the financial incentive to overprovide therapy in order to receive a higher payment. The PDGM would base case-mix adjustment for home health payment solely on patient characteristics, a more patient-focused approach to payment. Finally, the PDGM relies more heavily on clinical characteristics and other patient information (for example, diagnosis, functional level, comorbid conditions, admission source) to place patients into clinically meaningful payment categories. In total, there are 216 different payment groups in the PDGM.

Costs during an episode/period of care are estimated based on the concept of resource use, which measures the costs associated with visits performed during a home health episode/period. For the current HH PPS case-mix weights, we use Wage Weighted Minutes of Care (WWMC), which uses data from the Bureau of Labor Statistics (BLS) reflecting the Home Health Care Service Industry. For the PDGM, we propose shifting to a Cost-Per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from the Medicare Cost Report. The CPM + NRS approach incorporates a wider variety of costs (such as transportation) compared to the BLS estimates and the costs are available for individual HHA providers while the BLS costs are aggregated for the Home Health Care Service industry.

Similar to the current payment system, 30-day periods under the PDGM would be classified as ''early'' or ''late'' depending on when they occur within a sequence of 30-day periods. Under the current HH PPS, the first two 60-day episodes of a sequence of adjacent 60-day episodes are considered early, while the third 60-day episode of that sequence and any subsequent episodes are considered late. Under the PDGM, the first 30-day period is classified as early. All subsequent 30-day periods in the sequence (second or later) are classified as late. We propose to adopt this timing classification for 30-day periods with the implementation of the PDGM for CY 2020. Similar to the current payment system, we propose that a 30-day period could not be considered early unless there was a gap of more than 60 days between the end of one period and the start of another. The comprehensive assessment would still be completed within 5 days of the start of care date and completed no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, Condition of participation: Comprehensive assessment of patients. In addition, the plan of care would still be reviewed and revised by the HHA and the physician responsible for the home health plan of care no less frequently than once every 60 days, beginning with the start of care date, as currently required by § 484.60(c), Condition of participation: Care planning, coordination of services, and quality of care.

Under the PDGM, we propose that each period would be classified into one of two admission source categories —community or institutional— depending on what healthcare setting was utilized in the 14 days prior to home health. The 30-day period would be categorized as institutional if an acute or post-acute care stay occurred in the 14 days prior to the start of the 30-day period of care. The 30-day period would be categorized as community if there was no acute or post-acute care stay in the 14 days prior to the start of the 30-day period of care.

The PDGM would group 30-day periods into categories based on a variety of patient characteristics. We propose grouping periods into one of six clinical groups based on the principal diagnosis. The principal diagnosis reported would provide information to describe the primary reason for which patients are receiving home health services under the Medicare home health benefit. The proposed six clinical groups, are as follows:

- Musculoskeletal Rehabilitation.
- Neuro/Stroke Rehabilitation.
- Wounds—Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care.
- Complex Nursing Interventions.
- Behavioral Health Care (including Substance Use Disorders).
- Medication Management, Teaching and Assessment (MMTA).

Under the PDGM, we propose that each 30-day period would be placed into one of three functional levels. The level would indicate if, on average, given its responses on certain functional OASIS items, a 30-day period is predicted to have higher costs or lower costs. We are proposing to assign roughly 33 percent of periods within each clinical group to each functional level. The criteria for assignment to each of the three functional levels may differ across each clinical group. The proposed functional level assignment under the PDGM is very similar to the functional level assignment in the current payment system. Finally, the PDGM includes a comorbidity adjustment category based on the presence of secondary diagnoses. We propose that, depending on a patient's secondary diagnoses, a 30-day period may receive ''no'' comorbidity adjustment, a ''low'' comorbidity adjustment, or a ''high'' comorbidity adjustment. For low-utilization payment adjustments (LUPAs) under the PDGM, we propose that the LUPA threshold would vary for a 30-day period under the PDGM depending on the PDGM payment group to which it is assigned. For each payment group, we propose to use the 10th percentile value of visits to create a payment group specific LUPA threshold with a minimum threshold of at least 2 for each group.

Figure BBB1 represents how each 30-day period of care would be placed into one of the 216 home health resource groups (HHRGs) under the proposed PDGM for CY 2020.

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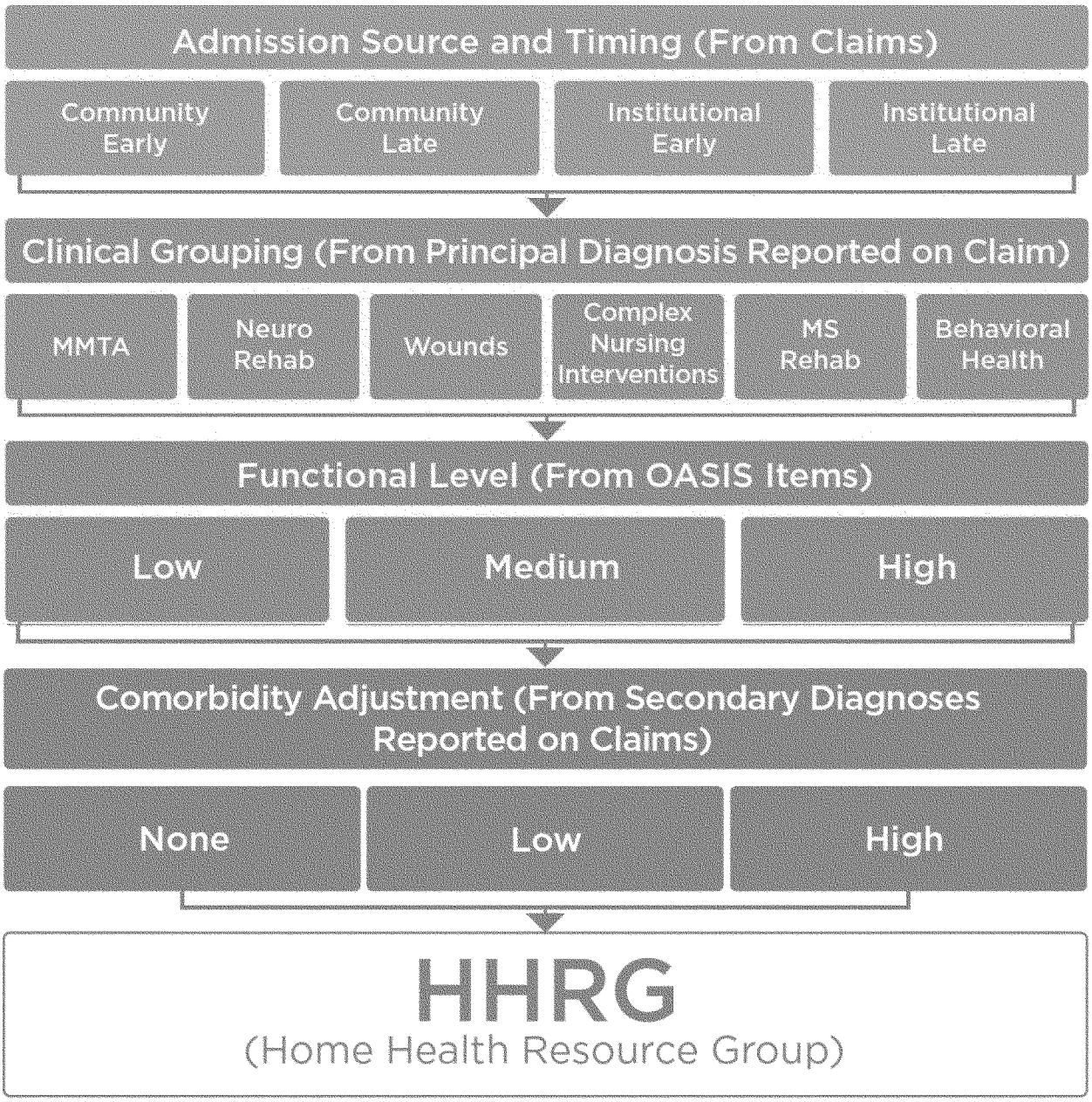
FIGURE 4: STRUCTURE OF THE PDGM



Under the Patient Driven Groupings Model, a 30-day period is grouped into one (and only one) subcategory under each larger colored category. A 30-day period's combination of subcategories places the 30-day period into one of 216 different payment groups.

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c. Data and File Construction

To create the PDGM proposed model and related analyses, a data file based on home health episodes of care as reported in Medicare home health claims was utilized. The claims data provide episode-level data (for example, episode From and Through Dates, total number of visits, HHRG, diagnoses), as well as visit-level data (visit date, visit length in 15-minute units, discipline of the staff, etc.). The claims also provide data on whether NRS was provided during the episode and total charges for NRS.

The core file for most of the analyses for this proposed rule includes 100 percent of home health episode claims with Through Dates in Calendar Year (CY) 2017, processed by March 2, 2018, accessed via the Chronic Conditions Data Warehouse (CCW). Original or adjustment claims processed after March 2, 2018, would not be reflected in the core file. The claims-based file was supplemented with additional variables that were obtained from the CCW, such as information regarding other Part A and Part B utilization.

The data were cleaned by processing any remaining adjustments and by

excluding duplicates and claims that were Requests for Anticipated Payment (RAP). In addition, visit-level variables needed for the analysis were extracted from the revenue center trailers (that is, the line items that describe the visits) and downloaded as a separate visit-level file, with selected episode-level variables merged onto the records for visits during those episodes. To account for potential data entry errors, the visit-level variables for visit length were top-censored at 8 hours.[23]

A set of data cleaning exclusions were applied to the episode-level file, which resulted in the exclusion of the following:

- Episodes that were RAPs.
- Episodes with no covered visits.
- Episodes with any missing units or visit data.
- Episodes with zero payments.
- Episodes with no charges.
- Non-LUPA episodes missing an HHRG.

The analysis file also includes data on patient characteristics obtained from the OASIS assessments conducted by home health agency (HHA) staff at the start of each episode. The assessment data are electronically submitted by HHAs to a central CMS repository. In constructing the core data file, 100 percent of the OASIS assessments submitted October 2016 through December 2017 from the CMS repository were uploaded by CMS to the CCW. A CCW-derived linking key (Bene ID) was used to match the OASIS data with CY 2017 episodes of care. Episodes that could not be linked with an OASIS assessment were excluded from the analysis file, as they included insufficient patient-level data to create the PDGM.

To construct measures of resource use, a variety of data sources were used (see section III.F.2 of this proposed rule for the proposed methodology used to calculate the cost of care under the PDGM). First, BLS data on average wages and fringe benefits were used to produce wage-weighted minutes of care (WWMC), the approach used in the current system to calculate the cost of care. The wage data are for North American Industry Classification System (NAICS) 621600—Home Health Care Services (see Table 29).

TABLE 29—BLS STANDARD OCCUPATION CLASSIFICATION (SOC) CODES FOR HOME HEALTH PROVIDERS

Standard Occupation Code (SOC) No.	Occupation title
29–1141	Registered Nurses.
29–2061	Licensed Practical and Licensed Vocational Nurses.
29–1123	Physical Therapists.
31–2021	Physical Therapist Assistants.
31–2022	Physical Therapist Aides.
29–1122	Occupational Therapists.
31–2011	Occupational Therapist Assistants.
31–2012	Occupational Therapist Aides.
29–1127	Speech-Language Pathologists.
21–1022	Medical and Public Health Social Workers.
21–1023	Mental Health and Substance Abuse Social Workers.
31–1011	Home Health Aides.

The WWMC approach determines resource use for each episode by multiplying utilization (in terms of the number of minutes of direct patient care provided by each discipline) by the corresponding opportunity cost of that care (represented by wage and fringe benefit rates from the BLS).[24] Table 30 shows the occupational titles and corresponding mean hourly wage rates from the BLS. The employer cost per hour worked shown in the fifth column is calculated by adding together the mean hourly wage rates and the fringe benefit rates from the BLS. For home health disciplines that include multiple occupations (such as skilled nursing), the opportunity cost is generated by weighting the employer cost by the proportions of the labor mix.[25] Otherwise, the opportunity cost is the same as the employer cost per hour.

TABLE 30—OCCUPATIONAL EMPLOYMENT AND WAGES PROVIDED BY THE FEDERAL BUREAU OF LABOR STATISTICS

Occupation title	National employment counts	Mean hourly wage	Estimate of benefits as a % of wages	Estimated employer cost per hour worked	Labor mix	Home health discipline	Opportunity cost
Registered Nurses	179,280	$33.34	43.85	$47.96	0.66	Skilled Nursing	$42.42
Licensed Practical and Licensed Vocational Nurses.	85,410	22.03	43.85	31.69	0.34		
Physical Therapists	24,810	47.23	40.92	66.55	0.66	Physical Therapy	58.55
Physical Therapist Assistants.	7,330	31.43	35.79	42.68	0.34		
Occupational Therapists	10,760	45.27	40.92	63.79	0.79	Occupational Therapy	59.97
Occupational Therapist Assistants.	2,270	33.83	35.79	45.94	0.21		
Speech-Language Pathologists.	5,360	47.08	40.92	66.34	.....	Speech Therapy	66.34
Medical and Public Health Social Workers.	18,930	28.76	40.92	40.53	0.97	Medical Social Service	40.42
Mental Health and Substance Abuse Social Workers.	500	25.85	40.92	36.43	0.03		
Home Health Aides	408,920	11.25	35.79	15.28	.....	Home Health Aide	15.28

Source: May 2016 National Industry-Specific Occupational Employment and Wage Estimates—NAICS 621600—Home Health Care Services.

[23] Less than 0.1 percent of all visits were recorded as having greater than 8 hours of service.

[24] Opportunity costs represent the foregone resources from providing each minute of care versus using the resources for another purpose (the next best alternative). Generally, opportunity costs represent more than the monetary costs, but in these analyses, they are proxied using hourly wage rates.

[25] Labor mix represents the percentage of employees with a particular occupational title (as obtained from claims) within a home health discipline. Physical therapist aides and occupational therapist aides were not included in the labor mix.

Home Health Agency Medicare Cost Report (MCR) data for FY 2016 were also used to construct a measure of resource use after trimming out HHAs whose costs were outliers (see section III.F.2 of this proposed rule). These data are used to provide a representation of the average costs of visits provided by HHAs in the six Medicare home health disciplines: Skilled nursing; physical therapy; occupational therapy; speech-language pathology; medical social services; and home health aide services. Cost report data are publicly available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/.* More details regarding how HHA MCR data were used in constructing the CPM+NRS measure of resource use can be found in section III.F.2 of this proposed rule.

A comment submitted in response to the CY 2018 HH PPS proposed rule questioned the trimming process for the Medicare cost report data used to calculate the cost-per-minute plus non-routine supplies (CPM+NRS) methodology used to estimate resource use (outlined in section III.F.2 of this rule). The commenter stated that for rebasing, CMS audited 100 cost reports and the findings of such audits found that costs were overstated by 8 percent and that finding was attributed to the entire population of HHA Medicare cost reports. The commenter questioned if CMS applied the 8 percent ''adjustment factor'' in last year's proposed rule, requested CMS provide the number of cost reports used for the proposed rule, asked if only cost reports of freestanding HHAs were used, and requested that CMS describe what percentage of cost reports did not list any costs for NRS, yet listed NRS charges.

For the calculations in the CY 2018 HH PPS proposed rule, CMS applied the trimming methodology described in detail in the ''Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates'' Report available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Analyses-in-Support-of-Rebasing-and-Updating-the-Medicare-Home-Health-Payment-Rates-Technical-Report.pdf.* This is also the trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284). Of note, for each discipline and for NRS, we also followed the methodology laid out in the ''Rebasing Report'' by trimming out values that fell in the top or bottom 1 percent of the distribution across all HHAs. This included the cost-per-visit values for each discipline and NRS cost-to-charge ratios that fell in the top or bottom 1 percent of the distribution across all HHAs. For this proposed rule, we applied the same trimming methodology.

We included both freestanding and facility-based HHA Medicare cost report data in our rebasing calculations as outlined in the CY 2014 HH PPS proposed and final rules and in our analysis of FY 2015 HHA Medicare cost report data for the CY 2018 HH PPS proposed rule. We similarly included both freestanding and facility-based HHA Medicare cost report data in our analysis of FY 2016 cost report data for this proposed rule. We note that although we found an 8 percent overstatement of costs from the Medicare cost reports audits performed to support the rebasing adjustments, we did not apply an 8 percent adjustment to HHA costs in the CY 2014 HH PPS proposed or final rules. We also did not apply an 8 percent adjustment to the costs in the CY 2018 HH PPS proposed rule or in this proposed rule. The 8 percent overstatement was determined using a small sample size of HHA Medicare cost reports and the CY 2014 HH PPS proposed rule included this information as illustrative only. The information was not used in any cost calculations past or present.

Before trimming, there were 10,394 cost reports for FY 2016. In this proposed rule, we used 7,458 cost reports. Of the 7,458 cost reports, 5,447 (73.4 percent) had both NRS charges and costs, 1,672 (22.4 percent) had neither NRS charges or costs, and 339 (4.5 percent) had NRS charges but no NRS costs. There were no cost reports with NRS costs, but no NRS charges.

The initial 2017 analytic file included 6,771,059 episodes. Of these, 959,410 (14.2 percent) were excluded because they could not be linked to OASIS assessments or because of the claims data cleaning process reasons listed above. This yielded a final analytic file that included 5,811,649 episodes. Those episodes are 60-day episodes under the current payment system, but for the PDGM those 60-day episodes were converted into two 30-day periods. This yielded a final PDGM analytic file that included 10,160,226, 30-day periods. Certain 30-day periods were excluded for the following reasons:

- Inability to merge to certain OASIS items to create the episode's functional level that is used for risk adjustment. For all the periods in the analytic file, there was a look-back through CY 2016 for a period with a Start of Care or Resumption of Care assessment that preceded the period being analyzed and was in the same sequence of periods. If such an assessment was found, it was used to impute responses for OASIS items that were not included in the follow-up assessment. Periods that were linked to a follow-up assessment which did not link to a Start of Care or Resumption of Care assessment using the process described above were dropped (after exclusions, n = 9,471,529).
- No nursing visits or therapy visits (after exclusions, n = 9,287,622).
- LUPAs were excluded from the analysis. Periods that are identified as LUPAs in the current payment system were excluded in the creation of the functional score. Following the creation of the score (and the corresponding levels), case-mix group specific LUPA thresholds were created and episodes/periods were excluded that were below the new LUPA threshold when computing the case-mix weights.[26] Therefore, the final analytic sample included 8,624,776 30-day periods that were used for the analyses in the PDGM.

In response to the CY 2018 HH PPS proposed rule, we received many comments stating there was limited involvement with the industry in the development of the alternative case-mix adjustment methodology. Commenters also stated that they were unable to obtain the necessary data in order to replicate and model the effects on their business. We note that, through notice and comment rulemaking and other processes, stakeholders always have the opportunity to reach out to CMS and provide suggestions for improvement in the payment methodology under the HH PPS. In the CY 2014 HH PPS final rule, we noted that we were continuing to work on improvements to our case-mix adjustment methodology and welcomed suggestions for improving the case-mix adjustment methodology as we continued in our case-mix research (78 FR 72287). The analyses and the ultimate development of an alternative case-mix adjustment methodology was shared with stakeholders via technical expert panels, clinical workgroups, and special open door forums. We also provided high-level summaries on our case-mix methodology refinement work in the HH PPS proposed rules for CYs 2016 and 2017 (80 FR 39839, and 81 FR 76702). A detailed technical report was posted on the CMS website in December of 2016, additional technical expert panel and clinical workgroup webinars were held after the posting of the technical report, and a National Provider call occurred in January 2017

[26] The case-mix group specific LUPA thresholds were determined using episodes that were considered LUPAs under the current payment system.

to further solicit feedback from stakeholders and the general public.[27] [28] As noted above, the CY 2018 HH PPS proposed rule further solicited comments on an alternative case-mix adjustment methodology. Ultimately the proposed alternative case-mix adjustment methodology, including a proposed change in the unit of payment from 60 days to 30 days, was not finalized in the CY 2018 HH PPS final rule in order to allow CMS additional time to consider public comments for potential refinements to the model (82 FR 51676).

On February 1, 2018, CMS convened another TEP, to gather perspectives and identify and prioritize recommendations from industry leaders, clinicians, patient representatives, and researchers with experience with home health care and/or experience in home health agency management regarding the case-mix adjustment methodology refinements described in the CY 2018 HH PPS proposed rule (82 FR 35270), and alternative case-mix models submitted during 2017 as comments to the CY 2018 HH PPS proposed rule. During the TEP, there was a description and solicitation of feedback on the components of the proposed case-mix methodology refinement, such as resource use, 30-day periods, clinical groups, functional levels, comorbidity groups, and other variables used to group periods into respective case-mix groups. Also discussed were the comments received from the CY 2018 HH PPS proposed rule, the creation of case-mix weights, and an open discussion to solicit feedback and recommendations for next steps. This TEP satisfied the requirement set forth in section 51001(b)(1) of the BBA of 2018, which requires that at least one session of such a TEP be held between January 1, 2018 and December 31, 2018. Lastly, section 51001(b)(3) of the BBA of 2018 requires the Secretary to issue a report to the Committee on Ways and Means and Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on the recommendations from the TEP members, no later than April 1, 2019. This report is available on the CMS HHA Center web page at: *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html* and satisfies the requirement of section 51001(b)(3) of the BBA of 2018.

Finally, with respect to comments regarding the availability of data to replicate and model the effects of the PDGM on HHAs, we note that generally the data needed to replicate and model the effects of the proposed PDGM are available by request through the CMS Data Request Center.[29] Although claims data for home health are available on a quarterly and annual basis as Limited Data Set (LDS) files and Research Identifiable Files (RIFs); we note that assessment data (OASIS) are not available as LDS files through the CMS Data Request Center. While CMS is able to provide LDS files in a more expedited manner, it may take several months for CMS to provide RIFs. Therefore, we will provide upon request a Home Health Claims-OASIS LDS file to accompany the CY 2019 HH PPS proposed and final rules. We believe that in making a Home Health Claims-OASIS LDS file available upon request in conjunction with the CY 2019 HH PPS proposed and final rules, this would address concerns from stakeholders regarding data access and transparency in annual ratesetting.

The Home Health Claims-OASIS LDS file can be requested by following the instructions on the following CMS website: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html* and a file layout will be available. This file will contain information from claims data matched with assessment data for CY 2017, both obtained from the Chronic Conditions Data Warehouse (CCW), and each observation in the file will represent a 30-day period of care with variables created that provide information corresponding to both the 30-day period of care and the 60-day episode of care. The file will also contain variables that show the case-mix group that a particular claim would be grouped into under both the new PDGM case-mix methodology and the current case-mix adjustment methodology as well as variables for all the assessment items used for grouping the claim into its appropriate case-mix group under the PDGM and variables used for calculating resource use. Because this Home Health Claims-OASIS LDS file includes variables used for calculating resource use, this file will also include publically available data from home health cost reports and the BLS. Some of the cost data in this file is trimmed and imputed before being used as outlined above. We note that much of the content of the Home Health Claims-OASIS LDS file will be derived from CMS data sources. That is, many elements of claims or elements of OASIS will not be copied to the LDS file as is. For example, we will have variables in the data files that will record the aggregated number of visits and minutes of service by discipline type. We will need to create those aggregates from the line item data available on the claims data. Because we will be taking data from different sources (claims, OASIS, and cost reports/BLS), we will match the data across those sources. Information from claims and costs reports will be linked using the CCN. OASIS assessment data will be linked to those sources using information available both on the claim and OASIS. As noted earlier in this section, any episodes that could not be linked with an OASIS assessment were excluded from the analysis file, as they included insufficient patient-level data to re-group such episodes into one of the 216 case-mix groups under the PDGM.

In addition, similar to the CY 2018 HH PPS proposed rule, we will again provide a PDGM Grouper Tool in conjunction with this proposed rule on CMS' HHA Center web page to allow HHAs to replicate the PDGM methodology using their own internal data.[30] In addition, in conjunction with this proposed rule, we will post a file on the HHA Center web page that contains estimated Home Health Agency-level impacts as a result of the proposed PDGM.

2. Methodology Used To Calculate the Cost of Care

To construct the case-mix weights for the PDGM proposal, the costs of providing care needed to be determined. A Wage-Weighted Minutes of Care (WWMC) approach is used in the current payment system based on data from the BLS. However, we are proposing to adopt a Cost-per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from HHA Medicare Cost Reports and Home Health Claims.

- *Home Health Medicare Cost Report Data:* All Medicare-certified HHAs must report their own costs through publicly-

[27] Abt Associates. ''Overview of the Home Health Groupings Model.'' *Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements.* Cambridge, MA, November 18, 2016. Available at *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

[28] Centers for Medicare & Medicaid Services (CMS). ''Certifying Patients for the Medicare Home Health Benefit.'' MLN Connects™ National Provider Call. Baltimore, MD, December 16, 2016. Slides, examples, audio recording and transcript available at *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-01-18-Home-Health.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=descending.*

[29] *https://www.resdac.org/cms-data/request/cms-data-request-center.*

[30] *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html.*

available home health cost reports maintained by the Healthcare Cost Report Information System (HCRIS). Freestanding HHAs report using a HHA-specific cost report while HHAs that are hospital-based report using the HHA component of the hospital cost reports. These cost reports enable estimation of the cost per visit by provider and the estimated NRS cost to charge ratios. To obtain a more robust estimate of cost, a trimming process was applied to remove cost reports with missing or questionable data and extreme values.[31]

• *Home Health Claims Data:* Medicare home health claims data are used in both the previous WWMC approach and in the CPM+NRS method to obtain minutes of care by discipline of care.

Under the proposed PDGM, we group 30-day periods of care into their case-mix groups taking into account admission source, timing, clinical group, functional level, and comorbidity adjustment. From there, the average resource use for each case-mix group dictates the group's case-mix weight. We propose that resource use be estimated with the cost of visits recorded on the home health claim plus the cost of NRS recorded on the claims. The cost of NRS is generated by taking NRS charges on claims and converting them to costs using a NRS cost to charge ratio that is specific to each HHA. NRS costs are then added to the resource use estimates. That overall resource use estimate is then used to establish the case-mix weights. Similar to the current system, NRS would still be paid prospectively under the PDGM, but the PDGM eliminates the separate case-mix adjustment model for NRS.

Under the proposed alternative case-mix methodology discussed in the CY 2018 HH PPS proposed rule, we proposed to calculate resource use using the CPM+NRS approach (82 FR 35270). In response to the CY 2018 HH PPS proposed rule, several commenters expressed support for the proposed change to the CPM+NRS methodology used to measure resource use, noting that such an approach incorporates a wider variety of costs (such as transportation) compared to the current WWMC approach. Alternatively, other commenters responding to last year's proposed rule objected to using Medicare cost report data rather than Wage-Weighted Minutes of Care (WWMC) to calculate resource use. The commenters indicated that the strength and utility of period-specific cost depends on the accuracy and consistency of agencies' reported charges, cost-to-charge ratios, and period minutes and indicated that they believe there are no incentives for ensuring the accuracy of HHA cost reports, which they believe may result in erroneous data. Several commenters also indicated that the use of cost report data in lieu of WWMC favors facility-based agencies because they believe that facility-based agencies have the ability to allocate indirect overhead costs from their parent facilities to their service cost and argued that the proposed alternative case-mix methodology would reward inefficient HHAs with historically high costs. A few commenters stated that Non-Routine Supplies (NRS) should not be incorporated into the base rate and then wage-index adjusted (as would be the case if CMS were to use the CPM+NRS approach to estimate resource use). The commenters stated that HHAs' supply costs are approximately the same nationally, regardless of rural or urban locations and regardless of the wage-index, and including NRS in the base rate will penalize rural providers and unnecessarily overpay for NRS in high wage-index areas. We note that in accordance with the requirement of section 51001 of the BBA of 2018, a Technical Expert Panel (TEP) convened in February 2018 to solicit 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. We received similar comments on the approach to calculating resource use using the CPM+NRS approach, versus the WWMC approach, bothin response to the CY 2018 HH PPS proposed rule and those provided by the TEP participants.

We believe that using HHA Medicare cost report data, through the CPM+NRS approach, to calculate the costs of providing care better reflects changes in utilization, provider payments, and supply amongst Medicare-certified HHAs. Using the BLS average hourly wage rates for the entire home health care service industry does not reflect changes in Medicare home health utilization that impact costs, such as the allocation of overhead costs when Medicare home health visit patterns change. Utilizing data from HHA Medicare cost reports better represents the total costs incurred during a 30-day period (including, but not limited to, direct patient care contract labor, overhead, and transportation costs), while the WWMC method provides an estimate of only the labor costs (wage and fringe benefit costs) related to direct patient care from patient visits that are incurred during a 30-day period. With regards to accuracy, we note that each HHA Medicare cost report is required to be certified by the Officer or Director of the home health agency as being true, correct, and complete with potential penalties should any information in the cost report be a misrepresentation or falsification of information.

As noted above, and in the CY 2018 HH PPS proposed rule, we applied the trimming methodology described in detail in the ''Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates'' Report. This is also the trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) in determining the rebased national, standardized 60-day episode payment amount. For each discipline and for NRS used in calculating resource use using the CPM+NRS approach, we also followed the methodology laid out in the ''Rebasing Report'' by trimming out values that fall in the top or bottom 1 percent of the distribution across all HHAs. This included the cost per visit values for each discipline and NRS cost-to-charge ratios that fall in the top or bottom 1 percent of the distribution across all HHAs. Normalizing data by trimming out missing or extreme values is a widely accepted methodology both within CMS and amongst the health research community and provides a more robust measure of average costs per visit that is reliable for the purposes of establishing base payment amounts and case-mix weights under the HH PPS. Using HHA Medicare cost report data to establish the case-mix weight aligns with the use of this data in determining the national, standardized 60-day episode payment amount under the HH PPS.

In response to commenters' concerns regarding the allocation of overhead costs by facility-based HHAs, we note that a single HHA's costs impact only a portion of the calculation of the weights and costs are blended together across all HHAs. The payment regression was estimated using 8,624,776 30-day periods from 10,480 providers. On average, each provider contributed 823 30-day periods to the payment regression, which is only 0.010 percent of all 30-day periods. Therefore, including or excluding any single HHA, on average, would not dramatically

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

impact the results of the payment regression. Further, facility-based HHAs are only 8 percent of HHAs whereas 92 percent of HHAs are freestanding, and coincidentally the percentage of 30-day periods furnished by facility-based versus freestanding HHAs is also 8 and 92 percent, respectively. Additionally, in the PDGM, we estimate the payment regression using provider-level fixed effects; therefore we are looking at the within provider variation in resource use.

In the CY 2008 HH PPS final rule, CMS noted that use of non-routine medical supplies is unevenly distributed across episodes of care in home health. In addition, the majority of episodes do not incur any NRS costs and, at that time, the current payment system overcompensated for episodes with no NRS costs. In the CY 2008 HH PPS proposed rule, we stated that patients with certain conditions, many of them related to skin conditions, were more likely to require high non-routine medical supply utilization (72 FR 49850), and that we would continue to look for ways to improve our approach to account for NRS costs and payments in the future (72 FR 25428). We believe that the proposed PDGM offers an alternative method for accounting for NRS costs and payments by grouping patients more likely to require high NRS utilization. For example, while the Wound group and Complex Nursing Interventions groups comprise about 9 percent and 4 percent of all 30-day periods of care, respectively; roughly 27 percent of periods where NRS was supplied were assigned to the Wound and Complex Nursing Interventions groups and 44 percent of NRS costs fall into the Wound and Complex Nursing groups. We note that CY 2017 claims data indicates that about 60 percent of 60-day episodes did not provide any NRS.

In using the CPM + NRS approach to calculate the cost of proving care (resource use), NRS costs are reflected in the average resource use that drives the case-mix weights. If there is a high amount of NRS cost for all periods in a particular group (holding all else equal), the resource use for those periods will be higher relative to the overall average and the case-mix weight will correspondingly be higher. Similar to the current system, NRS would still be paid prospectively under the PDGM, but the PDGM eliminates the separate case-mix adjustment model for NRS. Incorporating the NRS cost into the measure of overall resource use (that is, the dependent variable of the payment model) requires adjusting the NRS charges submitted on claims based on the NRS cost-to-charge ratio from cost report data.

The following steps would be used to generate the measure of resource use under this CPM + NRS approach:

(1) From the cost reports, obtain total costs for each of the six home health disciplines for each HHA.

(2) From the cost reports, obtain the number of visits by each of the six home health disciplines for each HHA.

(3) Calculate discipline-specific cost per visit values by dividing total costs [1] by number of visits [2] for each discipline for each HHA. For HHAs that did not have a cost report available (or a cost report that was trimmed from the sample), imputed values were used as follows:

- A state-level mean was used if the HHA was not hospital-based. The state-level mean was computed using all non-hospital based HHAs in each state.
- An urban nationwide mean was used for all hospital-based HHAs located in a Core-based Statistical Area (CBSA). The urban nation-wide mean was computed using all hospital-based HHAs located in any CBSA.
- A rural nationwide mean was used for all hospital-based HHAs not in a CBSA. The rural nation-wide mean was computed using all hospital-based HHAs not in a CBSA.

(4) From the home health claims data, obtain the average number of minutes of care provided by each discipline across all episodes for a HHA.

(5) From the home health claims data, obtain the average number of visits provided by each discipline across all episodes for each HHA.

(6) Calculate a ratio of average visits to average minutes by discipline by dividing average visits provided [5] by average minutes of care [4] by discipline for each HHA.

(7) Calculate costs per minute by multiplying the HHA's cost per visit [3] by the ratio of average visits to average minutes [6] by discipline for each HHA.

(8) Obtain 30-day period costs by multiplying costs per minute [7] by the total number of minutes of care provided during a 30-day period by discipline. Then, sum these costs across the disciplines for each period.

This approach accounts for variation in the length of a visit by discipline. NRS costs are added to the resource use calculated in [8] in the following way:

(9) From the cost reports, determine the NRS cost-to-charge ratio for each HHA. The NRS ratio is trimmed if the value falls in the top or bottom 1 percent of the distribution across all HHAs from the trimmed sample. Imputation for missing or trimmed values is done in the same manner as it was done for cost per visit (see [3] above).

(10) From the home health claims data, obtain NRS charges for each period.

(11) Obtain NRS costs for each period by multiplying charges from the home health claims data [10] by the cost-to-charge ratio from the cost reports [9] for each HHA.

Resource use is then obtained by:

(12) Summing costs from [8] with NRS costs from [11] for each 30-day period.

Table 31 shows these costs for 30-day periods in CY 2017 (n = 8,624,776). On average, total 30-day period costs as measured by resource use are $1,570.68. The distribution ranges from a 5th percentile value of $296.66 to a 95th percentile value of $3,839.91.

TABLE 31—DISTRIBUTION OF AVERAGE RESOURCE USE USING CPM + NRS APPROACH

[30 Day periods]

Statistics	Mean	N	5th Percentile	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile	95th Percentile
Average Resource Use (CPM + NRS)	$1,570.68	8,624,776	$296.66	$394.31	$679.12	$1,272.18	$2,117.47	$3,107.93	$3,839.91

The distributions and magnitude of the estimates of costs for the CPM + NRS method versus the WWMC method are very different. The differences arise because the CPM + NRS method incorporates HHA-specific costs that represent the total costs incurred during a 30-day period (including overhead costs), while the WWMC method provides an estimate of only the labor costs (wage + fringe) related to direct patient care from patient visits that are incurred during a 30-day period. Those costs are not HHA-specific and do not account for any non-labor costs (such as

transportation costs) or the non-direct patient care labor costs (such as, administration and general labor costs). Because the costs estimated using the two approaches are measuring different items, they cannot be directly compared. However, if the total cost of a 30-day period is correlated with the labor that is provided during visits, the two approaches should be highly correlated. The correlation coefficient (estimated by comparing a 30-day period's CPM + NRS resource use to the same period's WWMC resource use) between the two approaches to calculating resource use is equal to 0.8512 (n = 8,624,776). Therefore, the relationship in relative costs is similar between the two methods.

Using cost report data to develop case-mix weights more evenly weights skilled nursing services and therapy services than the BLS data. Table 32 shows the ratios between the estimated costs per hour for each of the home health disciplines compared with skilled nursing resulting from the CPM + NRS versus WWMC methods. Under the CPM + NRS methodology, the ratio for physical therapy costs per hour to skilled nursing is 1.14 compared with 1.36 using the WWMC method.

TABLE 32—RELATIVE VALUES IN COSTS PER HOUR BY DISCIPLINE

[Skilled nursing is base]

Estimated cost per hour	Skilled nursing	Physical therapy	Occupational therapy	Speech therapy	Medical social service	Home health aide
CPM + NRS	1.00	1.14	1.15	1.25	1.39	0.40
WWMC	1.00	1.36	1.38	1.56	0.94	0.35

In response to the CY 2018 HH PPS proposed rule (82 FR 35270), a few commenters, stated that based on their operational experiences with clinical staffing labor costs, HHA cost report data suggests more parity exists between skilled nursing (''SN'') versus physical therapist (''PT'') costs than in fact exists. Commenters stated that BLS data showing a 40 percent difference between SN and PT costs are more reflective of the human resources experiences in the markets where they operate. As such, commenters believe the use of cost report data would cause the proposed alternative case-mix methodology to overpay for nursing services and underpay for therapy services, although it was not clear from the comments why the relative relationship in cost between disciplines would necessarily mean that nursing would be overpaid or underpaid relative to therapy.

We note that the HHA Medicare cost report data reflects all labor costs, including contract labor costs. The BLS data only reflects employed staff. This may partially explain why a 40 percent variation between SN and PT costs is not evident in the cost report data. However, the comparison is somewhat inappropriate because the BLS data only reflects labor costs whereas the HHA Medicare cost report data includes labor and non-labor costs. As noted earlier in Table 32, there is only a 14 percent variation using the CPM + NRS methodology. Moreover, in aggregate, about 15 percent of compensation costs are contract labor costs and this varies among the disciplines with contract labor costs accounting for a much higher proportion of therapy visit costs compared to skilled nursing visit costs. Utilization also varies among freestanding providers with smaller providers having a higher proportion of contract labor costs, particularly for therapy services compared to larger providers. The decision of whether to/or what proportion of contract labor to use is at the provider's discretion. Finally, we note that in order to be eligible for Medicare HH PPS payments, providers must complete the HHA Medicare cost report and certify the report by the Officer or Director of the home health agency as being true, correct, and complete; therefore, such data can and should be used to calculate the cost of care.

We have determined that using cost report data to calculate the cost of home health care better aligns the case-mix weights with the total relative cost for treating various patients. In addition, using cost report data allows us to incorporate NRS into the case-mix system, rather than maintaining a separate payment system. Therefore, we are re-proposing to calculate the cost of a 30-day period of home health care under the proposed PDGM using the cost per minute plus non-routine supplies (CPM + NRS) approach outlined above, as also outlined in the CY 2018 proposed rule. We invite comments on the proposed methodology for calculating the cost of a 30-day period of care under the PDGM.

3. Change From a 60-Day to a 30-Day Unit of Payment

a. Background

Currently, HHAs are paid for each 60-day episode of home health care provided. In the CY 2018 HH PPS proposed rule, CMS proposed a change from making payment based on 60-day episodes to making payment based on 30-day periods, effective for January 1, 2019. Examination of the resources used within a 60-day episode of care identified differences in resources used between the first 30-day period within a 60-day episode and the second 30-day period within a 60-day episode. Episodes have more visits, on average, during the first 30 days compared to the last 30 days and costs are much higher earlier in the episode and lesser later on; therefore, dividing a single 60-day episode into two 30-day periods more accurately apportioned payments. In addition, with the proposed removal of therapy thresholds from the case-mix adjustment methodology under the HH PPS, a shorter period of care reduced the variation and improved the accuracy of the case-mix weights generated under the PDGM. CMS did not finalize the implementation of a 30-day unit of payment in the CY 2018 HH PPS final rule (82 FR 51676).

Section 1895(b)(2)(B) of the Act, as added by section 51001(a)(1) of the BBA of 2018, requires the Secretary to apply a 30-day unit of service for purposes of implementing the HH PPS, effective January 1, 2020. We note that we interpret the term ''unit of service'' to be synonymous with ''unit of payment'' and will henceforth refer to ''unit of payment'' in this proposed rule with regards to payment under the HH PPS. We propose to make HH payments based on a 30-day unit of payment effective January 1, 2020. While we are proposing to change to a 30-day unit of payment, we note that the comprehensive assessment would still be completed within 5 days of the start of care date and completed no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, Condition of participation: Comprehensive assessment of patients.

In addition, the plan of care would still be reviewed and revised by the HHA and the physician responsible for the home health plan of care no less frequently than once every 60 days, beginning with the start of care date, as currently required by § 484.60(c), Condition of participation: Care planning, coordination of services, and quality of care.

b. 30-Day Unit of Payment

Under section 1895(b)(3)(A)(iv) of the Act, we are required to calculate a 30-day payment amount for CY 2020 in a budget neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of payment. Furthermore, as also required by section 1895(b)(3)(A)(iv) of the Act, to calculate a 30-day payment amount in a budget-neutral manner, we are required to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment. In addition, in calculating a 30-day payment amount in a budget-neutral manner, we must take into account behavior changes that could occur as a result of the case-mix adjustment factors that are implemented in CY 2020. We are also required to calculate a budget-neutral 30-day payment amount before the provisions of section 1895(b)(3)(B) of the Act are applied, that is, the home health applicable percentage increase, the adjustment for case-mix changes, the adjustment if quality data is not reported, and the productivity adjustment.

In calculating the budget-neutral 30-day payment amount, we propose to make three assumptions about behavior change that could occur in CY 2020 as a result of the implementation of the 30-day unit of payment and the implementation of the PDGM case-mix adjustment methodology outlined in this proposed rule:

- *Clinical Group Coding:* A key component of determining payment under the PDGM is the 30-day period's clinical group assignment, which is based on the principal diagnosis code for the patient as reported by the HHA on the home health claim. Therefore, we assume that HHAs will change their documentation and coding practices and would put the highest paying diagnosis code as the principal diagnosis code in order to have a 30-day period be placed into a higher-paying clinical group. While we do not support or condone coding practices or the provision of services solely to maximize payment, we often take into account expected behavioral effects of policy changes related to the implementation of the proposed rule.
- *Comorbidity Coding:* The PDGM further adjusts payments based on patients' secondary diagnoses as reported by the HHA on the home health claim. While the OASIS only allows HHAs to designate 1 primary diagnosis and 5 secondary diagnoses, the home health claim allows HHAs to designate 1 principal diagnosis and 24 secondary diagnoses. Therefore, we assume that by taking into account additional ICD–10–CM diagnosis codes listed on the home health claim (beyond the 6 allowed on the OASIS), more 30-day periods of care will receive a comorbidity adjustment than periods otherwise would have received if we only used the OASIS diagnosis codes for payment. The comorbidity adjustment in the PDGM can increase payment by up to 20 percent.
- *LUPA Threshold:* Rather than being paid the per-visit amounts for a 30-day period of care subject to the low-utilization payment adjustment (LUPA) under the proposed PDGM, we assume that for one-third of LUPAs that are 1 to 2 visits away from the LUPA threshold HHAs will provide 1 to 2 extra visits to receive a full 30-day payment.[32] LUPAs are paid when there are a low number of visits furnished in a 30-day period of care. Under the PDGM, the LUPA threshold ranges from 2–6 visits depending on the case-mix group assignment for a particular period of care (see section F.9 of this proposed rule for the LUPA thresholds that correspond to the 216 case-mix groups under the PDGM).

Table 33 includes estimates of what the 30-day payment amount would be for CY 2019 (using CY 2017 home health utilization data) in order to achieve budget neutrality both with and without behavioral assumptions and including the application of the proposed home health payment update percentage of 2.1 percent outlined in section C.2 of this proposed rule. We note that these are only estimates to illustrate the 30-day payment amount if we had proposed to implement the 30-day unit of payment and the proposed PDGM for CY 2019. However, because we are proposing to implement the 30-day unit of payment and proposed PDGM for CY 2020, we would propose the actual 30-day payment amount in the CY 2020 HH PPS proposed rule calculated using CY 2018 home health utilization data, and we would calculate this amount before application of the proposed home health update percentage required for CY 2020 (as required by section 1895(b)(3)(iv) of the Act). In order to calculate the budget neutral 30-day payment amounts in this proposed rule, both with and without behavioral assumptions, we first calculated the total, aggregate amount of expenditures that would occur under the current case-mix adjustment methodology (as described in section III.B. of this rule) and the 60-day episode unit of payment using the proposed CY 2019 payment parameters (*e.g.,* proposed 2019 payment rates, proposed 2019 case-mix weights, and outlier fixed-dollar loss ratio). That resulted in a total aggregate expenditures target amount of $16.1 billion.[33] We then calculated what the 30-day payment amount would need to be set at in CY 2019, with and without behavior assumptions, while taking into account needed changes to the outlier fixed-dollar loss ratio under the PDGM in order to pay out no more than 2.5 percent of total HH PPS payments as outlier payments (refer to section III.F.12 of this proposed rule) and in order for Medicare to pay out $16.1 billion in total expenditures in CY 2019 with the application of a 30-day unit of payment under the PDGM.

[32] Current data suggest that what would be about ⅓ of the LUPA episodes with visits near the LUPA threshold move up to become non-LUPA episodes. We assume this experience will continue under the PDGM, with about ⅓ of those episodes 1 or 2 visits below the thresholds moving up to become non-LUPA episodes.

[33] The initial 2017 analytic file included 6,771,059 60-day episodes ($18.2 billion in total expenditures). Of these, 959,410 (14.2 percent) were excluded because they could not be linked to OASIS assessments or because of the claims data cleaning process reasons listed in section III.F.1 of this proposed rule. We note that of the 959,410 claims excluded, 620,336 were excluded because they were RAPs without a final claim or they were claims with zero payment amounts, resulting in $17.4 billion in total expenditures. After removing all 959,410 excluded claims, the 2017 analytic file consisted of 5,811,649 60-day episodes ($16.4 billion in total expenditures). 60-day episodes of duration longer than 30 days were divided into two 30-day periods in order to calculate the 30-day payment amounts. As noted in section III.F.1 of this proposed rule, there were instances where 30-day periods were excluded from the 2017 analytic file (for example, we could not match the period to a start of care or resumption of care OASIS to determine the functional level under the PDGM, the 30-day period did not have any skilled visits, or because information necessary to calculate payment was missing from claim record). The final 2017 analytic file used to calculate budget neutrality consisted of 9,285,210 30-day periods ($16.1 billion in total expenditures) drawn from 5,456,216 60-day episodes.

TABLE 33—ESTIMATES OF 30-DAY BUDGET-NEUTRAL PAYMENT AMOUNTS

Behavioral assumption	30-day budget neutral (BN) standard amount	Percent change from no behavioral assumptions
No Behavioral Assumptions	$1,873.91	
LUPA Threshold (⅓ of LUPAs 1–2 visits away from threshold get extra visits and become case-mix adjusted)	1,841.05	−1.75
Clinical Group Coding (among available diagnoses, one leading to highest payment clinical grouping classification designated as principal)	1,793.69	−4.28
Comorbidity Coding (assigns comorbidity level based on comorbidities appearing on HHA claims and not just OASIS)	1,866.76	−0.38
Clinical Group Coding + Comorbidity Coding	1,786.54	−4.66
Clinical Group Coding + Comorbidity Coding + LUPA Threshold	1,753.68	−6.42

If no behavioral assumptions were made, we estimate that the 30-day payment amount needed to achieve budget neutrality would be $1,873.91. The clinical group and comorbidity coding assumptions would result in the need to decrease the budget-neutral 30-day payment amount to $1,786.54 (a 4.66 percent decrease from $1,873.91). Adding the LUPA assumption would require us to further decrease that amount to $1,753.68 (a 6.42 percent decrease from $1,873.91).

We note that we are also required under section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, to analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and new case-mix adjustment methodology, to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. We interpret actual behavior change to encompass both behavior changes that were outlined above, as assumed by CMS when determining the budget-neutral 30-day payment amount for CY 2020, and other behavior changes not identified at the time the 30-day payment amount for CY 2020 is determined. The data from CYs 2020 through 2026 will be available to determine whether a prospective adjustment (increase or decrease) is needed no earlier than in years 2022 through 2028 rulemaking. As noted previously, under section 1895(b)(3)(D)(ii) of the Act, we are required to provide one or more permanent adjustments to the 30-day payment amount on a prospective basis, if needed, to offset increases or decreases in estimated aggregate expenditures as calculated under section 1895(b)(3)(D)(i) of the Act. Clause (iii) of section 1895(b)(3)(D) of the Act requires the Secretary to make temporary adjustments to the 30-day payment amount, on a prospective basis, in order to offset increases or decreases in estimated aggregate expenditures, as determined under clause (i) of such section. The temporary adjustments allow us to recover excess spending or give back the difference between actual and estimated spending (if actual is less than estimated) not addressed by permanent adjustments. For instance, if expenditures are estimated to be $18 billion in CY 2020, but expenditures are actually $18.25 billion in CY 2020, then we can reduce payments (temporarily) in the future to recover the $250 million.

As noted above, section 1895(b)(3)(A)(iv) of the Act requires the Secretary to calculate a budget-neutral 30-day payment amount to be paid for home health units of service that are furnished and end during the 12-month period beginning January 1, 2020. For implementation purposes, we propose that the 30-day payment amount would be paid for home health services that start on or after January 1, 2020. More specifically, for 60-day episodes that begin on or before December 31, 2019 and end on or after January 1, 2020 (episodes that would span the January 1, 2020 implementation date), payment made under the Medicare HH PPS would be the CY 2020 national, standardized 60-day episode payment amount. For home health units of service that begin on or after January 1, 2020, the unit of service would now be a 30-day period and payment made under the Medicare HH PPS would be the CY 2020 national, standardized prospective 30-day payment amount. For home health units of service that begin on or after December 2, 2020 through December 31, 2020 and end on or after January 1, 2021, the HHA would be paid the CY 2021 national, standardized prospective 30-day payment amount.

We are soliciting comments on our proposals, including the proposed behavior change assumptions outlined above to be used in determining the 30-day payment amount for CY 2020 and the corresponding regulation text changes outlined in section III.F.13 and IX. of this proposed rule.

c. Split Percentage Payment Approach for a 30-Day Unit of Payment

In the current HH PPS, there is a split percentage payment approach to the 60-day episode. The first bill, a Request for Anticipated Payment (RAP), is submitted at the beginning of the initial episode for 60 percent of the anticipated final claim payment amount. The second, final bill is submitted at the end of the 60-day episode for the remaining 40 percent. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes are paid at a 50/50 percentage payment split.

In the CY 2018 HH PPS proposed rule (82 FR 35270), we solicited comments as to whether the split payment approach would still be needed for HHAs to maintain adequate cash flow if the unit of payment changes from 60-day episodes to 30-day periods of care. In addition, we solicited comments on ways to phase-out the split percentage payment approach in the future. Specifically, we solicited comments on reducing the percentage of the upfront payment over a period of time and if in the future the split percentage approach was eliminated, we solicited comments on the need for HHAs to submit a notice of admission (NOA) within 5 days of the start of care to assure being established as the primary HHA for the beneficiary and so that the claims processing system is alerted that a beneficiary is under a HH period of care to enforce the consolidating billing edits as required by law. Commenters generally expressed support for continuing the split percentage payment approach in the future under the proposed alternative case-mix model. While we solicited comments on the possibility of phasing-out the split percentage payment approach in the future and the need for a NOA, commenters did not provide suggestions for a phase-out approach, but stated that they did not agree with requiring a NOA given the

experience with such a process under the Medicare hospice benefit.

While CMS did not finalize the implementation of a 30-day unit of payment in the CY 2018 HH PPS final rule (82 FR 51676), the BBA of 2018 now requires a change to the unit of payment from a 60-day episode to a 30-day period of care, as outlined in section F.3.b above, effective January 1, 2020. We continue to believe that as a result of the reduced timeframe for the unit of payment, that a split percentage approach to payment may not be needed for HHAs to maintain adequate cash flow. Currently, about 5 percent of requests for anticipated payment are not submitted until the end of a 60-day episode of care and the median length of days for RAP submission is 12 days from the start of the 60-day episode. As such, we are reevaluating the necessity of RAPs for existing and newly-certified HHAs versus the risks they pose to the Medicare program.

RAP payments can result in program integrity vulnerabilities. For example, a final claim was never submitted for $321 million worth of RAP payments between July 1, 2015 and July 31, 2016. While CMS typically can recoup RAP overpayments from providers that continue to submit final claims to the Medicare program, some fraud schemes have involved collecting these RAP payments, never submitting final claims, and closing the HHA before Medicare can take action. Below are two examples of HHAs that were identified for billing large amounts of RAPs with no final claim:

- Provider 1 is a Home Health Agency located in Michigan. It was identified for submitting home health claims for beneficiaries located in California and Florida. Further analysis found that the HHA was submitting RAPs with no final claims. CMS discovered that the address on record for the HHA was vacant for an extended period of time. In addition, CMS determined that although Provider 1 had continued billing and receiving payments for RAP claims, it had not submitted a final claim in 10 months. Ultimately, the HHA submitted a total of $50,234,430.36 in RAP payments and received $37,204,558.80 in RAP payments. In addition to the large amount of money paid to the HHA, Medicare beneficiaries were also impacted by the HHA's billing behavior. For example, a Florida beneficiary who needed home health services was unable to receive the care required due to the RAP submission by this Provider.
- Provider 2 is a Home Health Agency that is also located in Michigan that submitted a significant number of RAPs with no final claim. While the majority of these beneficiaries were located in Michigan, data analysis identified beneficiaries who were not likely homebound or qualified for home health services. CMS discovered that the address on record for the HHA was vacant. Provider 2 had not submitted any final claims in more than one year and was no longer billing the Medicare program. However, the HHA was paid a total of $5,765,261.04 in RAP payments that had no final claim.

Given the program integrity concerns outlined above and the reduced timeframe for the unit of payment (30-days rather than 60-days), we are proposing not to allow newly-enrolled HHAs, that is HHAs certified for participation in Medicare effective on or after January 1, 2019, to receive RAP payments beginning in CY 2020. This would allow newly-enrolled HHAs to structure their operations without becoming dependent on a partial, advanced payment and take advantage of receiving full payments for every 30-day period of care. We are proposing that HHAs, that are certified for participation in Medicare effective on or after January 1, 2019, would still be required to submit a ''no pay'' RAP at the beginning of care in order to establish the home health episode, as well as every 30-days thereafter. RAP submissions are currently operationally significant as the RAP establishes the HHA as the primary HHA for the beneficiary during that timeframe and alerts the claims processing system that a beneficiary is under the care of an HHA to enforce the consolidating billing edits required by law under section 1842(b)(6)(F) of the Act. Without such notification, there would be an increase in denials of claims subject to the home health consolidated billing edits that are prevented when an episode/period is established in the common working file (CWF) by the RAP, potentially resulting in increases in appeals, and increases in situations where other providers, including other HHAs, would not have easy information on whether a patient was already being served by an HHA. CMS invites comments on whether the burden of submitting a ''no-pay'' RAP by newly-enrolled HHAs outweighs the risks to the Medicare program and providers associated with not submitting them.

We propose that existing HHAs, that is HHAs certified for participation in Medicare with effective dates prior to January 1, 2019, would continue to receive RAP payments upon implementation of the 30-day unit of payment and the proposed PDGM case-mix adjustment methodology in CY 2020. However, we are again soliciting comments on ways to phase-out the split percentage payment approach in the future given that CMS is required to implement a 30-day unit of payment beginning on January 1, 2020 as outlined above. Specifically, we are soliciting comments on reducing the percentage of the upfront payment incrementally over a period of time. If in the future the split percentage approach was eliminated, we are also soliciting comments on the need for HHAs to submit a NOA within 5 days of the start of care to assure being established as the primary HHA for the beneficiary during that timeframe and so that the claims processing system is alerted that a beneficiary is under a HH period of care to enforce the consolidating billing edits as required by law. As outlined above, there are significant drawbacks to both Medicare and providers of not establishing a NOA process upon elimination of RAPs.

In summary, we invite comments on the change in the unit of payment from a 60-day episode of care to a 30-day period of care; the proposed calculation of the 30-day payment amount in a budget-neutral manner and behavior change assumptions for CY 2020; the proposed interpretation of the statutory language regarding actual behavior change; the proposal not to allow newly-enrolled HHAs (HHAs certified for participation in Medicare effective on or after January 1, 2019) to receive RAP payments upon implementation of the 30-day unit of payment in CY 2020, yet still require the submission of a ''no pay'' RAP at the beginning of care; the proposal to maintain the split percentage payment approach for existing HHAs and applying such policy to 30-day periods of care; and the associated regulations text changes outlined in section III.F.13 and IX of this proposed rule. We are also soliciting comments on ways the split percentage payment approach could be phased-out and whether to implement a NOA process if the split percentage payment approach is eliminated in the future.

4. Timing Categories

In the CY 2018 HH PPS proposed rule, we described analysis showing the impact of timing on home health resource use and proposed to classify the 30-day periods under the proposed alternative case-mix adjustment methodology as ''early'' or ''late'' depending on when they occur within a sequence of 30-day periods (82 FR 35307). Under the current HH PPS, the first two 60-day episodes of a sequence of adjacent 60-day episodes are considered early, while the third 60-day

episode of that sequence and any subsequent episodes are considered late. Under the alternative case-mix adjustment methodology, we proposed that the first 30-day period would be classified as early and all subsequent 30-day periods in the sequence (second or later) would be classified as late. Similar to the current payment system, we proposed that a 30-day period could not be considered early unless there was a gap of more than 60 days between the end of one period and the start of another, or it was the first period in a sequence of periods in which there was no more than 60 days between the end of that period and the start of the next period.

In response to the CY 2018 HH PPS proposed rule, several commenters were supportive of the inclusion of the timing category in the alternative case-mix adjustment methodology, stating that this differentiation would reflect that HHA costs are typically highest during the first 30 days of care. However, other commenters expressed concerns regarding timing, stating that HHAs may modify the ways in which they provide care, that the change would cause a decrease in overall payment to HHAs and an increase in hospital readmissions, and that the categories would not account for increased costs in the later periods of care. Several commenters described concerns regarding the potential for problematic provider behavior due to financial incentives as well as the potential for problems with operational aspects of the timing element of the alternative case-mix adjustment methodology. Additionally, some commenters suggested that we modify the definition of an ''early'' 30-day period to either the first two 30-day periods or the first four 30-days of care, stating that those definitions would more closely mirror the current payment system's definition of ''early'' and that HHAs would otherwise experience a payment decrease when compared to the current 60-day episode payment amount.

As described in detail in the CY 2018 HH PPS proposed rule, our proposal regarding the timing element of the alternative case-mix adjustment methodology was intended to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the HH PPS (82 FR 35270). Analysis of home health data demonstrates that under the current payment system, when analyzed by 30-day periods, HHAs provide more resources in the first 30-day period of home health (''early'') than in later periods of care. The differences in the average resource use during early and late home health episodes when divided into 30-day periods are presented in Table 34, and shows the first 30-day periods in a home health sequence have significantly higher average resource use at $2,113.66 as compared with subsequent 30-day periods. Specifically, the later 30-day periods showed an average resource use of $1,311.73, a difference of more than $800 or a 38 percent decrease. Table 34 also shows a significant difference between the early and late median values of resource use. The median for the first 30-day period is $1,866.79, while the median for subsequent 30-day periods is $987.94, a difference of more than $878 or an approximately 47 percent decrease.

TABLE 34—AVERAGE RESOURCE USE BY TIMING

[30-Day periods]

Timing	Average resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Early 30-Day Periods	$2,113.66	2,785,039	32.3	$1,236.30	$1,232.23	$1,866.79	$2,707.04
Late 30-Day Periods	1,311.73	5,839,737	67.7	1,125.44	534.82	987.94	1,735.69
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).

There is significant difference in the resource utilization between early and late 30-day periods as demonstrated in Table 34. Moreover, the predictive power of the proposed PDGM in terms of estimating resource utilization improved when separating episodes into 30-day periods rather than 60-day periods (that is, the first and second 30-day periods). We believe that a PDGM that accounts for the demonstrated increase in resource utilization in the first 30-day period better captures the variations in resource utilization and further promotes the goal of payment accuracy within the HH PPS.

Moreover, we note that the resource cost estimates are derived from a very large, representative dataset. Therefore, we expect that the proposal reflects agencies' average costs for all home health service delivered in the period examined. We have constructed the revised case-mix adjustment model based upon the actual resources expended by home health agencies for Medicare beneficiaries, which show that typically HHAs provide more visits during the first 30 days of care and utilize less resources thereafter. We reiterate that the timing categories are reflective of the utilization patterns observed in the data analyzed for the purposes of constructing the PDGM. The weights of the two timing categories are driven by the mix of services provided, the costs of services provided as determined by cost report data, the length of the visits, and the number of visits provided. The categorization of 30-day periods as ''early'' and ''late'' serves to better align payments with already existing resource use patterns. This alignment of payment with resource use is not to be interpreted as placing a value judgment on particular care patterns or patient populations. Our goal in developing the PDGM is to provide an appropriate payment based on the identified resource use of different patient groups, not to encourage, discourage, value, or devalue one type of skilled care over another.

For the reasons described above, we are proposing to classify the 30-day periods under the proposed PDGM as ''early'' or ''late'' depending on when they occur within a sequence of 30-day periods. For the purposes of defining ''early'' and ''late'' periods for the proposed PDGM, we are proposing that only the first 30-day period in a sequence of periods be defined as ''early'' and all other subsequent 30-day periods would be considered ''late''. Additionally, we are proposing that the definition of a ''home health sequence'' (as currently described in § 484.230) will remain unchanged relative to the current system, that is, 30-day periods are considered to be in the same sequence as long as no more than 60 days pass between the end of one period and the start of the next, which is consistent with the definition of a ''home health spell of illness'' described at section 1861(tt)(2) of the Act. We note

that because section 1861(tt)(2) of the Act is a definition related to eligibility for home health services as described at section 1812(a)(3) of the Act, it does not affect or restrict our ability to implement a 30-dayunit of payment.

At this time, the data do not support the notion that the first two 30-day periods should be defined as early, as only the first 30-day period presents marked increase in resource use. We believe the PDGM's definition of ''early'' as the first 30-day period most accurately reflects agencies' average costs for patients with characteristics measured on the OASIS and used in defining payment groups and supports the shift from the current ''early'' category as defined by two 60-day episodes. We continue to believe that a PDGM that accounts for the actual, demonstrated increase in resource utilization in the first 30-day period better captures the variations in resource utilization.

Additionally, in our CY 2008 HH PPS final rule, we implemented an ''early'' and ''late'' distinction in the HH PPS in which the late episode groupings were weighted more heavily than those episodes designated as early due to heavier resource use during later episodes (72 FR 49770). At that time, commenters expressed concerns that this heavier weighting for later episodes could lead to gaming by providers, with patients on service longer than would be appropriate, and providers not discharging patients when merited. During our analysis in support of subsequent refinements to the HH PPS in 2015, we analyzed the utilization patterns observed in the CY 2013 claims data and observed that the resource use for later episodes had indeed shifted such that later episodes had less resource use than earlier periods, which was the opposite of the pattern observed prior to CY 2008. Furthermore, in its 2016 Report to Congress, MedPAC noted that, between 2002 and 2014, a pattern in home health emerged where the number of episodes of care provided to home health beneficiaries trended upwards, with the average number of episodes per user increasing by 18 percent, rising from 1.6 to 1.9 episodes per user.[34] MedPAC noted that this upward trajectory coincided with, among other changes, higher payments for the third and later episodes in a consecutive spell of home health episodes. Given the longitudinal variation in terms of resource provision during home health episodes, we believe that restricting the ''early'' definition to the first 30-day period is most appropriate for this facet of the PDGM. Our analysis of home health resource use as well as comments from the public that confirm that more resources are provided in the first 30 days provide compelling evidence to limit the definition of early to the first 30-day period.

Moreover, the public comments we received in response to the CY 2018 HH PPS proposed rule presented conflicting predictions regarding anticipated provider behavior in response to the implementation of the alternative case-mix adjustment methodology. Several commenters stated that they expected providers to discharge patients after the first 30-days of care, given that the case-mix weights are, on average, higher for the first 30-days of care. Other commenters expressed concern that providers may attempt to keep home health beneficiaries on service for as long as possible. Additionally, meeting the requirement of section 51001 of the BBA of 2018, a Technical Expert Panel (TEP) was convened in February 2018 to solicit 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 timing categories 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. We note the PDGM case-mix weights reflect existing patterns of resource use observed in our analyses of CY 2016 home health claims data. Since we propose to recalibrate the PDGM case-mix weights on an annual basis to ensure that the case-mix weights reflect the most recent utilization data available at the time of rulemaking, future recalibrations of the PDGM case-mix weights may result in changes to the case-mix weights for early versus late 30-day periods of care as a result of changes in utilization patterns.

Several commenters responding to the CY 2018 HH PPS proposed rule suggested that we revise the model such that a readmission to home health within the 60-day gap period results in an ''early'' instead of a ''late'' 30-day period. However, we note that the PDGM also includes a category determined specifically by source of admission, which would account for any readmission to home health. Under the PDGM we already account for whether the patient was admitted to home health care from the community or following an institutional stay, including inpatient stays that occur after the commencement of a home health care. For example, if the original home health stay was categorized as community and subsequently the patient experienced an inpatient stay, the subsequent home health stay would reset to institutional upon discharge from the inpatient setting. Similarly, we note that for the purposes of the timing component of the PDGM, an intervening hospital stay would not trigger re-categorization to an ''early'' period unless there were a 60-day gap in home health care. Therefore, we do not believe that the timing element of the PDGM would create a financial incentive to inappropriately encourage the admission of home health patients to an acute care setting in order to receive a subsequent home health referral in the higher-paid ''early'' category. Our proposal was intended to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the prospective payment system. Therefore, we expect that the addition of both the source of admission, as well as the timing categories do reflect agencies' average costs for home health patients and used in defining payment groups. We believe that crafting a multi-pronged case-mix adjustment model, which includes adjustments based both on timing within a home health sequence as well as the source of the beneficiary admission, will serve to more accurately account for resources required for Medicare beneficiaries and similarly provide a differentiated payment amount for care.

Several commenters responding to the CY 2018 HH PPS proposed rule expressed concern regarding the operational aspects of the timing element of the alternative case-mix adjustment methodology. As we described in the CY 2018 HH PPS proposed rule, and as we are proposing in this rule, we would use Medicare claims data and not the OASIS assessment in order to determine if a 30-day period is considered ''early'' or ''late'' (82 FR 35309). We have developed claims processing procedures to reduce the amount of administrative burden associated with the implementation of the PDGM. Providers would not have to determine whether a 30-day period is early (the first 30-day period) or later (all adjacent 30-day periods beyond the first 30-day period) if they choose not to. Information from Medicare systems would be used during claims processing to automatically assign the appropriate timing category.

[34] *http://www.medpac.gov/docs/default-source/reports/chapter-8-home-health-care-services-march-2016-report-.pdf.*

To identify the first 30-day period within a sequence, the Medicare claims processing system would verify that the claim ''From date'' and ''Admission date'' match. If this condition were to be met, our systems would send the ''early'' indicator to the HH Grouper for the 30-day period of care. When the claim was received by CMS's Common Working File (CWF), the system would look back 60 days to ensure there was not a prior, related 30-day period. If not, the claim would continue to be paid as ''early.'' If another related 30-day period were to be identified, that is an earlier 30-day period in the sequence, the claim would be flagged as ''late'' and returned to the shared systems for subsequent regrouping and re-pricing. Those periods that are not the first 30-day period in a sequence of adjacent periods, separated by no more than a 60 day gap, would be categorized as ''late'' periods and placed in corresponding PDGM categories.

Early 30-day periods are defined as the initial 30-day period in a sequence of adjacent 30-day periods. Late 30-day periods are defined as all subsequent adjacent periods beyond the first 30-day period. Periods are considered to be adjacent if they are contiguous, meaning that they are separated by no more than a 60-day period between 30-day periods of care. In determining a gap, we only consider whether the beneficiary was receiving home health care from traditional fee-for-service Medicare.

For example, if the beneficiary has not received home health care through traditional Medicare for at least 60 days, and then receives home health care from agency A, that is an early 30-day period. If that 30-day period receives a PEP adjustment and agency B recertifies the beneficiary for a second 30-day period, that second 30-day period is now considered a late 30-day period. However, the beneficiary could have received home health care from other traditional Medicare providers within 60 days before coming to agency A. The designation of early or late would depend upon how many adjacent periods of care were received prior to coming to agency A. The CWF will examine claims upon receipt in comparison to all previously processed 30-day period to verify that the period is correctly designated as early or later.

The 60-day period to determine a gap that will begin a new sequence of 30-day periods will be counted in most instances from the calculated end date of the 30-day period. That is, in most cases CWF will count from ''day 30'' of a 30-day period without regard to an earlier discharge date. The exception to this is for 30-day periods that were subject to PEP adjustment. In PEP cases, CWF will count 60 days from the date of the last billable home health visit provided. Under the current HH PPS, the partial episode payment (PEP) adjustment is a proportion of the episode payment that is based on the span of days, including the start-of-care date or first billable service date, through and including the last billable service date under the original plan of care, before the intervening event in a home health beneficiary's care, which is 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. Because PEPs are paid based upon the last billable service date and not necessarily based on the last day of a 60-day episode, we would consider the end of the PEP HH episode as the last billable home health visit provided and begin the count of gap days from the date of the last billable home health visit and not ''day 30'' of a 30-day period.

Regarding PEP adjustments, consider the following example: A 30-day period is opened on January 1, 2020 which would normally span until January 30, 2020. If this 30-day period were not subject to a PEP adjustment, any 30-day period beginning within 60 days following January 30, 2020 would be considered an adjacent 30-day period. In the case of a PEP adjustment, the determination of an adjacent 30-day period would no longer be based on day 60, but would instead be based on the latest billable visit in the 30-day period. Assume in the example, the patient is transferred to another HHA (triggering the PEP adjustment) on January 15, 2020 but the last billable visit is provided on January 13, 2020. In this case, any 30-day period beginning within 60 days following the January 13, 2020 visit would be considered an adjacent 30-day period.

Intervening stays in inpatient facilities will not create any special considerations in counting the 60-day gap. If an inpatient stay occurred within a period, it would not be a part of the gap, as counting would begin at ''day 60'' which in this case would be later than the inpatient discharge date. If an inpatient stay occurred within the time after the end of the HH period and before the beginning of the next one, those days would be counted as part of the gap just as any other days would.

If periods are received after a particular claim is paid that change the sequence initially assigned to the paid period (for example, by service dates falling earlier than those of the paid period, or by falling within a gap between paid periods), Medicare systems will initiate automatic adjustments to correct the payment of any necessary periods.

Upon receipt of a HH period coded to represent the early 30-day period in a sequence, Medicare systems will search the period history records that are maintained for each beneficiary. If an existing 30-day period is found on that history, the claim for the new period will be recoded to represent its sequence correctly and paid according to the changed code. In addition, when any new 30-day period is added to those history records for each beneficiary, the coding representing period sequence on previously paid periods will be checked to see if the presence of the newly added period causes the need for changes to those periods. If the need for changes is found, Medicare systems will initiate automatic adjustments to those previously paid periods.

For example, a given 30-day period is initially determined to be and paid as the early period in a sequence of periods. After some amount of time, a claim is submitted by another HHA that occurs before the previously designated first period in the sequence of adjacent periods and is less than 60 days before the beginning of that previously designated first period. In such a case, the 30-day period corresponding to the newly submitted claim becomes the first 30-day period of this sequence of adjacent 30-day periods and thus is considered to be an early period. The 30-day period previously designated as the first 30-day period in the sequence of periods now becomes the second 30-day period in the sequence of adjacent periods, thus changing its status from that of an early period to that of a late period.

We plan to develop materials regarding timing categories, including such topics as claims adjustments and resolution of claims processing issues. We will also update guidance in the Medicare Claims Processing Manual, as well as the Medicare Benefit Manual as appropriate with detailed procedures. We will also work with our Medicare Administrative Contractors (MACs) to address any concerns regarding the processing of home health claims as well as develop training materials to facilitate all aspects of the transition the PDGM, including the unique aspects of the timing categories.

Several commenters responding to the CY 2018 HH PPS proposed rule had concerns regarding the potential for problematic provider behavior due to financial incentives. We note that we

fully intend to monitor provider behavior in response to the new PDGM. As we receive and evaluate new data related to the provision of Medicare home health care under the PDGM, we will reassess the appropriateness of the payment levels for ''early'' and ''late'' periods in a sequence of periods. Additionally, we will share any concerning behavior or patterns with the Medicare Administrative Contracts (MACs) as well as our Center for Program Integrity. We plan to monitor for and identify any variations in the patterns of care provided to home health patients, including both increased and decreased provision of care to Medicare beneficiaries. We note that an increase in the volume of Medicare beneficiaries receiving home health care may, in fact, represent a positive outcome of the PDGM, signaling increased access to care for the Medicare population, so long as said increase in volume of beneficiaries is appropriate and in keeping with eligibility guidelines for the Medicare home health benefit.

We invite public comments on the timing categories in the proposed PDGM and the associated regulations text changes outlined in section III.F.13. of this proposed rule.

5. Admission Source Category

In the CY 2018 HH PPS proposed rule, we described analysis showing the impact of the source of admission on home health resource use and proposed to classify periods into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to home health (82 FR 35309). We proposed that a 30-day period would be categorized as institutional if an acute or post-acute care (PAC) stay occurred in the 14 days prior to the start of the 30-day period of care. We also proposed that a 30-day period would be categorized as community if there was no acute or PAC stay in the 14 days prior to the start of the 30-day period of care. We proposed to adopt this categorization by admission source with the implementation of alternative case-mix adjustment methodology refinements.

The proposed admission source category was discussed in detail in the CY 2018 HH PPS proposed rule and we solicited public comments on the admission source component of the proposed alternative case-mix adjustment methodology. Several commenters expressed their support for the admission categories within the framework of the alternative case-mix adjustment methodology refinements, as they believe that these groups would be meaningful and would more appropriately align the cost of Medicare home health care with payments, thereby improving the accuracy of the HH payment system under the alternative case-mix adjustment methodology refinements. Commenters also expressed a variety of concerns regarding admission source, stating that the source of a home health admission may not always correspond with home health beneficiary needs and associated provider costs, that the categories would discourage the admission of community entrants due to lower reimbursement, that the differentiation may encourage HHAs to favor hospitalization during an episode of home health care, that agencies' ability to provide the care for beneficiaries in the community would be reduced, and that small HHAs with no hospital affiliation would be negatively impacted. Several commenters recommended that CMS consider incorporating other clinical settings into the definition of the institutional category, including hospices and outpatient facilities. Several commenters also expressed concern regarding the operational aspects of the admission source category, requesting guidance for retroactive adjustments, plans for the claims readjustment process due to institutional claim issues, definitions for timely filing, and guidance regarding when occurrence codes may be utilized. Moreover, in accordance with the requirement of section 51001 of the BBA of 2018, a Technical Expert Panel (TEP) convened in February 2018 to solicit 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 admission source categories and suggestions for refinement to this element of the alternative case-mix system were very similar between those received in response to the CY 2018 HH PPS proposed rule and those provided by the TEP participants.

We appreciate commenters' feedback regarding the admission source element of the alternative case-mix adjustment methodology. The intention of the proposal included in the CY 2018 HH PPS proposed rule, including the admission source component, was to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the HH prospective payment system, and we believe that the differing weights for source of admission will serve to promote appropriate alignment between costs and payment within the HH PPS.

As described in the CY 2018 HH PPS proposed rule, our analytic findings demonstrate that institutional admissions have higher average resource use when compared with community admissions, which ultimately led to the inclusion of the admission source category within the framework of the alternative case-mix adjustment methodology refinements (82 FR 35309). The differences in care needs during home health based on admission source are illustrated in the resource utilization figures presented in Table 35, which shows the distribution of admission sources as well as average resource use for 30-day periods by admission source.

TABLE 35—AVERAGE RESOURCE USE BY ADMISSION SOURCE (14 DAY LOOK-BACK; 30 DAY PERIODS) ADMISSION SOURCE, COMMUNITY AND INSTITUTIONAL ONLY

	Average resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Community	$1,363.11	6,408,805	74.3	$1,119.20	$570.26	$1,062.05	$1,817.75
Institutional	2,171.00	2,215,971	25.7	1,303.24	1,246.05	1,920.06	2,791.91
Total	1,570.68	8,624,776	100.0	1,221.38	679.12	1,272.18	2,117.47

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

Institutional admissions have significantly higher average resource use at $2,171.00 compared with community admissions at $1,363.11, a difference of $807.89. Median values of resource use also show a significant difference

between sources of admission, with institutional resource use at $1,920.06 while community resource use is at $1,062.05, a difference of $858.01. The pattern of higher resource use for institutional admissions as compared to community admissions remains consistent for the 25th and 75th percentiles, with a difference of approximately $675 and $974, respectively.

Additionally, we note that we do not show preference to any particular patient profile, but rather aim to better align home health payment with the costs associated with providing care. As discussed in our CY 2018 HH PPS proposed rule, current research around those patients who are discharged from acute and PAC settings shows that these beneficiaries tend to be sicker upon admission, are being discharged rapidly back to the community, and are more likely to be re-hospitalized after discharge due to the acute nature of their illness.[35] Additionally, as further described in the CY 2018 HH PPS proposed rule, research studies indicate that patients admitted to home health from institutional settings are vulnerable to adverse effects and injury because of the functional decline that occurs due to their institutional stay, indicating that the patient population referred from an institutional setting requires more concentrated resources and supports to account for and mitigate this functional decline.[36] Moreover, as described in the CY 2018 HH PPS proposed rule, research suggests that the reduction in monitoring from the level typically experienced in an inpatient facility to that in the home environment can potentially cause gaps in care and consequently increased risk for adverse events for the newly-admitted home health beneficiary, and any negative impacts of the transition to the home setting can be reduced by an appropriate increase in care for the beneficiary, particularly through more frequent assessment of their condition and ongoing monitoring once transferred to the home environment.[37] Furthermore, research discussed in our CY 2018 HH PPS proposed rule shows that beneficiaries discharged from institutional settings are more vulnerable because of, among other factors, the need to manage new health care issues, major modifications to medication interventions, and the coordination of follow-up appointments, which could lead to the risk for adverse drug events, for errors in a beneficiary's medication regimen, and for the need to readmit to the hospital due to deterioration of the patient's condition.[38] Additionally, we note that the goal of the admission source variable is not to identify or evaluate for increases in re-hospitalization in the home health beneficiary population but rather to align payment with the costs of providing home health care. Other CMS initiatives such as the HH QRP as well as the HH VBP demonstration take into account readmissions, among other measures of quality. However, because this population is at higher risk for possible readmission to an institutional setting, we believe that more intensive supports, partnered with differentiated payment weights, are appropriate in crafting a payment system that better reflects the costs incurred by HHAs while also promoting the delivery of quality care to the Medicare population. In summary, clinical research continues to indicate that the needs of the institutional population are intensive. Likewise, our analysis of home health data shows that costs sustained by home health agencies for those beneficiaries admitted from institutional settings are higher than community entrants. Therefore, we believe that accounting for these material differences in the care needs of the beneficiary population admitted from institutional settings and their resultant, differentiated resource use, will serve to better align payments with actual costs incurred by HHAs when caring for Medicare beneficiaries.

We expect that HHAs will continue to provide the most appropriate care to Medicare home health beneficiaries, regardless of admission source or any other category related to home health payment. As we noted in the CY 2018 HH PPS proposed rule, the primary goal of home health care is to provide restorative care when improvement is expected, maintain function and health status if improvement is not expected, slow the rate of functional decline to avoid institutionalization in an acute or post-acute care setting, and/or facilitate transition to end-of-life care as appropriate (82 FR 35348). The primary goal of the HH PPS is to align payment with the costs of providing home health care. Furthermore, in our CY 2000 HH PPS final rule, commenters asserted that patients admitted to home health from the hospital were often more acutely ill and resource-intensive than other patients, particularly when compared with beneficiaries who had no institutional care prior to admission (64 FR 41147). We appreciate the concerns expressed in response to the CY 2018 HH PPS proposed rule regarding possible behavioral changes by providers given the perceived incentives created by the admission source categories within the alternative case-mix adjustment methodology. However, we continue to expect that HHAs will provide the appropriate care needed by all beneficiaries who are eligible for the home health benefit, including those beneficiaries with medically-complex conditions who are admitted from the community. We will carefully monitor the outcomes of the proposed change, including any impacts to community entrants, and make further refinements as necessary.

Regarding the incorporation of other clinical settings into the definition of the institutional category under the alternative case-mix adjustment methodology that some commenters raised in response to the CY 2018 HH PPS proposed rule, such as emergency department (ED) use and observational stays, we propose to only include those stays that are considered institutional stays in other Medicare settings. For example, observational stays do not count towards the 3-day window for an admission to a SNF because they are not categorized as inpatient. Additionally, in our analysis of 2017 HH claims data, we identified those HH stays that, within the 14 days prior to admission to HH, had been preceded by ED visits or outpatient observational stays and isolated these stays from stays that would otherwise be grouped into the community admission source category. As demonstrated in Table 36, 30-day periods of care for beneficiaries with a preceding ED visit (which would otherwise be grouped into the community admission source category) do not show higher resource use when compared to those beneficiaries entering from acute or PAC settings, with an average resource use at $1,660.64 per home health period as compared to $2,171.00 for institutional admits. When compared with those patients admitted from the community, admissions from

[35] O'Connor, M. (2012, February). Hospitalization Among Medicare-Reimbursed Skilled Home Health Recipients. Retrieved March 02, 2017, from *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4690459.*

[36] Rosati, R. J., Huang, L., Navaie-Waliser, M., & Feldman, P. H. (2003). Risk Factors for Repeated Hospitalizations Among Home Healthcare Recipients. Journal For Healthcare Quality, 25(2), 4–11. doi:10.1111/j.1945–1474.2003.tb01038.x.

[37] Forster, A. J. (2003). The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital. Annals of Internal Medicine, 138(3), 161. doi:10.7326/0003–4819–138–3–200302040–00007.

[38] Meyers, A. G., Salanitro, A., Wallston, K. A., Cawthon, C., Vasilevskis, E. E., Goggins, K. M., . . . Kripalani, S. (2014). Determinants of health after hospital discharge: Rationale and design of the Vanderbilt Inpatient Cohort Study (VICS). BMC Health Services Research, 14(1). doi:10.1186/1472–6963–14–10.

the ED show somewhat higher resource use at $1,660.64 per home health period as compared to $1,337.73 for community admits. We note that the volume of patients with preceding ED visits is relatively low, at about 5.8 percent of total home health periods.

TABLE 36—AVERAGE RESOURCE USE BY ADMISSION SOURCE (14 DAY LOOK-BACK, 30 DAY PERIODS) ADMISSION SOURCE: COMMUNITY, INSTITUTIONAL, AND EMERGENCY DEPARTMENT

	Average resource use	Number of 30-day periods	Percent of 30-day periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Community	$1,337.73	5,905,217	68.5	$1,108.57	$558.54	$1,035.34	$1,779.73
Institutional	2,171.00	2,215,971	25.7	1,303.24	1,246.05	1,920.06	2,791.91
Emergency Department	1,660.64	503,588	5.8	1,197.60	782.63	1,396.50	2,225.38
Total	1,570.68	8,624,776	100.0	1,221.38	679.12	1,272.18	2,117.47

Similarly, 30-day periods for beneficiaries with preceding observational stays (which would otherwise be grouped into the community admission source category) also do not show higher resource use when compared to those beneficiaries entering from acute or PAC settings, as described in Table 37, with average resource use at $1,820.06 per home health period as compared to $2,171.00 for institutional admits.

TABLE 37—AVERAGE RESOURCE USE BY ADMISSION SOURCE (14 DAY LOOK-BACK; 30 DAY PERIODS) ADMISSION SOURCE: COMMUNITY, INSTITUTIONAL, AND OBSERVATIONAL STAYS

	Average resource use	Number of 30-day periods	Percent of 30-day periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Community	$1,350.90	6,242,043	72.4%	$1,114.94	$564.31	$1,048.86	$1,799.27
Institutional	2,171.00	2,215,971	25.7%	1,303.24	1,246.05	1,920.06	2,791.91
Observational Stays	1,820.06	166,762	1.9%	1,180.96	960.15	1,589.08	2,399.68
Total	1,570.68	8,624,776	100.0%	1,221.38	679.12	1,272.18	2,117.47

When compared with those patients admitted from the community, admissions from observational stays show higher resource use at $1,820.06 per home health period as compared to $1,350.90 for community admits. However, the volume of patients with preceding observational stays is very low, at about 2 percent of total home health periods.

In summary, home health stays with preceding observational stays and ED visits show resource use that falls between that of the institutional and community categories. However, the resource use is not equivalent to that of the institutional settings; therefore, we do not believe it appropriate to include observational stays and ED visits in the institutional category for the purposes of the PDGM. Additionally, including these stays in the institutional category would lead to a small reduction in the overall average resource use and related case mix weights for groups admitted from acute and PAC settings. Moreover, including ED or observational stays with discharges from acute care hospitals, LTCHs, IRFs and SNFs would be inconsistent with section 1861(tt)(1) of the Act, which defines the term ''post-institutional home health services'' as discharges from hospitals (which include IRFs and LTCHs) and SNFs within 14 days of when home health care is initiated.

We explored the option of creating a third admission source category specifically for observational stays/ED visits. In order to more fully understand the potential impact of a third category, we analyzed the overall impact of the creation of such a category. For the purposes of this analysis, in the event that a home health stay was preceded by both an institutional stay and an observation stay or ED visit, the case would be grouped into the institutional category. Our findings indicate for those HH stays with a preceding outpatient observational stay/ED visit, the overall payment weight for associated groups for ''early'' 30-day periods (as defined in section III.F.4 of this rule) would be approximately 6 percent higher than the community admission counterparts, whereas institutional stays would see weights that are approximately 19 percent higher than community admissions. When examining the overall payment weights for ''late'' 30-day periods (as defined in section III.F.4 of this rule), HH stays with a preceding outpatient admission would observe weights that are approximately 10 percent higher than the community admission counterparts, whereas institutional stays would see weights that are approximately 43 percent higher than community admissions. However, we are concerned that a third admission source category for observational stays and ED visits could create an incentive for providers to encourage outpatient encounters both prior to a 30-day period of care or within a 30-day period of care within 14 days of the start of the next 30-day period, thereby potentially inappropriately increasing costs to the Medicare program overall. The clinical threshold for an observational stay or an ED visit is not as high as that required for an institutional admission, and we are concerned that home health agencies may encourage beneficiaries to engage with emergency departments before initiating a home health stay.

For example, in the FY 2014 IPPS/LTCH PPS final rule and also the Medicare Benefit Policy Manual Chapter 1—Inpatient Hospital Services Covered Under Part A, CMS clarified and specified in the regulations that an individual becomes an inpatient of a hospital, including a long term care hospital or a Critical Access Hospital, when formally admitted as such pursuant to an order for inpatient admission by a physician or other qualified practitioner described in the final regulations (78 FR 50495). The

order is required for payment of hospital inpatient services under Medicare Part A. CMS also specified that for those hospital stays in which the physician expects the beneficiary to require care that crosses two midnights and admits the beneficiary based upon that expectation, Medicare Part A payment is generally appropriate. Additionally, for the purposes of admissions to skilled nursing facilities, the Medicare Benefit Policy Manual Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance states that in order to qualify for post-hospital extended care services, the individual must have been an inpatient of a hospital for a medically necessary stay of at least three consecutive calendar days and that time spent in observation or in the emergency room prior to (or in lieu of) an inpatient admission to the hospital does not count toward the 3-day qualifying inpatient hospital stay, as a person who appears at a hospital's emergency room seeking examination or treatment or is placed on observation has not been admitted to the hospital as an inpatient; instead, the person receives outpatient services. Furthermore, admission to an inpatient rehabilitation facility (IRF) requires that for IRF care to be considered reasonable and necessary, the documentation in the patient's IRF medical record must demonstrate a reasonable expectation that the patient must require active and ongoing intervention of multiple therapy disciplines, at least one of which must be PT or OT; require an intensive rehabilitation therapy program, generally consisting of 3 hours of therapy per day at least 5 days per week; or in certain well-documented cases, at least 15 hours of intensive rehabilitation therapy within a 7-consecutive day period, beginning with the date of admission; reasonably be expected to actively participate in, and benefit significantly from the intensive rehabilitation therapy program; require physician supervision by a rehabilitation physician, with face-to-face visits at least 3 days per week to assess the patient both medically and functionally and to modify the course of treatment as needed; and require an intensive and coordinated interdisciplinary team approach to the delivery of rehabilitative care, as described in detail in Medicare Benefit Policy Manual, Chapter 1—Inpatient Hospital Services Covered Under Part A 110.2—Inpatient Rehabilitation Facility Medical Necessity Criteria.

Conversely, CMS specified that for hospital stays in which the physician expects the patient to require care less than two midnights, payment under Medicare Part A is generally inappropriate. (However, we note that in the CY 2016 Outpatient Prospective Payment System final rule, CMS adopted a policy such that for stays for which the physician expects the patient to need less than two midnights of hospital care (and the procedure is not on the inpatient-only list or otherwise listed as a national exception), an inpatient admission may be payable under Medicare Part A on a case-by-case basis based on the judgment of the admitting physician (80 FR 70297).)

Regarding emergency department visits by Medicare beneficiaries, services are generally covered by Medicare Part B in instances where a beneficiary experiences an injury, a sudden illness, or an illness that quickly worsens. In the case of observational stays, as described in the Medicare Claims Processing Manual, Chapter 12, observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. As described in the Medicare Benefit Policy Manual, Chapter 6—Hospital Services Covered Under Part B 20.6—Outpatient Observation Services, observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. Moreover, the Medicare Claims Processing Manual in Chapter 4—Part B Hospital, 290—Outpatient Observation Services states that observation services are covered by Medicare only when provided by the order of a physician or another individual authorized by state licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient tests. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. In summary, the clinical thresholds for coverage and payment for an admission to institutional settings are higher when compared with ED visits and observational stays. Finally, we note that the proportion of home health periods with admissions from ED visits and observational stays is low relative to community and institutional counterparts. Creating a third community admission source category for observational stays and ED visits would potentially introduce added complexity into the payment system for a small portion of home health stays, which could lead to the creation of payment groups that contain very few stays with very little difference in case-mix weights across the landscape of groups.

For all of these reasons, we believe that incorporating HH stays with preceding observational stays and ED visits into the community admission category is most appropriate at this time. However, we note that as we receive and evaluate new data related to the provision of Medicare home health care under the PDGM, we will continue to assess the appropriateness of the payment levels for admission source within a home health period and give consideration to any cost differentiation evidenced by the resources required by those home health patients with a preceding outpatient event.

Regarding the operational aspects of the admission source category, as described in the CY 2018 HH PPS proposed rule, we have developed automated claims processing procedures with the goal of reducing the amount of administrative burden associated with the admission source category of the alternative case-mix adjustment methodology (82 FR 35309). For example, Medicare systems will automatically determine whether a beneficiary has been discharged from an institutional setting for which Medicare paid the claim, using information used during claims processing to systematically identify admission source and address this issue. When the Medicare claims processing system receives a Medicare home health claim, the systems will check for the presence of a Medicare acute or PAC claim for an institutional stay. If such an institutional claim is found, and the institutional stay occurred within 14 days of the home health admission, our systems will trigger an automatic adjustment of the corresponding HH claim to the appropriate institutional category. Similarly, when the Medicare claims processing system receives a Medicare acute or PAC claim for an institutional stay, the systems will check for the presence of a subsequent HH claim with a community payment group. If such a HH claim is found, and the institutional stay occurred within 14 days of the home health admission, our systems will trigger an automatic

adjustment of the HH claim to the appropriate institutional category. This process may occur any time within the 12-month timely filing period for the acute or PAC claim. The OASIS assessment will not be utilized in evaluating for admission source information.

Moreover, as we also proposed in the CY 2018 HH PPS proposed rule, we propose in this rule that newly-created occurrence codes would also be established, allowing HHAs to manually indicate on Medicare home health claims that an institutional admission had occurred prior to the processing of an acute or PAC Medicare claim, if any, in order to receive the higher payment associated with the institutional admission source sooner (82 FR 35312). However, the usage of the occurrence codes is limited to situations in which the HHA has information about the acute or PAC stay. We also noted that the use of these occurrence codes would not be limited to home health beneficiaries for whom the acute or PAC claims were paid by Medicare. HHAs would also use the occurrence codes for beneficiaries with acute or PAC stays paid by other payers, such as the Veterans Administration (VA).

If a HHA does not include on the HH claim the occurrence code indicating that a home health patient had a previous institutional stay, processed either by Medicare or other institutions such as the VA, such an admission will be categorized as ''community'' and paid accordingly. However, if later a Medicare acute or PAC claim for an institutional stay occurring within 14 days of the home health admission is submitted within the timely filing deadline and processed by the Medicare systems, the HH claim would be automatically adjusted and re-categorized as an institutional admission and appropriate payment modifications would be made. If there was a non-Medicare institutional stay occurring within 14 days of the home health admission but the HHA was not aware of such a stay, upon learning of such a stay, the HHA would be able to resubmit the HH claim that included an occurrence code, subject to the timely filing deadline, and payment adjustments would be made accordingly.

We note that the Medicare claims processing system will check for the presence of an acute or PAC Medicare claim for an institutional stay occurring within 14 days of the home health admission on an ongoing basis and automatically assign the home health claim as ''community'' or ''institutional'' appropriately. As a result, with respect to a HH claim with a Medicare institutional stay occurring within 14 days of home health admission, we will not require the submission of an occurrence code in order to appropriately categorize the HH claim to the applicable admission source. With respect to a HH claim with a non-Medicare institutional stay occurring with 14 days of home health admission, a HHA would need to submit an occurrence code on the HH claim in order to have the HH claim categorized as ''institutional'' and paid the associated higher amount. Additionally, we plan to provide education and training regarding all aspects of the admission source process and to develop materials for guidance on claims adjustments, for resolution of claims processing issues, for defining timely filing windows, and for appropriate usage of occurrence codes through such resources as the Medicare Learning Network. We will also update guidance in the Medicare Claims Processing Manual as well as the Medicare Benefit Policy Manual as appropriate with detailed procedures. We will also work with our Medicare Administrative Contractors (MACs) to address any concerns regarding the processing of home health claims as well as develop training materials to facilitate all aspects of the transition to the PDGM, including the unique aspects of the admission source categories.

With regards to the length of time for resubmission of home health claims that reflect a non-Medicare institutional claim, all appropriate Medicare rules regarding timely filing of claims will still apply. Procedures required for the resubmission of home health claims will apply uniformly for those claims that require editing due to the need to add or remove occurrence codes. Details regarding the timely filing guidelines for the Medicare program are available in the Medicare Claims Processing Manual, Chapter 1—General Billing Requirements, which is available at the following website: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c01.pdf.* Additionally, adjustments to any re-submitted home health claims will be processed in the same manner as other edited Medicare home health claims. Additionally, we plan to perform robust testing within the Medicare claims processing system to optimize and streamline the payment process.

Regarding the process by which HHAs should verify a non-Medicare institutional stay, as we noted in in the CY 2018 HH PPS proposed rule, we expect home health agencies would utilize discharge summaries from all varieties of institutional providers (that is, Medicare and non-Medicare) to inform the usage of these occurrence codes, and these discharge documents should already be part of the beneficiary's home health medical record used to support the certification of patient eligibility as outlined in § 424.22(c) (82 FR 35309). Providers should utilize existing strategies and techniques for verification of such stays and incorporate relevant clinical information into the plan of care, as is already required by our Conditions of Participation.

Our evaluation process within the Medicare claims processing system will check for the presence of an acute or PAC Medicare claim for an institutional stay occurring within 14 days of the home health admission on an ongoing basis. Under this approach, the Medicare systems would only evaluate for whether an acute or PAC Medicare claim for an institutional stay occurring within 14 days of the home health admission was processed by Medicare, not whether it was paid. Therefore, we do not expect that a home health claim will be denied due to unpaid Medicare claims for preceding acute or PAC admissions. Moreover, as previously stated above, we note that providers would have the option to submit the occurrence code indicating a preceding institutional stay in order to categorize the home health admission as ''institutional.'' In the case of a HHA submitting an occurrence code because of a preceding Medicare institutional stay, if upon medical review after finding no Medicare acute or PAC claims in the National Claims History, and there is documentation of a Medicare acute or PAC stay within the 14 days prior to the home health admission, but the institutional setting did not submit its claim in a timely fashion, or at all, we would permit the institutional categorization for the payment of the home health claim through appropriate administrative action. Similarly, in the case of a HHA submitting an occurrence code because of a preceding non-Medicare institutional stay, if documentation of a non-Medicare acute or PAC stay within the 14 days prior to the home health admission, is found, we would permit the categorization of the home health claim as ''institutional''.

However, if upon medical review after finding no acute or PAC Medicare claims in the National Claims History, and there is no documentation of an acute or PAC stay, either a Medicare or non-Medicare stay, within 14 days of the home health admission, we would

correct the overpayment. If upon medical review after finding no Medicare acute or PAC claims in the National Claims History and we find that an HHA is systematically including occurrence codes that indicate the patient's admission source was ''institutional,'' but no documentation exists in the medical record of Medicare or non-Medicare stays, we would refer the HHA to the zone program integrity contractor (ZPIC) for further review. Moreover, we intend to consider targeted approaches for medical review after the implementation of the admission source element of the PDGM, including potentially identifying HHAs that have claims that are consistently associated with acute or PAC denials, whose utilization pattern of acute or PAC occurrence codes is aberrant when compared with their peers, or other such metrics that would facilitate any targeted reviews.

For all of the reasons described above, we are proposing to establish two admission source categories for grouping 30-day periods of care under the PDGM—institutional and community—as determined by the healthcare setting utilized in the 14 days prior to home health admission. We are proposing that 30-day periods for beneficiaries with any inpatient acute care hospitalizations, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long term care hospital (LTCH) stays within the 14 days prior to a home health admission would be designated as institutional admissions. We are proposing that the institutional admission source category would also include patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted (that is, the admission date and from date for the subsequent 30-day period of care do not match) as we acknowledge that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital discharge. However, we are proposing that we would not categorize PAC stays (SNF, IRF, LTCH stays) that occur during a previous 30-day period and within 14 days of a subsequent, contiguous 30-day period of care (that is, the admission date and from date for the subsequent 30-day period of care do not match) as institutional, as we would expect the HHA to discharge the patient if the patient required PAC in a different setting and then readmitted the patient, if necessary, after discharge from such setting. If the patient was discharged and then readmitted to home health, the admission date and ''from'' date on the 30-day claim would match and the claims processing system will look for an acute or a PAC stay within 14 days of the home health admission date. This admission source designation process would be applicable to institutional stays paid by Medicare or any other payer. All other 30-day periods would be designated as community admissions.

For the purposes of a RAP, we would only adjust the final home health claim submitted for source of admission. For example, if a RAP for a community admission was submitted and paid, and then an acute or PAC Medicare claim was submitted for that patient before the final home health claim was submitted, we would not adjust the RAP and would only adjust the final home health claim so that it reflected an institutional admission. Additionally, HHAs would only indicate admission source occurrence codes on the final claim and not on any RAPs submitted.

We invite public comments on the admission source component of the proposed PDGM payment system.

6. Clinical Groupings

In the CY 2018 HH PPS proposed rule (82 FR 35307), we discussed the findings of the Home Health Study Report to Congress, which indicates that the current payment system may encourage HHAs to select certain types of patients over others.[39] Patients with a higher severity of illness, including those receiving a greater level of skilled nursing care; for example, patients with wounds, with ostomies, or who are receiving total parenteral nutrition or mechanical ventilation were associated with higher resource use and lower margins. This may have produced a disincentive for providing care for patients with higher clinical acuity, and thereby may have limited access of home health services to these vulnerable patient populations.[40] We noted that payment should be predicated on resource use and proposed that adjusting payment based on identified clinical characteristics and associated services would better align payment with resource use.

For these reasons, we propose grouping 30-day periods of care into six clinical groups: Musculoskeletal Rehabilitation, Neuro/Stroke Rehabilitation, Wounds—Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care, Behavioral Health Care (including Substance Use Disorder), Complex Nursing Interventions, Medication Management, Teaching and Assessment (MMTA). These clinical groups are designed to capture the most common types of care that HHAs provide. We propose placement of each 30-day period of care into a specific clinical group based on the primary reason the patient is receiving home health care as determined by the principal diagnosis reported on the claim. Although the principal diagnosis code is the basis for the clinical grouping, secondary diagnosis codes and patient characteristics would then be used to case-mix adjust the period further through the comorbidity adjustment and functional level. A complete list of ICD–10–CM codes and their assigned clinical groupings is posted on the CMS HHA Center web page (*https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html*). More information on the analysis and development of the groupings can be found in the CY 2018 HH PPS proposed rule as well as the HHGM technical report from December 2016, also available on the HHA Center webpage.

In the CY 2018 HH PPS proposed rule, we solicited comments on the clinical groups and the assigned clinical groupings of the ICD–10–CM codes. Additionally, in February 2018, a Technical Expert Panel (TEP) was held in order to gain insight from industry leaders, clinicians, patient representatives, and researchers with experience in home health care and/or experience in home health agency management. Many commenters and TEP members supported the patient-centered approach to grouping patients by clinical characteristics, and several commenters felt that the clinical groupings did capture the majority of characteristics of the home health population. Specifically, commenters generally approved of the higher-weighted complex nursing and wound groups, and agreed with the ''importance the HHGM places on these complex patients through its proposed payment rate.'' One commenter stated that ''the most complex and costly beneficiaries for a HHA are those that require intensive nursing care, while

[39] Report to Congress. Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations. Available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf.*

[40] Report to the Congress: Medicare Payment Policy. (2015)Home health care services: Assessing payment adequacy and updating payments. Ch.9 *http://www.medpac.gov/docs/default-source/reports/chapter-9-home-health-care-services-march-2015-report-.pdf?sfvrsn=0.*

those that require intensive therapy produce a significant margin with less cost.'' Additional comments on the clinical groups generally included the following: Concern that some diagnosis codes are not used to group claims into the six clinical groups; concern about reduced therapy use in the clinical groups that aren't specifically for musculoskeletal or neurological rehabilitation; concern that the groups do not capture clinically complex patients that require multiple home health disciplines; suggestions that the clinical groups should be based on impairments rather than diagnoses; and concern that the MMTA clinical group encompasses too many diagnosis codes. Several commenters expressed concern that certain ICD 10–CM diagnosis codes were not used for payment (for example, codes that were not used to group claims into the six clinical groupings), which could possibly restrict access to the benefit or force beneficiaries to seek care in institutional settings. Others had concerns regarding specific diagnosis codes they felt should be reassigned to different clinical groups.

As outlined in the HHGM technical report from December 2016 and in the CY 2018 HH PPS proposed rule (82 FR 35314), there were several reasons why a diagnosis code was not assigned to one of the six clinical groups. These included if the diagnosis code was too vague, meaning the code does not provide adequate information to support the need for skilled home health services (for example H57.9, Unspecified disorder of eye and adnexa); the code, based on ICD 10–CM, American Hospital Association (AHA) Coding Clinic, or Medicare Code Edits (MCE) would indicate a non-home health service (for example, dental codes); the code is a manifestation code subject to a manifestation/etiology convention, meaning that the etiology code must be reported as the principal diagnosis, or the code is subject to a code first sequencing convention (for example, G99.2 myelopathy in diseases classified elsewhere); the code identifies a condition which would be unlikely to require home health services (for example, L81.2, Freckles); the code is restricted to the acute care setting per ICD 10–CM/AHA Coding Clinic, or the diagnosis indicates death as the outcome (for example S06.1X7A, Traumatic cerebral edema with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness). We did, however, review and re-group certain codes based on commenter feedback. For example, with regard to the classification of N39.0, Urinary tract infection, site not specified as an invalid code to group the home health period of care, we do agree that absent definitive information provided by the referring physician, a home health clinician would not know the exact site of a urinary tract infection (UTI). As such, Urinary tract infection, site not specified (N39.0) will be grouped under MMTA, as the home health services required would most likely involve teaching about the treatment for the UTI, as well as evaluating the effectiveness of the medication regimen. We encourage HHAs to review the list of diagnosis codes in the PDGM Grouping Tool posted on the HHA Center web page at: *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html.* Additionally, the ICD–10–CM code set exceeds the ICD–9–CM in the number of diagnoses and conditions and contains codes that are much more granular. Therefore, we disagree that excluding certain codes from payment will restrict access, considering the increase in diagnoses potentially requiring home health.

With regard to commenter concern that the HHGM clinical groups did not account for the need for therapy in home health periods that are not specifically grouped into musculoskeletal or neurological rehabilitation, we continue to expect the ordering physician, in conjunction with the therapist to develop and follow a plan of care for any home health patient, regardless of clinical group, as outlined in the skilled service requirements at § 409.44, when therapy is deemed reasonable and necessary. Although the principal diagnosis is a contributing factor in the PDGM and determines the clinical group, it is not the only consideration in determining what home health services are needed in a patient's plan of care. It is the responsibility of the patient's treating physician to determine if and what type of therapy the patient needs regardless of clinical grouping. In accordance with § 409.44(c)(1)(i), the therapy goals must be established by a qualified therapist in conjunction with the physician when determining the plan of care. As such, therapy may likely be included in the plan of care for a patient in any of the six clinical groupings. Any therapy indicated in the plan of care is expected to meet the requirements outlined in § 409.44, which states that all therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist). Additional requirements dictate that the amount, frequency, and duration of the services must be reasonable and necessary, as determined by a qualified therapist and/or physician, using accepted standards of clinical practice. One goal in developing the PDGM is to provide an appropriate payment based on the identified resource use of different patient groups, not to encourage, discourage, value, or devalue one type of skilled care over another.

Likewise, for patients requiring two or three home health disciplines, the PDGM takes into account the functional level and comorbidities of the patient after the primary reason for the period is captured by the clinical grouping. Decreasing functional status, as indicated by a specific set of OASIS items, and the presence of certain comorbid conditions, is associated with increased resource use. Here is where, when combined with the clinical grouping, any multi-disciplinary therapy patients would be captured. For instance, a patient grouped into the Neuro-Rehabilitation clinical grouping with a high Functional Level (meaning high functional impairment) indicates increased therapy needs, potentially utilizing all skilled therapy disciplines. Additionally, the comorbidity adjustment further case mixes the period and increases payment to capture the additional resource use for a patient regardless of whether the services are skilled nursing or therapy based. Therefore, a patient with complex needs, including multiple therapy disciplines and medical management, is captured by the combination of the different levels of the PDGM. Furthermore, the current case-mix adjustment methodology does not differentiate between utilization of therapy disciplines and whether or not all three are utilized for the same patient. We have determined that the PDGM's functional level when combined with the clinical grouping and comorbidity adjustment actually provides a much clearer picture of the patient's needs, particularly in relation to therapy services.

Comments on the CY 2018 HH PPS proposed rule and at the 2018 TEP indicated that diagnosis does not always correlate with need and that impairments and functional limitations are better predictors of therapy services. Additionally, some commenters stated that clinicians are more likely to focus on impairments and functional limitations when conceptualizing overall patient care, and suggested using them as the basis for the clinical groups rather than diagnosis codes. We do agree that diagnosis alone does not

provide the entire clinical picture of the home health patient; however, in the same way the clinical group is one aspect of the PDGM, therapy services are only one aspect of home health. In fact, the multidisciplinary nature of the benefit is precisely the reason that diagnosis should be an important aspect of the clinical groupings model. The various home health disciplines have different but overlapping roles in treating the patient; however, a diagnosis is used across disciplines and has important implications for patient care. A patient's diagnosis consists of a known set of signs and symptoms agreed upon by the medical community. Each different healthcare discipline uses these identifiable signs and symptoms to apply its own approach and skill set to treat the patient. However, it remains a patient centered approach.

Several commenters and TEP participants alike, stated that the MMTA clinical group is too broad and should be divided into more clinical groups or subgroups. One commenter questioned whether it made sense to assign patients to different clinical groupings if roughly 60 percent of 30-day periods will fall into the MMTA category. Others considered it an ''other'' category that was counter to the goal of clarifying the need for home health.

A significant goal of the PDGM is to clearly define what types of services are provided in home health and accurately ascribe payment to resource use. Our analysis showed that there are four very broad categories of interventions frequently provided in the home that are not attributable to one specific intervention or diagnosis: Health teaching; guidance and counseling; case management; treatments and procedures; and surveillance. These categories cross the spectrum of diagnoses, medications, and interventions, which understandably is why this clinical grouping represents the majority of home health episodes. We believe that these four broad categories of interventions in MMTA cannot be underestimated in importance. We stated in the CY 2018 HH PPS proposed rule that many home health patients have multi-morbidity and polypharmacy, making education and surveillance crucial in the management of the home health patient in order to prevent medication errors and adverse effects. However, the principal diagnosis necessitating home care for these patients may not involve a complex nursing intervention, behavioral health, rehabilitation, or wound care. This group represents a broader, but no less important reason for home care. We believe MMTA is not so much an ''other'' category as much as it appears to represent the foundation of home health. Many commenters highlighted the complexity of home health patients; pointing to multi-morbidity, ''quicker and sicker'' discharges, and polypharmacy as important factors in maintaining home health access. CMS agrees that these issues alone are important reasons for ordering home health services and necessitate their own clinical grouping.

When initially developing the model, we looked at breaking MMTA into subgroups in order to account for differences amongst diagnoses within the broader category of this group. We found that the variation in resource use was similar across those subgroups and determined separating diagnoses further would only serve to make the model more complex and without significant variations in case-mix. However, in response to public comments and the discussion at the 2018 TEP,[20] we performed further analysis on the division of MMTA into subgroups in order to estimate the payment regression if these groups were separated from MMTA. We conducted a thorough review of all the diagnosis codes grouped into MMTA. We then grouped the codes into subgroups based on feedback from public comments, which mainly focused on cardiac, oncology, infectious, and respiratory diagnoses. We created the additional subgroups (Surgical/Procedural Aftercare, Cardiac/Circulatory, Endocrine, GI/GU, Infectious Diseases/Neoplasms, Respiratory, and Other) based on data that showed above-average resource use for the codes in those groups, and then combined certain groups that had a minimal number of codes. Those results are shown in Table 38.

TABLE 38—DISTRIBUTION OF RESOURCE USE BY 30-DAY PERIODS

[MMTA subgroups]

Subgroup	N	Mean	Median
Aftercare	304,871	$1,605.43	$1,326.03
Cardiac/Circulatory	1,594,149	1,433.02	1,121.27
Endocrine	425,077	1,524.45	1,062.41
GI/GU	402,322	1,414.44	1,115.29
Infectious Diseases/Neoplasms/Blood-forming Diseases	347,755	1,400.65	1,077.58
Respiratory	724,722	1,411.61	1,122.23
Other	1,226,750	1,366.56	1,035.76
Total	5,025,646	1,428.17	1,105.20

Table 39 shows the impact each MMTA variable has on case-mix weight. The impact is calculated by taking the regression coefficient for each variable (unreported here) and dividing by the average resource use of the 30-day periods in the model. Model 1 shows the result when MMTA clinical group is not separated into subgroups. Model 1 shows that all else equal, being in MMTA—Low Functional impairment causes no increase in case-mix weight (for example, a 30-day period's case-mix weight would be calculated with the coefficients from the constant of the model plus the admission source/timing of the period plus the comorbidity adjustment). A 30-day period in MMTA—Medium Functional would increase the case-mix weight by 0.1560. A 30-day period in MMTA—High Functional would increase the case-mix weight by 0.2731. Model 2 shows the same information but now includes the MMTA subgroups. In any given functional level, many of the MMTA subgroups have an impact on the case-mix weight that is similar to what is found in Model 1. For example, a period in MMTA (Other)—Medium Functional

[20] *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html.*

has an increase in case-mix of 0.1568 (which is very similar to the 0.1560 value found in Model 1). There are some groups like Aftercare, Endocrine, and GI/GU which show different impacts than Model 1. Also, to a lesser extent these differences also exist for the ''Infectious Diseases/Neoplasms/Blood forming Diseases'' and ''Respiratory'' subgroups. Some of these differences are driven by periods which are paid using an outlier adjustment. Model 3 removes outliers and the corresponding results for the Endocrine subgroup are very similar to Model 1. Some differences (for example in Aftercare) persist; however, the change in case-mix weight remains similar to Model 1.

TABLE 39—CHANGE IN CASE-MIX WEIGHT ASSOCIATED WITH MMTA VARIABLES

	Model 1	Model 2	Model 3 (outliers excluded)
	Change in case-mix weight	Change in case-mix weight	Change in case-mix weight
Variable			
MMTA—Low Functional	0.000	.....	.....
MMTA—Medium Functional	0.1560	.....	.....
MMTA—High Functional	0.2731	.....	.....
MMTA (Other)—Low Functional	.....	0.000	0.000
MMTA (Other)—Medium Functional	.....	0.1568	0.1523
MMTA (Other)—High Functional	.....	0.2896	0.2748
MMTA (Aftercare)—Low Functional	.....	−0.1082	−0.1196
MMTA (Aftercare)—Medium Functional	.....	0.0798	0.0701
MMTA (Aftercare)—High Functional	.....	0.2588	0.2491
MMTA (Cardiac/Circulatory)—Low Functional	.....	−0.0239	−0.0050
MMTA (Cardiac/Circulatory)—Medium Functional	.....	0.1371	0.1652
MMTA (Cardiac/Circulatory)—High Functional	.....	0.2737	0.2952
MMTA (Endocrine)—Low Functional	.....	0.1105	0.0282
MMTA (Endocrine)—Medium Functional	.....	0.2859	0.1833
MMTA (Endocrine)—High Functional	.....	0.4071	0.3086
MMTA (GI/GU)—Low Functional	.....	−0.0751	−0.0639
MMTA (GI/GU)—Medium Functional	.....	0.0997	0.1256
MMTA (GI/GU)—High Functional	.....	0.1992	0.2231
MMTA (Infectious Diseases/Neoplasms/Blood forming Diseases)—Low Functional	.....	−0.0452	−0.0472
MMTA (Infectious Diseases/Neoplasms/Blood forming Diseases)—Medium Functional	.....	0.1068	0.1128
MMTA (Infectious Diseases/Neoplasms/Blood forming Diseases)—High Functional	.....	0.2281	0.2379
MMTA (Respiratory)—Low Functional	.....	−0.0501	−0.0488
MMTA (Respiratory)—Medium Functional	.....	0.1027	0.1163
MMTA (Respiratory)—High Functional	.....	0.2241	0.2400

The results show that the change in case-mix weight was minimal for the 30-day periods assigned to these subgroups compared to the case-mix weights without the subgroups. Additionally, the impact of other variables in the model (admission source/timing, comorbidity adjustment) on the final case-mix weights were similar whether or not MMTA subgroups were used.

Overall, using the MMTA subgroup model would result in more payment groups but not dramatic differences in case-mix weights across those groups. For this reason, we are not proposing to divide the MMTA clinical group into subgroups and to leave them as is shown in Table 40. However, we are soliciting comments from the public on whether there may be other compelling reasons why MMTA should be broken out into subgroups as shown in Table 38, even if the additional subgroups do not result in significant differences in case-mix weights across those subgroups. We note that we also plan continue to examine trends in reporting and resource utilization to determine if future changes to the clinical groupings are needed after implementation of the PDGM.

TABLE 40—PROPOSED CLINICAL GROUPS USED IN THE PDGM

Clinical groups	The primary reason for the home health encounter is to provide:
Musculoskeletal Rehabilitation	Therapy (physical, occupational or speech) for a musculoskeletal condition.
Neuro/Stroke Rehabilitation	Therapy (physical, occupational or speech) for a neurological condition or stroke.
Wounds—Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care.	Assessment, treatment & evaluation of a surgical wound(s); assessment, treatment & evaluation of non-surgical wounds, ulcers, burns, and other lesions.
Behavioral Health Care	Assessment, treatment & evaluation of psychiatric conditions, including substance use disorders.
Complex Nursing Interventions	Assessment, treatment & evaluation of complex medical & surgical conditions including IV, TPN, enteral nutrition, ventilator, and ostomies.
Medication Management, Teaching and Assessment (MMTA).	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the above listed groups.

7. Functional Levels and Corresponding OASIS Items

As part of the overall payment adjustment under an alternative case-mix adjustment methodology, in the CY 2018 Home Health Prospective Payment System proposed rule (82 FR 35317), we proposed including a functional level adjustment to 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 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 web page.[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]

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 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

[42] Burke, R. MD, MS, Whitfield, E. Ph.D., Hittle, D. Ph.D., Min, S. Ph.D., Levy, C. MD, Ph.D., 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.

[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.

[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.*

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 web page.[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

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

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 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 web page 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 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).

[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''.

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 web page 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 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

[49] ''Outcome and Assessment I OASIS Information Set 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.*

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, arterioles and capillaries with ulceration and non-pressure chronic ulcers	365.78
Skin 4	Includes stages Two-Four and unstageable pressure ulcers by site	484.83

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
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

TABLE 45—COMORBIDITY SUBGROUP INTERACTIONS FOR COMORBIDITY ADJUSTMENT—Continued

Comorbidity subgroup interaction	Comorbidity subgroup	Description	Comorbidity subgroup	Description	Sum of interaction term plus single comorbidity coefficients
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
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	Hypertentive 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 ulcers.	306.63
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
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
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 web page 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 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

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

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 web page 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

TABLE 47—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED PDGM PAYMENT GROUPS—Continued

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)
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
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
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

TABLE 47—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED PDGM PAYMENT GROUPS—Continued

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)
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
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

TABLE 47—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED PDGM PAYMENT GROUPS—Continued

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)
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
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

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

Variable	Coefficient	Coefficient divided by average resource use
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

TABLE 49—CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Proposed CY 2019 weight
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
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

TABLE 49—CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Proposed CY 2019 weight
2EC31	MS Rehab—High	Early—Institutional	2	1.7466
2FA11	Behavioral Health—Low	Early—Institutional	0	1.0969
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
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

TABLE 49—CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Proposed CY 2019 weight
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
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 CY2017 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 medical record documentation from the HHA to be used to support the basis for certification and/or recertification of

[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.*

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 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 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

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

[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.*

[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, DC: June 2016).

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 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 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 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,

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

[57] The 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*).

[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.

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)
- 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

[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.*

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

Prediction model for	Number of OASIS items used	Number of clinical categories	R-squared value
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 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.

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

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

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
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.

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

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
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.

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Figure 5

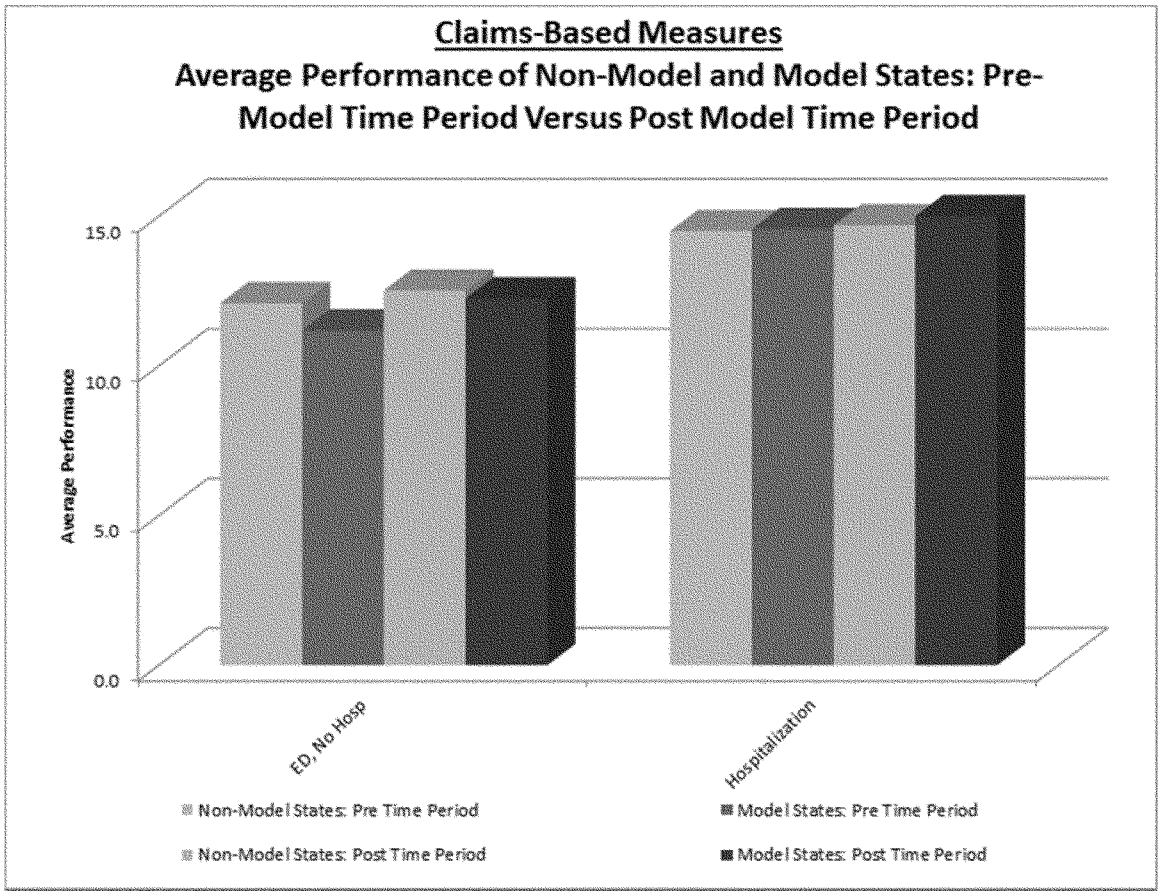

Figure 6

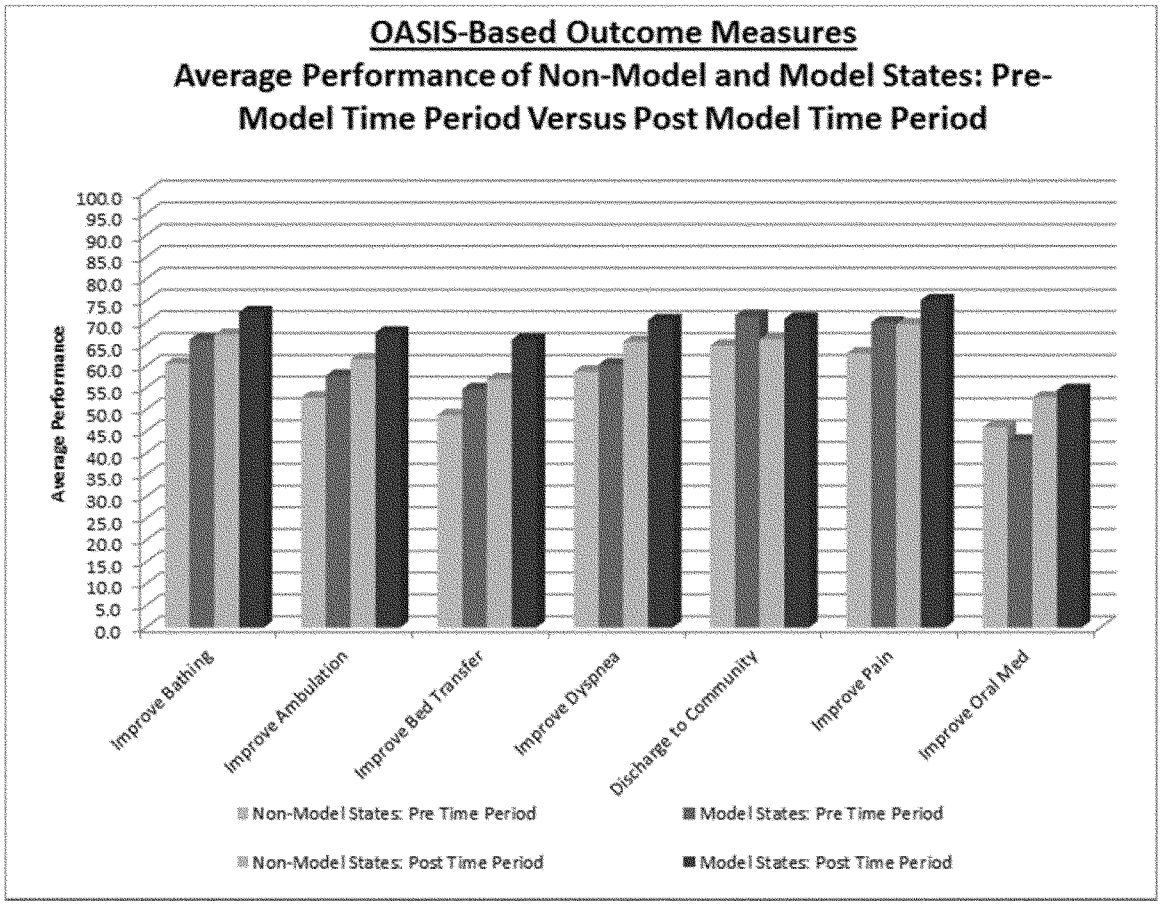

Table 52 shows the current and proposed weights for each measure based on this proposal to change the weighting methodology from weighting each individual measure equally to weighting the OASIS, claims-based, and HHCAHPS measure categories at 35-percent, 35-percent and 30-percent, respectively. Table 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.

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

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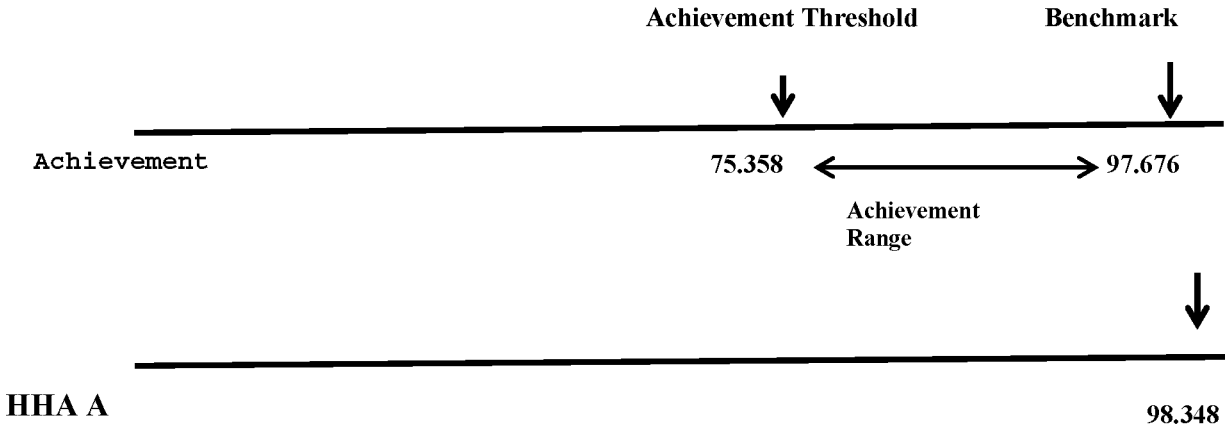
[62] Achievement points are calculated as 9 * (HHA Performance Year Score − Achievement Threshold)/(Benchmark − Achievement threshold) + 0.5.

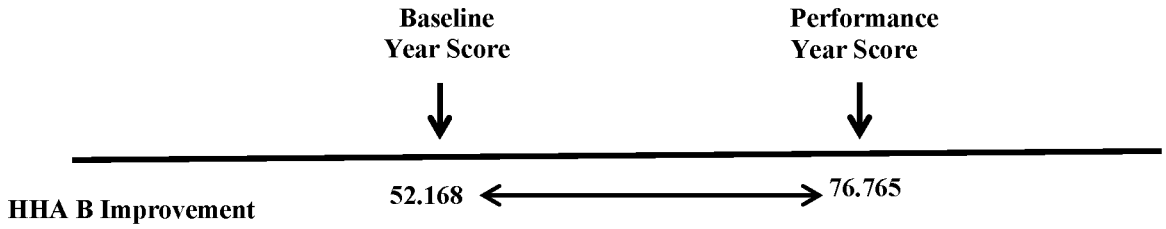
[63] The formula for calculating improvement points is 9 * (HHA Performance Year Score − HHA Baseline Period Score)/(HHA Benchmark − HHA Baseline Period Score) − 0.5.

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

Measure: Improvement in Pain

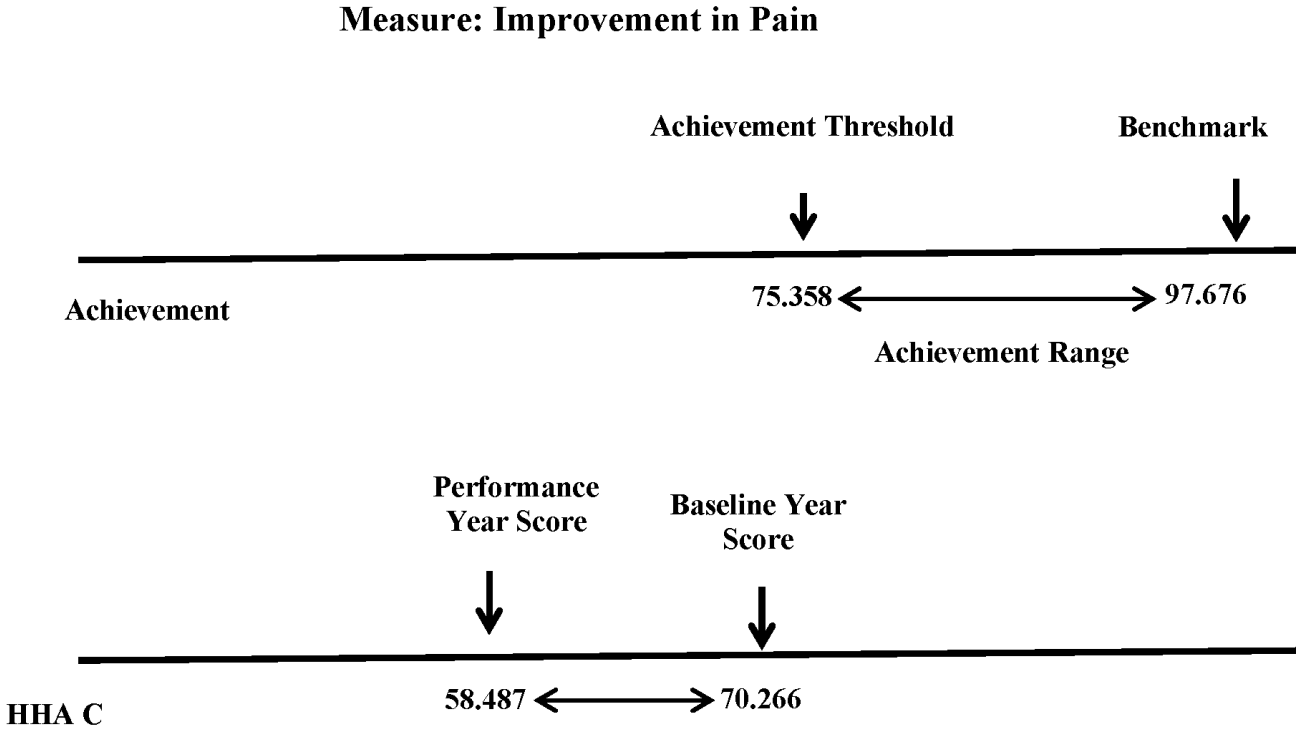


HHA A Score: 10 maximum points for achievement



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



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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 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

[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.*

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

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 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.

TABLE 54—MEASURES CURRENTLY ADOPTED FOR THE CY 2020 HH QRP—Continued

Short name	Measure name & data source
Rehospitalization	Rehospitalization During the First 30 Days of HH (NQF #2380).
HHCAHPS-Based	
Communication	How well did the home health team communicate with patients.
Overall Rating	How do patients rate the overall care from the home health agency.
Professional Care	How often the home health team gave care in a professional way.
Team Discussion	Did the home health team discuss medicines, pain, and home safety with patients.
Willing to Recommend	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 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.

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

[68] Beekman A.T., Deeg D.J., Braam A.W., 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*).

[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.

[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).

implemented (at the time of or at any time since the most recent SOC/ROC assessment). The measure numerator is calculated using 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 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 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

[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*).

[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*).

[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*).

[78] The Advisory Committee on Immunization Practices was established under section 222 of the Public Health Service Act (42 U.S.C. 2l7a), as

Continued

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 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.

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 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 for the HH QRP,[85] and also at the time point of

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.

[80] Tomczyk S., Bennett N.M., 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.

[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*).

[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.

[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),

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 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

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).

[86] 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*).

[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.

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 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 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

[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.*

[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 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

[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.''

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 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).[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 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

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

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

[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.*

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), and 1819 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.

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.

[96] Infusion Therapy: Standards of Practice, Journal of Infusion Nursing, Wolters Kluwer: Jan/Feb 2016 pp S25–S26.

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 administration calendar day is for the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. An infusion drug administration visit that begins in one calendar day and spans into the next calendar day would be considered one visit using the date the visit ended as the service date. We are soliciting comment on the proposed definition of infusion drug administration calendar day in regulation, as detailed in section IX of this proposed rule.

c. Eligible Home Infusion Suppliers, Eligible Individuals, and Relationship to Home Health

Section 1842(u)(7)(F) of the Act defines eligible home infusion suppliers as suppliers that are enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies, and that maintain all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered. This means that existing DME suppliers that are enrolled as pharmacies that provide external infusion pumps and supplies are considered eligible home infusion suppliers, as are potential pharmacy suppliers that enroll and comply with the Medicare program's supplier standards (found at 42 CFR 424.57(c)) and quality standards to become accredited for furnishing external infusion pumps and supplies.[97] Home infusion therapy services are furnished by eligible home infusion suppliers in the individual's home to an individual who is under the care of an applicable provider and where there is a plan of care established and periodically reviewed by a physician prescribing the type, amount, and duration of infusion therapy services. In section VI.C.2.f below, regarding the home infusion therapy benefit for CY 2021 and subsequent years, we are soliciting comments regarding the interaction between home infusion therapy services and home health services. However, for purposes of this proposed temporary transitional payment for home infusion therapy services for CYs 2019 and 2020, we anticipate the relationship between home infusion therapy and home health to be as described in section VI.C.2.f of this proposed rule.

d. Payment Categories

As outlined in section 1834(u)(7)(C) of the Act, identified HCPCS codes for transitional home infusion drugs are assigned to three payment categories for which a single payment amount will be established for home infusion therapy services furnished on each infusion drug administration calendar day. Payment category 1 includes antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, and chelation drugs. Payment category 2 includes subcutaneous immunotherapy infusions. Payment category 3 includes certain chemotherapy drugs. Table 55 provides the complete list of J-codes associated with the infusion drugs that

[97] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html.*

fall within each of the payment categories.

TABLE 55—INFUSION DRUG J-CODES ASSOCIATED WITH TEMPORARY TRANSITIONAL PAYMENT CATEGORIES FOR HOME INFUSION THERAPY SERVICES

J-Code	Drug
Category 1:	
J0133	Injection, acyclovir, 5 mg.
J0285	Injection, amphotericin b, 50 mg.
J0287	Injection, amphotericin b lipid complex, 10 mg.
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg.
J0289	Injection, amphotericin b liposome, 10 mg.
J0895	Injection, deferoxamine mesylate, 500 mg.
J1170	Injection, hydromorphone, up to 4 mg.
J1250	Injection, dobutamine hydrochloride, per 250 mg.
J1265	Injection, dopamine hcl, 40 mg.
J1325	Injection, epoprostenol, 0.5 mg.
J1455	Injection, foscarnet sodium, per 1,000 mg.
J1457	Injection, gallium nitrate, 1 mg.
J1570	Injection, ganciclovir sodium, 500 mg.
J2175	Injection, meperidine hydrochloride, per 100 mg.
J2260	Injection, milrinone lactate, 5 mg.
J2270	Injection, morphine sulfate, up to 10 mg.
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg.
J2278	Injection, ziconotide, 1 microgram.
J3010	Injection, fentanyl citrate, 0.1 mg.
J3285	Injection, treprostinil, 1 mg.
Category 2:	
J1555 JB[98]	Injection, immune globulin (cuvitru), 100 mg.
J1559 JB	Injection, immune globulin (hizentra), 100 mg.
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (*e.g.,* liquid), 500 mg.
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg.
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (*e.g.,* liquid), 500 mg.
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin.
Category 3:	
J9000	Injection, doxorubicin hydrochloride, 10 mg.
J9039	Injection, blinatumomab, 1 microgram.
J9040	Injection, bleomycin sulfate, 15 units.
J9065	Injection, cladribine, per 1 mg.
J9100	Injection, cytarabine, 100 mg.
J9190	Injection, fluorouracil, 500 mg.
J9200	Injection, floxuridine, 500 mg.
J9360	Injection, vinblastine sulfate, 1 mg.
J9370	Injection, vincristine sulfate, 1 mg.

The payment category for subsequent transitional home infusion drug additions to the LCDs and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be determined by the Medicare administrative contractors.

e. Payment Amounts

As set out at new section 1834(u)(7)(D) of the Act, as added by section 50401 of the BBA of 2018 (Pub. L. 115–123), each payment category will be paid at amounts in accordance with the Physician Fee Schedule for each infusion drug administration calendar day in the individual's home for drugs assigned to such category without geographic adjustment. Table 56 provides the payment categories associated with the HCPCS codes.

TABLE 56—PAYMENT CATEGORIES FOR TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES

HCPCS code	Description	Units
Category 1:		
96365	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)—up to one hour.	1
96366	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)—each additional hour.	3
Category 2:		
96369	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)—up to one hour.	1
96370	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)—each additional hour.	3
Category 3:		

[98] The JB modifier indicates that the route of administration is subcutaneous.

TABLE 56—PAYMENT CATEGORIES FOR TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES—Continued

HCPCS code	Description	Units
96413	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration—up to one hour.	1
96415	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration—each additional hour.	3

Section 1834(u)(7)(E)(ii) of the Act requires that in the case that two (or more) home infusion drugs or biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category would be made.

f. Billing

For eligible home infusion suppliers to bill for home infusion therapy services for an infusion drug administration calendar day, we will create three new HCPCS G-codes for each of the three payment categories. The eligible home infusion supplier would submit, in line-item detail on the claim, a G-code for every visit made by the nurse to provide professional services to the patient in his/her home on a day in which a drug is being infused. Each visit reported would include the length of time in which professional services were provided (in 15 minute increments). However, only one payment would be made per infusion drug administration calendar day at the standard amount described by each of the payment categories noted previously, for a total payment equivalent to 4 hours per infusion drug administration calendar day. These G-codes could be billed separately from or on the same claim as the DME, supplies, and infusion drug; and would be processed through the DME MACs. The supplier furnishing the DME, pump, the infusion drug, and other supplies must also provide the professional services under the home infusion therapy benefit during the temporary transitional payment period.

For the purposes of this temporary transitional payment for home infusion therapy services, section 1834(u)(7)(D)(i) requires that payment amounts would be equal to the amounts determined under the Physician Fee Schedule established under section 1848 of the Act for services furnished during the year for codes and units for such codes specified without application of geographic wage adjustment under section 1848(e) of the Act. In the event that multiple drugs, which are not all assigned to the same payment category, are administered on the same infusion drug administration calendar day, section 1834(u)(7)(E)(ii) requires that a single payment would be made that is equal to the highest payment category. In order to implement the requirements of section 1834(u)(7) of the Act for this temporary transitional payment, we would issue a Change Request (CR) prior to implementation of this temporary transitional payment, including the G-codes needed for billing, outlining the requirements for the claims processing changes needed to implement this payment.

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

Upon the expiration of the home infusion therapy services temporary transitional payment, we would be fully implementing the home infusion therapy services payment system under section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act (Pub. L. 114–255). In anticipation of future rulemaking, we are soliciting comments regarding the payment system for home infusion therapy services beginning in CY 2021.

a. Relationship to DME

As mentioned previously, Medicare Part B covers certain infusion pumps and supplies (including certain home infusion drugs) that are necessary for the effective use of the infusion pump, through the DME benefit. To be covered under the Part B DME benefit, the drug must be reasonable and necessary for the treatment of illness or injury or to improve the function of a malformed body member, and the drug must be necessary for the effective use of the DME. However, there is no separate Medicare Part B DME payment for professional services associated with the administration of home infusion drugs, including nursing services, or for training and education, monitoring, and remote monitoring services. Therefore, we consider the home infusion therapy benefit principally to be a separate payment in addition to the existing payment made under the DME benefit, thus explicitly and separately paying for the home infusion therapy services.

b. Definition of Infusion Drug Administration Calendar Day

Section 1834(u)(7)(E)(i) of the Act applies the same definition of ''infusion drug administration calendar day'' for both the home infusion therapy temporary transitional payment and the home infusion therapy services benefit. We anticipate retaining the definition of infusion drug administration calendar day, as proposed in section IV.C.2. of this proposed rule for the full implementation of the home infusion therapy services benefit. This means that payment for an infusion drug administration calendar day is for the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. An infusion drug administration visit that begins in one calendar day and spans into the next calendar day would be considered one visit using the date the visit ended as the service date. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. We are soliciting comments on the definition as discussed in section IV.C.2. of this proposed rule.

c. Payment Basis, Limitation on Payment, Required and Discretionary Adjustments, and Billing Procedures

Section 1834(u)(1)(A) of the Act requires the establishment of a unit of single payment for each infusion drug administration calendar day. Section 1834(u)(1)(A)(iii) of the Act limits the unit of single payment by requiring that it must not exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services furnished in a calendar day if furnished in a physician's office, and the single payment must not reflect more than five hours for a particular therapy in a calendar day. Additionally, section 1834(u)(1) of the Act includes provisions for payment adjustments to

the unit of single payment for home infusion therapy. Section 1834(u)(1)(B) of the Act requires adjustments to reflect factors such as patient acuity and complexity of drug administration, and a geographic wage index and other costs that may vary by region. While the three payment categories used for the temporary transitional payment in CYs 2019 and 2020 reflect the therapy type and complexity of the drug administration under the Physician Fee Schedule, we are soliciting comments on other ways to account for therapy type and complexity of administration, as well as ways to capture patient acuity.

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted by a geographic wage index; therefore, we are considering using the Geographic Practice Cost Indices (GPCIs) to account for regional variations in wages and adjust the payment for the professional services. A GPCI has been established for every Medicare payment locality for each of the three components of a procedure's relative value unit (RVU) (for example, the RVUs for work, practice expense, and malpractice). The GPCIs are applied in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.[99] Finally, section 1834(u)(1)(C) of the Act allows for discretionary adjustments which may include outlier situations and other factors as deemed appropriate by the Secretary, and are required to be made in a budget neutral manner. We request feedback on situations that may incur an outlier payment and potential designs for an outlier payment calculation.

For CY 2021 and subsequent years, although not required by law, the Part B qualified home infusion therapy supplier could potentially submit a claim for home infusion therapy services on a Part B practitioner claim and processed through the A/B MACs, rather than the DME MACs. We are soliciting comment on whether submitting a Part B practitioner claim processed through the A/B MACs is reasonable given that other types of suppliers and providers of services (such as physicians and HHAs), and not just DME suppliers, can meet the requirements under section 1861(iii) of the Act, such as accreditation, to provide home infusion therapy services. In addition, when Part B practitioner claims are processed through the A/B MACs a mechanism is already in place for the geographic wage adjustment, as required for the home infusion therapy payment system, and we are considering the use of GPCI as described previously. In order to bill for the home infusion therapy services, beginning on January 1, 2021, a qualified home infusion therapy supplier will need to enroll in Medicare as a Part B Home Infusion Therapy supplier. Additionally, in order to furnish DME equipment and supplies, that same qualified home infusion therapy supplier must also be enrolled as a DME supplier since the home infusion therapy services are required to be for the furnishing of DME infusion drugs through a DME infusion pump. In other words, both enrollments would be necessary for the same supplier to bill for home infusion therapy services and the DME equipment and supplies. Therefore, in order to be paid for all elements of home infusion therapy, two claims would need to be submitted: (1) The first claim for the DME drug, equipment, and supplies on the 837P/CMS–1500 professional and supplier claims form submitted to the DME MAC; and (2) a second claim for the professional services on the 837P/CMS–1500 professional and supplier claims form submitted to the A/B MAC.

We invite comments on the unit of single payment, limitations on payment, and required and discretionary adjustments. We are also soliciting comments on whether it is reasonable to require two separate claims submissions to account for all components of home infusion therapy using the 837P/CMS–1500 professional and supplier claims form, and submitting claims to both the DME MACs and the A/B MACs for processing. Finally, we are soliciting any additional suggestions as to how qualified home infusion therapy suppliers should bill and be paid for services under the home infusion therapy benefit.

d. Definition of Professional/Nursing Services and Monitoring Related to the Administration of Home Infusion Drugs

In accordance with section 1861(iii)(2) of the Act, items and services covered under the home infusion therapy benefit are as follows:

- Professional services, including nursing services, furnished in accordance with the plan.
- Training and education (not otherwise paid for as DME),
- Remote monitoring, and monitoring services for the provision of home infusion drugs furnished by a qualified home infusion therapy supplier.

Section 1861(n) of the Act defines DME as equipment used in the patient's home. Furthermore, the regulations at 42 CFR 424.57(c)(12) state 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.'' As the medications in the DME external infusion pump LCDs are considered supplies to the external infusion pump, and have been identified as drugs and biologicals that can be self-infused in the home, ongoing nursing supervision is not required once the patient and/or caregiver has been sufficiently taught to safely manage the pump. We recognize that the DME supplier standards require a DME supplier to 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 (42 CFR 424.57(c)(12)). Therefore, the in-home nursing services under the home infusion therapy benefit would include a limited amount of teaching and training on the provision of home infusion drugs that is not already covered under the DME benefit in accordance.

In determining the reasonable and necessary number of infusion therapy visits, the home infusion therapy supplier must consider whether the training and education provided constitutes reinforcement of teaching provided previously in an institutional setting or in the home, or whether it represents initial instruction. Where the teaching represents initial instruction, the supplier should consider patient acuity, including the unique abilities of the patient, and complexity of the infusion. Where the teaching constitutes reinforcement, the supplier should evaluate the patient's retained knowledge and anticipated learning progress to determine the appropriate number of visits. Re-teaching or retraining for an appropriate period may be considered reasonable and necessary where there is a change in the infusion protocol or the patient's condition that requires re-teaching, or where the patient, family, or caregiver is not properly carrying out the task. The medical record should document the anticipated number of training and education visits required, patient/caregiver response to training, and if necessary, the reason that the re-teaching or retraining is required. Where it becomes apparent after a reasonable period of time that the patient/caregiver is not able to be trained, or if the patient/caregiver has been taught to safely and effectively use the infusion

[99] *https://www.cms.gov/apps/physician-fee-schedule/documentation.aspx.*

pump in the home, then further teaching and training would cease to be reasonable and necessary. In accordance with section 1861(iii)(1)(B), an individual must be under a plan of care established by a physician, prescribing the type, amount, and duration of infusion therapy services that are to be furnished in coordination with the furnishing of home infusion drugs under Part B. These home infusion drugs, defined under section 1861(iii)(3)(C) of the Act, must be administered intravenously, or subcutaneously for an administration period of 15 minutes or more through a pump that is an item of DME in order for home infusion therapy services to be reasonable and necessary for the treatment of the illness or injury. In order to satisfy the definition of DME, an item must be appropriate for use in the home. In this case, in order to be considered appropriate for use in the home, the patient must be able to safely and effectively operate the infusion pump. Therefore, if a patient is unable to safely and effectively operate the infusion pump in the home, then the patient would not be eligible for the home infusion therapy benefit.

It is important to reiterate that the professional services covered under this benefit are not intended to provide on-going nursing supervision throughout each infusion. If applicable, the reason why a training was unsuccessful should be documented in the record. We invite comments regarding what constitutes a reasonable and necessary amount of training and education for the provision of home infusion drugs. We outline in this section additional, more detailed information on the professional and nursing services that would be covered, as well as remote monitoring services for the provision of home infusion drugs, as defined in 1861(iii)(3)(C) of the Act, relative to the therapy types currently included in the DME external infusion pump LCD.[100]

(1) Central Vascular Access Device Maintenance

As many of the drugs and biologicals included in the DME external infusion pump LCD are given continuously, given on a long-term basis, or are vesicants or irritants that should not be given peripherally, many beneficiaries would likely have central vascular access devices (CVAD), such as peripherally inserted central catheters (PICC), central lines, or ports requiring training and education regarding maintenance and hygiene, and site care and dressing changes. The qualified home infusion therapy supplier would be responsible for educating the patient on properly disinfecting access points and connectors, what to do in the event of a dislodgement or occlusion, and signs/symptoms of infection. This also includes teaching the patient about flushing the CVAD after the infusion to ensure all of the medication has been flushed through the tubing and catheter, and locking the catheter to prevent blood from backing into the catheter and clotting. Education regarding specific techniques and solutions (saline or heparin) may be given to minimize catheter occlusion.[101]

(2) Medication Education and Disease Management

The qualified home infusion therapy supplier would be responsible for ensuring that the patient has been properly educated about his/her disease, medication therapy, and lifestyle changes. This could include self-monitoring instruction (for example, nutrition, temperature, blood pressure, heart rate, daily weight, abdominal girth measurement, edema, urine output) and identification of complications or problems necessitating a call to the infusion nurse/pharmacist, or emergency protocols if they arise. The qualified home infusion therapy supplier would ensure proper understanding of the medication therapy including: Drug; route of administration; prescription (dosage, how often to administer, and duration of therapy); side effects and interactions with other medications; adverse reactions to therapy; goals of therapy; and indications of progress. Lifestyle education regarding behavior and food/fluid modifications/restrictions, symptom management, and infection control are also important aspects of this education. As some drugs covered under the DME benefit involve extensive lifestyle changes and dietary restrictions, training and education as included in the home infusion therapy benefit could entail any ancillary services such as visits with social workers or dieticians as needed, and documented in the medical record. For patients on continuous, potentially life long IV therapy, the nurse, social worker, or dietician would assess the need for further training and education regarding the concept of long-term drug infusion and address aspects of life-style changes and realistic expectations for life with an infusion pump.

(3) Patient Evaluation and Assessment

Comprehensive patient assessment is imperative when providing home infusion therapy in order to ensure the accuracy of the medication administration and safety of the patient, and to determine whether changes in the home infusion therapy plan of care are necessary. The qualified home infusion therapy supplier would evaluate patient history, current physical and mental status, including patient response to therapy, any adverse effects or infusion complications, lab reports, cognitive and psychosocial status, family/care partner support, prescribed treatment, concurrent oral prescriptions, and over-the-counter medications. This includes obtaining any necessary blood-work and vital signs.

(4) Medication Administration

As the DME supplier is responsible, under the DME benefit,[102] for training the patient and caregiver on pump operation, maintenance, and troubleshooting; the qualified home infusion therapy supplier would be responsible for all other aspects of medication administration, including inspection of medications, containers, supplies prior to use; proper drug storage and disposal; household precautions for chemotherapy drugs including spills, handling body wastes, and physical contact precautions; hand hygiene and aseptic technique; pre/post medication/hydration administration; and medication preparation.

(5) Remote Monitoring and Monitoring Services

Section 1861(iii)(3)(D)(i)(II) of the Act requires that the qualified home infusion therapy supplier ''ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.'' Therefore, the qualified home infusion therapy supplier would closely monitor lab values, patient response to therapy, and assess compliance. Direct communication and coordination with the patient, caregivers, applicable providers, and pharmacist regarding changes in the patient's condition should be on-going so that any adjustment to treatment is made as needed and in a timely fashion.

Monitoring services, as indicated on the plan of care, would dictate either the

[100] *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD.*

[101] Gabriel J (2013) Venous access devices part 2: preventing and managing complications of CVADs. *Nursing Times;* 109: 40, 20–23.

[102] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/DMEPOSAccreditationStandardsCMB.pdf.*

need for daily monitoring of indicated vitals (through remote monitoring) or specify the interval for in-person evaluation and assessment of the patient. The use of remote monitoring services for those patients receiving home infusion therapy would likely be limited to patients receiving continuous infusion medications as identified in the plan of care. These patients are considered high risk patients and require daily monitoring, but generally do not need to be seen by a practitioner daily. This can be achieved, for example, through the use of a remote monitoring service that includes monitoring equipment through which the patient electronically submits self-obtained vital signs, such as weight, blood pressure, and heart rate. In this example, an off-site monitoring service would communicate any abnormal results to the home infusion therapy supplier for analysis and consultation with the provider overseeing the patient's care (that is, physician, nurse practitioner, or physician assistant) regarding potential treatment plan changes.

We invite comments on any additional interpretations of professional, nursing, training and education, and monitoring services that may be considered under the scope of the home infusion therapy benefit. We also specifically welcome comments on the use of remote monitoring under the home infusion therapy benefit.

e. The Role of Prior Authorization Under the Home Infusion Therapy Benefit

Section 1834(u)(4) of the Act states that the Secretary may apply prior authorization for home infusion services. Generally, prior authorization requires that a decision by a health insurer or plan be rendered to confirm that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary.[103] Prior authorization helps to ensure that a service, such as home infusion therapy, is being provided appropriately. Private health plans generally require prior authorization before home infusion therapy can begin. We would maintain the discretion to decide if certain drugs or frequency in visits require prior authorization before therapy can be covered. The emphasis would be on the appropriateness of the drug and the necessity of associated professional services and not the site of care. We are soliciting comments as to whether and how prior authorization could potentially be utilized for home infusion therapy.

f. Home Infusion Therapy and the Relationship to/Interaction With Home Health

A beneficiary does not have to be considered confined to the home (that is, homebound) in order to be eligible for the home infusion therapy benefit. However, homebound beneficiaries requiring home health services also may be eligible for the home infusion therapy benefit. Therefore, there may be circumstances when a patient may utilize both the home health benefit and the home infusion therapy benefit concurrently.

HHAs are required to furnish necessary DME and coordinate home infusion services when a patient is under a home health plan of care. In accordance with the Home Health Conditions of Participation at 42 CFR 484.60, the HHA must assure communication with all physicians involved in the plan of care, as well as integrate orders and services provided by all physicians and disciplines. In order to qualify for the Medicare home health benefit, the beneficiary must—

- Be confined to the home;
- Be under the care of a physician;
- Receive services under a plan of care established and periodically reviewed by a physician;
- Be in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology, or have a continuing need for occupational therapy; and
- Have had a face-to-face encounter related to the primary reason for home health care with an allowed provider type and within the required timeframe.

If a patient meets the requirements listed previously and a home health visit is furnished that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS payment and billed on the home health claim. When the HHA providing services under the Medicare home health benefit is also the same entity furnishing services as the qualified home infusion therapy supplier, and a home visit is exclusively for the purpose of furnishing items and services related to home infusion therapy, the HHA would submit a claim for payment as a home infusion therapy supplier and receive payment under the home infusion therapy benefit. If the home visit includes the provision of other home health services in addition to, and separate from, items and services related to the home infusion therapy, the HHA would submit both a home health claim and a home infusion therapy claim, but must separate the time spent performing services covered under the HH PPS from the time spent performing services covered under the home infusion therapy benefit. We anticipate this would be similar to the approach for furnishing negative pressure wound therapy using a disposable device as described in the regulations at 42 CFR 484.205(b).

We are soliciting feedback on the relationship between the Medicare home health benefit and the home infusion therapy benefit, including how payment would be made for a beneficiary who meets eligibility requirements for home health services and home infusion therapy services.

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

A. Background

To participate in the Medicare program, Medicare-certified providers and suppliers of health care services, must be substantially in compliance with specified statutory requirements of the Act, as well as any additional regulatory requirements related to the health and safety of patients specified by the Secretary of the Department of Health and Human Services (HHS). Medicare certified providers and suppliers are enrolled in the Medicare program by entering into an agreement with Medicare. They include 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, and ambulatory surgical centers. These health and safety requirements are generally called conditions of participation (CoPs) for most providers, requirements for skilled nursing facilities (SNFs), conditions for coverage (CfCs) for ambulatory surgical centers (ASCs) and other suppliers, and conditions for certification for rural health clinics (RHCs). A Medicare-certified provider or supplier that does not substantially comply with the applicable health and safety requirements risks having its participation in the Medicare program terminated.

In accordance with section 1864 of the Act, state health departments or similar agencies, under an agreement with CMS, survey health care providers and suppliers to ascertain compliance with the applicable CoPs, CfCs, conditions of certification, or requirements, and certify their findings to us. Based on these State Survey

[103] *https://www.healthcare.gov/glossary/preauthorization/.*

Agency (SA) certifications, we determine whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program.

Section 1865(a) of the Act allows most health care facilities to demonstrate compliance with Medicare CoPs, requirements, CfCs, or conditions for certification through accreditation by a CMS-approved program of a national accreditation body. If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider or supplier accredited by the AO's CMS-approved accreditation program may be deemed by us to meet the Medicare conditions or requirements.

We are responsible for the review, approval and subsequent oversight of national AOs' Medicare accreditation programs, and for ensuring providers or suppliers accredited by the AO meet the quality and patient safety standards required by the Medicare CoPs, requirements, CfCs, and conditions for certification. Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Act must apply for and be approved by CMS for a period not to exceed six years.

The AO must reapply for renewed CMS approval of an accreditation program before the date its approval period expires. This allows providers or suppliers accredited under the program to continue to be deemed to be in compliance with the applicable Medicare CoPs, requirements, CfCs, and conditions for certification. Regulations implementing these provisions are found at 42 CFR 488.1 through 488.9.

We believe that it is necessary to revise the regulations for Medicare-certified providers and providers to add two new requirements for the AOs that accredit certified providers and providers. First, we are proposing at § 488.5 to require AOs for Medicare-certified providers and suppliers to include a written statement in their application which states that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the AO's CMS-approved accreditation program, the AO must continue the facility's current accreditation until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first. We are also proposing to modify the AO oversight regulations at § 488.5 by adding new requirements for training for AO surveyors.

B. Proposed Changes to Certain Requirements for Medicare-Certified Providers and Suppliers at Part 488

1. Continuation of Term of Accreditation When a Medicare-Certified Provider or Supplier Decides to Voluntarily Terminate the Services of an Accrediting Organization (§ 488.5)

We propose to add a new regulation at § 488.5(a)(17)(iii), which would require that, with an initial or renewal application for CMS-approval of a Medicare certified provider or supplier accreditation program, an AO must include a written statement agreeing that when a fully accredited, deemed provider or supplier in good standing notifies its AO that it wishes to voluntarily withdraw from the AO's accreditation program, the AO would honor the provider's or supplier's current term of accreditation until the effective date of withdrawal identified by the facility, or the expiration date of the term of accreditation, whichever comes first. We make this proposal because we have received numerous complaints from accredited and deemed facilities in good standing with their current AO stating that once they provide notification to the AO of their intent to voluntary withdrawal their accreditation from that AO, the AO frequently terminates their accreditation immediately without regard to their current accreditation status, up to date payment of fees, contract status, or the facility's requested effective date of withdrawal. Accreditation is voluntary for Medicare certified providers and suppliers that participate in Medicare. It is not required for participation in Medicare. Therefore, we do not believe it is reasonable for AOs to penalize facilities because they choose to terminate the services of an AO. Medicare certified providers and suppliers may freely choose to demonstrate compliance with the Medicare conditions.by receiving surveys from any CMS-approved AO of their choice, or the SA.

2. Training Requirements for Accrediting Organization Surveyors (§ 488.5(a)(7))

We are proposing to add a new requirement at § 488.5(a)(7) which imposes a new training requirement for surveyors of AO that accredit Medicare certified provider and supplier types by amending the provision at § 488.5(a)(7). We are proposing that all AO surveyors be required to complete the relevant program-specific CMS online trainings initially, and thereafter, consistent with requirements established by CMS for state surveyors. CMS provides a wide variety of comprehensive trainings through an on-demand integrated surveyor training website. These online trainings are available and can be accessed by state and federal surveyors and the public, free of charge, 24 hours a day, 365 days a year. These online trainings are currently publically available for the SA surveyors.

As part of our oversight of the AOs performance, CMS has contracted with the SAs to perform validation surveys on a sample of providers and suppliers (such as hospitals, critical access hospital, ambulatory surgical centers, and home health agencies) accredited by the AOs that accredit Medicare certified providers and suppliers. Validation surveys must be performed by the SA within 60 days of the survey performed by the AO. As a validation survey is performed within 60 days of the AO survey, we believe that the conditions at the hospital or other facility being surveyed would be similar at the time of the validation survey.

The purpose of a validation survey is to compare the survey findings of the AO to the survey findings of the SA to see if there are any disparities. The amount of disparities found in the AO's survey is called the ''disparity rate'' and is tracked by CMS as an indication of the quality of the surveys performed by the AO.

CMS has determined that many of the AOs' disparity rates have been consistently high. This means that the AOs have consistently failed to find the same condition level deficiencies in the care provided by the hospital or other providers surveyed that were found by the SA during the validation survey.

We believe that the disparity in findings made by the AO surveyors and those of the SA surveyors can largely be attributed the difference in the training and education provided to the AO surveyors. Each AO is responsible for providing training and education to their surveyors. The surveyor training and education provided varies from AO to AO and is not consistent. CMS provides comprehensive online training to the SA surveyor staff on the CMS Surveyor Training website [104] which are specific to each type of provider of supplier type to be surveyed.

It is our belief that the AO's disparity rate would be decreased if all surveyors took the same training. We believe completion of the same surveyor training by both SA and AO surveyors would increase the consistency between the results of the surveys performed by the SAs and AOs and have a positive impact on the historically high disparity

[104] *https://surveyortraining.cms.hhs.gov/.*

rate. Therefore we are proposing that all AO surveyors be required to take the CMS online surveyor training offered on the CMS website. We would require each AO to provide CMS with documentation which provides proof that each of their surveyors has completed the CMS online surveyor training. If the AO fails to provide this documentation, CMS could place the AO on an accreditation program review pursuant to § 488.8(c).

VIII. Requests for Information

This section addresses two requests for information (RFI). Upon reviewing the RFIs, respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; neither RFI constitutes a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor each RFI announcement for additional information pertaining to the request. Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care.[105] While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In 2015, ONC finalized the 2015 Edition health IT certification criteria (2015 Edition), the most recent criteria for health IT to be certified to under the ONC Health IT Certification Program. The 2015 Edition facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. CMS requires eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to the 2015 Edition beginning in CY 2019.

In addition, several important initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, and amending section 3000 of the Public Health Service Act (42 U.S.C. 300jj), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC ''. . . for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' In January 2018, ONC released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement,[106] which outlines principles and minimum terms and conditions for trusted exchange to enable interoperability across disparate health information networks (HINs). The Trusted Exchange Framework (TEF) is focused on achieving the following four important outcomes in the long-term:

- Professional care providers, who deliver care across the continuum, can access health information about their patients, regardless of where the patient received care.
- Patients can find all of their health information from across the care continuum, even if they do not remember the name of the professional care provider they saw.
- Professional care providers and health systems, as well as public and private health care organizations and public and private payer organizations

[105] These statistics can be accessed at: *https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php.*

[106] The draft version of the trusted Exchange Framework may be accessed at: *https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

accountable for managing benefits and the health of populations, can receive necessary and appropriate information on groups of individuals without having to access one record at a time, allowing them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives.

- The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation that will make health information more accessible and improve EHR usability.

ONC will revise the draft TEF based on public comment and ultimately release a final version of the TEF that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. The goal for stakeholders that participate in, or serve as, a HIN is to ensure that participants will have the ability to seamlessly share and receive a core set of data from other network participants in accordance with a set of permitted purposes and applicable privacy and security requirements. Broad adoption of this framework and its associated exchange standards is intended to both achieve the outcomes described above while creating an environment more conducive to innovation.

In light of the widespread adoption of EHRs along with the increasing availability of health information exchange infrastructure predominantly among hospitals, we are interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals, such as: Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

On November 3, 2015, we published a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113–185) and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals), critical access hospitals (CAHs), and home health agencies (HHAs) would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. However, several of the proposed requirements directly address the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

- Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient's practitioner, if the practitioner is known and has been clearly identified;
- Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/post-acute care providers, at the time of discharge; and
- Hospitals, CAHs, and HHAs would need to comply with the IMPACT Act requirements that would require hospitals, CAHs, and certain post-acute care providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of care and treatment preferences.

We published another proposed rule (81 FR 39448) on June 16, 2016, that updated a number of CoP requirements that hospitals and CAHs would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, including current medical records, within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

We also published a final rule (81 FR 68688) on October 4, 2016, that revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. In this rule, we made a number of revisions based on the importance of effective communication between providers during transitions of care, such as transfers and discharges of residents to other facilities or providers, or to home. Among these revisions was a requirement that the transferring LTC facility must provide all necessary information to the resident's receiving provider, whether it is an acute care hospital, an LTCH, a psychiatric facility, another LTC facility, a hospice, a home health agency, or another community-based provider or practitioner (42 CFR 483.15(c)(2)(iii)). We specified that necessary information must include the following:

- Contact information of the practitioner responsible for the care of the resident;
- Resident representative information including contact information;
- Advance directive information;
- Special instructions or precautions for ongoing care;
- The resident's comprehensive care plan goals; and
- All other necessary information, including a copy of the resident's discharge or transfer summary and any other documentation to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include reconciliation of the resident's medications, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. In addition, in the preamble to the rule, we encouraged LTC facilities to electronically exchange this information if possible and to identify opportunities to streamline the collection and exchange of resident information by using information that the facility is already capturing electronically.

Additionally, we specifically invite stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

• If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?

• Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?

• Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act?

• What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?

• Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?

• Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?

• Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

• What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the Federal Government, on this objective.

While some Medicare beneficiaries have had, for quite some time, the ability to download their Medicare claims information, in pdf or Excel formats, through the CMS Blue Button platform, the information was provided without any context or other information that would help beneficiaries understand what the data were really telling them. For beneficiaries, their claims information is useless if it is either too hard to obtain or, as was the case with the information provided through previous versions of Blue Button, hard to understand. In an effort to fully contribute to the Federal Government's MyHealthEData initiative, CMS developed and launched the new Blue Button 2.0, which represents a major step toward giving patients meaningful control of their health information in an easy-to-access and understandable way. Blue Button 2.0 is a developer-friendly, standards-based application programming interface (API) that enables Medicare beneficiaries to connect their claims data to secure applications, services, and research programs they trust. The possibilities for better care through Blue Button 2.0 data are exciting, and might include enabling the creation of health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete medication lists with their doctors to prevent dangerous drug interactions.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Home Health Agency Charge Information

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548 and 20549) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we stated that we intend to continue to review and post relevant charge data in a consumer-friendly way, as we previously have done by posting hospital and physician charge

information on the CMS website.[107] In the FY 2019 IPPS/LTCH PPS proposed rule, we also continued our discussion of the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. This discussion in the FY 2019 IPPS/LTCH PPS proposed rule continued a discussion we began in the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively). In all of these rules, we noted that section 2718(e) of the Public Health Service Act requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. In the FY 2015 IPPS/LTCH PPS proposed and final rules, we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH PPS proposed rule, we took one step to further improve the public accessibility of charge information. Specifically, effective January 1, 2019, we are updating our guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate.

In general, we encourage all providers and suppliers to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services. We encourage providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges.

We are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals and in other settings, and patients being surprised by facility fees, physician fees for emergency department visits, or fees for services that are part of the beneficiary's episode of care but that are not otherwise included in a hospital's chargemaster (for example, home health or physical therapy services that follow a hospital stay but are billed separately). We also are concerned that, for providers and suppliers that maintain a list of standard charges, the charge data may not be helpful to patients for determining what they are likely to pay for a particular service or facility encounter. In order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of current charge information.

We also are considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including when services could be offered in more than one setting. Therefore, we are seeking public comment from all providers and suppliers, including home health agencies, on the following:

- How should we define ''standard charges'' in the home health setting? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should ''standard charges'' be defined to mean: average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the HHA based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should ''standard charges'' be defined and reported for both some measure of the average contracted rate and the chargemaster, price list or charge list? Or is the best measure of a HHA's standard charges its chargemaster, price list or charge list?
- What types of information would be most beneficial to patients, how can HHAs best enable patients to use charge and cost information in their decision-making, and how can CMS and HHAs help third parties create patient-friendly interfaces with these data?
- Should HHAs be required to inform patients how much their out-of- pocket costs for a service will be before those patients are furnished that service? How can information on out-of-pocket costs be provided to better support patients' choice and decision-making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how co-pays and co-insurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should HHAs play any role in helping to inform patients of what their out-of-pocket obligations will be?
- If HHAs were required to provide patients with information on what Medicare pays for a particular service performed by that HHA, what changes would need to be made by HHAs? What burden would be added as a result of such a requirement?

In addition, we are seeking public comment on improving a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following particular questions:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care? What challenges do HHAs face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support HHAs that share out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management

[107] See, for example, Medicare Provider Utilization and Payment Data, available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html.*

and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, the following table (Table 57) presents the mean hourly wage rate, fringe benefits costs and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 57—MAY 2017 NATIONAL INDUSTRY–SPECIFIC OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES—NAICS 621600—HOME HEALTH CARE SERVICES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead (100%) ($/hr)	Adjusted hourly wage ($/hr)
Registered Nurse (RN)	29–1141	$33.77	$33.77	$67.54
Physical therapists HHAs	29–1123	46.19	46.19	92.38
Speech-Language Pathologists (SLP)	29–1127	43.93	43.93	87.86
Occupational Therapists (OT)	29–1122	43.70	43.70	87.40

This proposed rule makes reference to associated information collections that are not discussed in the regulation text contained in this document. These proposed changes are associated with the Information Collection Request (ICR) for CMS–10545—Outcome and Assessment Information Set (OASIS) OASIS–C2/ICD–10, approved under OMB control number 0938–1279. We note that on March 12, 2018 we published a notice in the **Federal Register** seeking public comment on a revision to CMS–10545 (OMB control number 0938–1279), which would modify the OASIS and refer to the revised item set as the OASIS–D upon implementation of the revised data set on January 1, 2019 (83 FR 10730). We are soliciting public comment on additional changes related to when certain OASIS items are required to be completed by HHA clinicians due to the proposed implementation of the patient-driven groupings model (PDGM) for CY 2020, as outlined in section III.F of this proposed rule; and the changes to due to the proposed removal of HH QRP measures beginning with the CY 2021 HH QRP, as outlined in section V.E of this proposed rule.

B. ICRs Regarding the OASIS

We believe that the burden associated with the OASIS is the time and effort associated with data collection and reporting. As of April 1, 2018, there are approximately 11,623 HHAs reporting OASIS data to CMS.

In section V.E.1 of the proposed rule, 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. The removal of this measure will not impact collection of information because OASIS Item M1730, which is used to calculate this measure, is also used as a risk adjuster to calculate other OASIS-based outcome measures currently adopted for the HH QRP.[108]

In section V.E.2 of the proposed rule, 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. This measure is calculated using OASIS Item M2401, row a at the time point of Transfer to an Inpatient Facility (TOC) and Discharge from Agency—Not to an Inpatient Facility (Discharge). Specifically, we are proposing to remove this one data element at the TOC and Discharge time points.

In section V.E.3 of the proposed rule, 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. This measure is calculated using OASIS Item M1910 at the time point of SOC/ROC. Specifically, we are proposing to remove this one data element at the SOC/ROC time point.

In section V.E.4 of the proposed rule, 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. This measure is calculated using OASIS Items M1051 and M1056 at the time points of TOC and Discharge. Specifically, we are proposing to remove these two data elements at the TOC and Discharge time points.

In section V.E.5 of the proposed rule, 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. The removal of this measure will not impact collection of information because OASIS Items M1340 and M1342 are

[108] 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).

used as risk adjusters to calculate other OASIS-based outcome measures currently adopted for the HH QRP and OASIS Items M1340 and M1342 are also used 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.[109] [110]

In sections V.E.6 and V.E.7 of the proposed rule, we are proposing to remove the Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure and 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. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. Because these are both claims-based measures, their removal will not impact collection of information.

Therefore, we are proposing the net reduction of 1 data element at SOC, 1 data element at ROC, 3 data elements at TOC and 3 data elements at Discharge associated with OASIS item collection as a result of the measure removal proposals from the HH QRP.

The OASIS instrument is used for meeting the home health Conditions of Participation, requirements under the HH QRP, and for payment purposes under the HH PPS. As outlined in section III.F of this proposed rule, to calculate the case-mix adjusted payment amount for the PDGM, we are proposing to add collection of two current OASIS items (10 data elements) at the FU time point:

- M1033: Risk for Hospitalization (9 data elements)
- M1800: Grooming (1 data element)

As outlined in section III.F of this proposed rule, several OASIS items would not be needed in case-mix adjusting the period payment for the PDGM; therefore, we are proposing to make 19 current OASIS items (48 data elements) optional at the FU time point:

- M1021: Primary Diagnosis (3 data elements)
- M1023: Other Diagnosis (15 data elements)
- M1030: Therapies (3 data elements)
- M1200: Vision (1 data element)
- M1242: Frequency of Pain Interfering (1 data element)
- M1311: Current Number of Unhealed Pressure Ulcers at Each Stage (12 data elements)
- M1322: Current Number of Stage 1 Pressure Ulcers (1 data element)
- M1324: Stage of Most Problematic Unhealed Pressure Ulcer that is Stageable (1 data element)
- M1330: Does this patient have a Stasis Ulcer? (1 data element)
- M1332: Current Number of Stasis Ulcer(s) that are Observable (1 data element)
- M1334: Status of Most Problematic Stasis Ulcer that is Observable (1 data element)
- M1340: Does this patient have a Surgical Wound (1 data element)
- M1342: Status of Most Problematic Surgical Wound that is Observable (1 data element)
- M1400: Short of Breath (1 data element)
- M1610: Urinary Incontinence or Urinary Catheter Presence (1 data element)
- M1620: Bowel Incontinence Frequency (1 data element)
- M1630: Ostomy for Bowel Elimination (1 data element)
- M2030: Management of Injectable Medications (1 data element)
- M2200: Therapy Need (1 data element)

Therefore, we are proposing the net reduction of 38 data elements at FU associated with OASIS item collection as a result of the implementation of the PDGM for CY 2020.

In summary, under our proposals, there would be a net reduction of 1 data element at SOC, 1 data element at ROC, 38 data elements at FU, 3 data elements at TOC and 3 data elements at Discharge associated with OASIS item collection as a result of the measure removal proposals from the HH QRP and the proposed implementation of the PDGM starting January 1, 2020.

We assume that each data element requires 0.3 minutes of clinician time to complete. Therefore, we estimate that there would be a reduction in clinician burden per OASIS assessment of 0.3 minutes at SOC, 0.3 minutes at ROC, 11.4 minutes at FU, 0.9 minutes at TOC and 0.9 minutes at Discharge.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2016 show that the SOC/ROC OASIS is completed by RNs (approximately 87 percent of the time), PTs (approximately 12.7 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). We estimated a weighted clinician average hourly wage of $70.75, inclusive of fringe benefits, using the hourly wage data in Table 57. Individual providers determine the staffing resources necessary.

Table 58 shows the total number of assessments submitted in CY 2017 and estimated burden at each time point.

TABLE 58—CY 2017 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time point	CY 2017 assessments completed	Estimated burden ($)
Start of Care	6,420,299	−$2,271,180.77
Resumption of Care	1,062,962	−376,022.81
Follow-up	3,688,651	−49,584,691.07
Transfer to an inpatient facility	1,925,270	−2,043,192.79
Death at Home	41,183	0
Discharge from agency	5,249,483	−5,571,013.83
Total	18,387,848	−59,846,101.27

* Estimated Burden ($) at each Time-Point = (# CY 2017 Assessments Completed) × (clinician burden [min]/60) × ($70.75 [weighted clinician average hourly wage]).

[109] 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).

[110] 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*).

Based on the data in Table 58 for the 11,623 active Medicare-certified HHAs in April 2018, we estimate the total average decrease in cost associated with proposed changes with OASIS item collection at $5,148.94 per HHA annually, or $59,846,101.27 for all HHAs annually. This corresponds to an estimated reduction in clinician burden associated with changes to collection of information associated with the OASIS of 72.8 hours per HHA annually, or 845,881.3 hours for all HHAs annually. This decrease in burden would be accounted for in the information collection under OMB control number 0938–1279.

C. ICRs Regarding Home Infusion Therapy

At § 486.520, Plan of Care, we propose that all patients must have a plan of care established by a physician that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. This requirement directly implements section 5012 of the 21st Cures Act. Accredited home infusion therapy suppliers are already required by their accrediting bodies to provide all care in accordance with a plan of care that specifies the type, amount, and duration of infusion therapy services to be furnished to each patient; therefore this proposed requirement would not impose a burden upon accredited agencies. Furthermore, all existing home infusion therapy suppliers are already accredited due to existing payment requirements established by private insurers and Medicare Advantage plans. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(3), this requirement exists even in the absence of a federal requirement; therefore, the associated burden is not subject to the PRA.

D. ICRs Regarding the Approval and Oversight of Accrediting Organizations for Home Infusion Therapy

1. Background

We are proposing to establish a new set of regulations related to the approval and oversight of accrediting organizations that accredit home infusion therapy suppliers. If finalized, these new regulatory requirements would impose burden on those new AOs that seek approval of their Home Infusion Therapy accreditation program. This burden would include, but is not limited to the time and costs associated with the following activities: (1) Preparation and filing of an initial application seeking CMS approval of the AOs home infusion therapy accreditation program; (2) participation in the application review process (that is, meetings, provide additional information and materials that may be required, participate in a site visit, etc.); (3) seeking new accreditation clients; (4) performing on-site surveys, off-site survey audits or the performance of other types of survey activities; (5) participation in CMS ongoing accreditation program review activities; (6) performance of periodic re-accreditation activities; (7) investigation of complaints and performing complaint surveys; (8) administration of the appeals process for providers that have been denied accreditation; (9) staff training, in-services and continuing education; and (10) ensuring that surveyor staff have the proper education, training, and credentials.

The following is a discussion of the potential ICR burdens associated with the proposed home infusion therapy supplier accreditation oversight regulations and well as any PRA exceptions that may apply.

2. Applicable PRA Exception

We believe that the information collection burden associated with the preparation and submission of an initial or renewal application for approval and designation as an home infusion therapy AO and the participation in other accreditation related activities does not meet the definition of ''collection of information'' as defined in 5 CFR 1320.3(c) because it is ''not imposed on 10 or more persons.'' This information collection burden would be imposed only on those national AOs that accredit home infusion therapy suppliers.

At this time, there are five CMS-approved AOs and one non-CMS-approved AO that provide accreditation for home infusion therapy suppliers (that is, The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation, and National Association of Boards of Pharmacy). However, these AOs offer home infusion therapy accreditation as part of the deeming accreditation of home health agencies or the home infusion therapy accreditation provided is CMS approved.

In this proposed rule, we have proposed to require that these AO must apply for CMS approval of a home infusion therapy accreditation that is separate and distinct from its home health accreditation program. When we do solicit AOs to accredit home infusion therapy suppliers, we do not anticipate receiving more than the six applications which would be submitted by the existing AOs seeking approval of a home infusion therapy accreditation program, because this is a specialized area of accreditation.

It is possible that the number of AOs that we designate to accredit home infusion therapy suppliers may increase to 10 or more in the future, when we begin accepting applications for home infusion therapy AOs. However, we do not anticipate that the number of AOs that would accredit home infusion therapy suppliers would increase to 10 or more in the foreseeable future.

Should the number of AOs that accredit home infusion therapy suppliers rise to 10 or more, we would prepare and submit an information collection request (ICR) for the burden associated with the accreditation process, as well as obtain OMB approval, prior to accepting additional applications.

E. ICR Regarding Modifications to 42 CFR 488.5

We have proposed to modify the AO approval and oversight regulations for Medicare certified providers and suppliers by adding 2 new requirements. The first proposed new requirement is to added to § 488.5(a)(7) and is a requirement that in their application for CMS approval, the AOs that accredited Medicare certified providers and suppliers must include a statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program specific CMS online trainings established for state surveyors, initially, and thereafter. The second requirement is to be added as § 488.5(a)(18)(iii) and would require that the AOs for Medicare certified providers and suppliers include a written statement in their application for CMS approval agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

1. Burden Associated With CMS Online Training for AO Surveyors

CMS provides a number of online surveyor training modules that are available to the State Survey Agency surveyors. We have proposed to require the AO surveyors to take this training in an attempt to decrease the historically

high disparity rate between the AOs survey results and those of the validation surveys performed by the State Survey Agency surveyors.

There are a total of 163 online training programs that are available the State Survey Agency surveyors on the CMS Surveyor Training website. This website provides courses that are general in nature such as ''Principles of Documentation Learning Activity—Long Term Care'' and ''Basic Writing Skills for Surveyor Staff'', infection control, patient safety, Emergency Preparedness. The CMS Surveyor Training website also offers courses related to specific healthcare settings, services, and regulations such as hospitals, CAHs, ASCs, CLIA, Community Mental Health Centers, EMTALA, Federally Qualified Health Centers (FQHCs), Home Health Agencies and OASIS, Hospices, Nursing Homes and the MDS, Outpatient Physical Therapy/Outpatient Speech Therapy. These courses are self-paced and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training course varies depending on the pace at which the trainee completes the training.

We estimate that each SA surveyor takes approximately 10 of these courses. We further estimate that it would take approximately 3–5 hours to complete each of these courses. Therefore a SA surveyor would incur a time burden of 30–50 hours for the completion of these CMS surveyor training courses. We believe that the surveyors for AOs that accredit Medicare certified providers would need to take the same number and type of surveyor training courses as the SA surveyors (that is—approximately 10 courses). This means that each of the AOs surveyors that takes this training would incur a time burden in the amount of 30–50 hours.

The AOs that accredit Medicare certified providers and suppliers would incur a cost burden for the wages of their surveyors for the time they spend taking these online surveyor training courses. Most surveyors are clinicians such as Registered Nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). As noted above, we estimated that it would take approximately 30–50 hours for each AO surveyor to complete 10 online surveyor courses. Therefore, the AO would incur wages in the amount of $1,060.80 to $1,768.00 per each surveyor that completes the CMS online surveyor training. The AO would also incur additional costs for fringe benefits and overhead in the amount of $1,060.80 to $1,768.00 per each surveyor that completes the CMS online surveyor training.

We are not able to accurately estimate to total time and cost burden to each AO for the wages incurred for the time spent by all surveyors of that AO that take the CMS online surveyor training courses, because we do not know exactly how many surveyors each AO has. However, if we estimate that each AO has 15 surveyors, the estimated time burden to each AO associated with this requirement would be 450 to 750 hours ((30 hours × 15 surveyors = 450 hours per all surveyors) and (50 hours × 15 surveyors = 750 hours per all surveyors)). The estimated cost burden to each AO for Medicare certified providers and supplies associated with this requirement would be $31,824 to $53,040 (($1,060.80 × 15 = $15,912) and ($1,768.00 × 15= $26,520) and ($15,912 to $26,520 for fringe benefits and overhead)).

There are currently 9 AOs that accredit Medicare certified providers and suppliers. We estimate that the time burden across all of these AOs associated with the requirement that their surveyors take the CMS online surveyor training would be 4,050 to 6,750 ((450 hours per all surveyors/AO × 9 AOs = 4,050 hours across all AOs) and (750 hours per all surveyors/AO × 9 AOs = 6,750 hours across all AOs). The estimated cost across all AOs that accredit Medicare certified providers and suppliers would be $763,776 ($15,912 × 9 AOs = $143,208) and ($26,520 × 9 AOs = $238,680) and ($381,888 for fringe benefits and overhead).

However, we believe that the information collection burden associated with the requirement that the surveyors of AOs that accredit Medicare certified providers and suppliers does not meet the definition of ''collection of information'' as defined in 5 CFR 1320.3(c) because it is ''not imposed on 10 or more persons.'' This information collection burden would be imposed only on those AOs that accredit Medicare certified providers and suppliers. At this time, there are nine CMS-approved AOs that accredit Medicare certified providers and suppliers (that is, AAAASF, AAAHC, ACHC, AOA–HFAP, Community Health Accreditation Partner (CHAP), CIHQ, DNV–GL, The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT)). Should the number of AOs that accredit Medicare certified providers and suppliers rise to 10 or more, we will seek OMB approval for the burden associated with the accreditation process.

2. Burden Associated With the Requirement for AOs To Continue a Medicare-Certified Provider's or Supplier's Accreditation

This proposal would require the AOs for Medicare certified providers and suppliers to include a written statement in their application for CMS approval of their accreditation program, agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

We believe that the AO would incur limited burden associated with this task, because this regulation simply requires that the AOs include a written statement in their application stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider of supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program. All AOs that accredit Medicare certified providers and suppliers are required to submit an initial application to CMS when they first seek CMS approval and to submit renewal applications to CMS every 6 years thereafter. In accordance wirh 42 CFR 488.5, the AOs are required to provide a number of written acknowledgements with their application. We believe that the AO could add the required written statement to the other written acknowledgements that are included with their applications. As the AO would already be preparing the other acknowledgements required to be submitted with their application, it would be little if any additional burden for the AO to add the required written statement to their application.

We estimate that the required written statement would consist of only 1–2 sentences and would take no more than 5 minutes to prepare. We further believe that clinicians such as registered nurses would prepare the required statement to be included in the AOs application. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a

non-industry specific registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the AOs associated with the preparation of the written statement would be approximately $17.68 (15 minutes × $35.36 per hour = $8.84 plus $8.84 in fringe benefits and overhead = $17.68).

There are 9 AOs that accredit Medicare certified providers and suppliers. The estimated time burden across all of these AOs would be 45 minutes (15 minutes × 9 AOs = 135 minutes per all AOs). The estimated cost burden across all AOs that accredit Medicare certified providers and suppliers would be $159.12 ($8.84 × 9 AOs = $79.56 per all AOs + $79.56 for fringe benefits and overhead).

However, we believe that the information collection burden associated with the requirement that the AOs that accredit Medicare certified providers and suppliers provide a written statement in their application stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider or supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, does not meet the definition of ''collection of information'' as defined in 5 CFR 1320.3(c) because it is ''not imposed on 10 or more persons.'' This information collection burden would be imposed only on those AOs that accredit Medicare-certified providers and suppliers. At this time, there are nine CMS-approved AOs that accredit Medicare-certified providers and suppliers (that is, AAAASF, AAAHC, ACHC, AOA–HFAP, Community Health Accreditation Partner (CHAP), CIHQ, DNV–GL, The Joint Commission (TJC), The Compliance Team (TCT)). Should the number of AOs that accredit Medicare certified providers or suppliers rise to 10 or more, we will seek OMB approval for the burden associated with the accreditation process.

F. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

We invite public comments on these information collection requirements. If you wish to comment, please identify the rule (CMS–1689–P) and, where applicable, the ICR's CFR citation, CMS ID number, and OMB control number.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

See this rule's **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

VIII. Regulatory Impact Analysis

A. Statement of Need

1. Home Health Prospective Payment System (HH PPS)

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Section 50208 of the BBA of 2018 (Pub. L. 115–123) requires the Secretary to implement a new methodology used to determine rural add-on payments for CYs 2019 through 2022.

Section 1895(b)(2) of the Act and section 1895(b)(3)(A) of the Act, as amended by section 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, require the Secretary to implement a 30-day unit of service, effective for CY 2020, and calculate a 30-day payment amount for CY 2020 in a budget neutral manner, respectively. In addition, section 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the BBA of 2018 requires the Secretary to eliminate the use of the number of therapy visits provided to determine payment, also effective for CY 2020.

Finally, the HHVBP Model applies a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and expenditures.

2. Home Infusion Therapy

Section 1861(iii) of the Act, as added by the Cures Act, sets forth three elements for home infusion therapy suppliers in three areas: (1) Ensuring 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, (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided, and (3) having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home. These

provisions serve as the basis for suppliers to participate 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. Section 1834(u)(7) of the Act, as added by BBA of 2018 requires the Secretary to provide a temporary transitional payment to eligible home infusion therapy suppliers for items and services associated with the furnishing of transitional home infusion drugs for CYs 2019 and 2020. Under this payment methodology (as described in section VI.C. of this proposed rule), the Secretary would establish three payment categories at amounts equal to the amounts determined under the Physician Fee Schedule established under section 1848 for services furnished during CY 2019 for codes and units of such codes, determined without application of the geographic adjustment.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate organizations to accredit qualified home infusion therapy suppliers furnishing home infusion therapy no later than January 1, 2021. 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 accrediting organization designated and approved by the Secretary; and meet other such requirements as the Secretary deems appropriate.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The net transfer impact related to the changes in payments under the HH PPS for CY 2019 is estimated to be $400 million (2.1 percent). The net transfer impact in CY 2020 related to the change in the unit of payment under the proposed PDGM is estimated to be $0 million as section 51001(a) of the BBA of 2018 requires such change to be implemented in a budget-neutral manner. The net transfer impact in CY 2019 related to the Temporary Transitional Payment for Home Infusion Therapy is estimated to be $60 million. The savings impacts related to the HHVBP model as a whole are estimated at $378 million. The cost impact related to OASIS item collection as a result of the proposed implementation of the PDGM and proposed changes to the HH QRP is estimated to be a net $60 million in annualized cost savings to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020. Finally, the estimated cost impact to each potential home infusion therapy AO is $23,258. We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS proposed rule would have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule is not applicable to hospitals. Therefore, the Secretary has determined this proposed rule would not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. This rule is not anticipated to have an effect on State, local, or tribal

governments, in the aggregate, or on the private sector of $150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments. If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique commenters on this year's proposed rule would be the similar to the number of reviewers of last year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which would review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 5.3 hours for the staff to review half of this proposed rule, which consists of approximately 160,000 words. For each HHA that reviews the rule, the estimated cost is $569.11 (5.3 hours × $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $767,729.39 ($569.11 × 1,349 reviewers).

1. HH PPS

a. HH PPS for CY 2019

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2019. Accordingly, the following analysis describes the impact in CY 2019 only. We estimate that the net impact of the policies in this rule is approximately $400 million in increased payments to HHAs in CY 2019. We applied a wage index budget neutrality factor and a case-mix weight budget neutrality factor to the rates as discussed in section III.C.3 of this proposed rule. Therefore, the estimated impact of the 2019 wage index and the recalibration of the case-mix weights for CY 2019 is $0 million. The $400 million increase reflects the distributional effects of the CY 2019 home health payment update of 2.1 percent ($400 million increase), a 0.1 percent increase in payments due to decreasing the FDL ratio in order to target to pay no more than 2.5 percent of total payments as outlier payments ($20 million increase) and a 0.1 percent decrease in payments due to the new rural add-on policy mandated by the BBA of 2018 for CY 2019 ($20 million decrease). The $400 million in increased payments is reflected in the last column of the first row in Table 59 as a 2.1 percent increase in expenditures when comparing CY 2018 payments to estimated CY 2019 payments.

With regards to options for regulatory relief, the rural add-on policy for CYs 2019 through 2022 is statutory and we do not have the authority to alter the methodology used to categorize rural counties or to revise the rural add-on percentages.

b. HH PPS for CY 2020 (Proposed PDGM)

We estimate no net impact of the proposed policies related to the implementation of the PDGM for the CY 2020 HH PPS, as the transition to the 30-day unit of payment is required to be budget neutral. However, since the PDGM eliminates the use of therapy thresholds as a factor in determining payment, HHAs that provide more nursing visits, and thus experience lower margins under the current payment system which may incentivize overutilization of therapy, may experience higher payments. Conversely, HHAs that provide more therapy visits compared to nursing visits, and thus may profit more from the current payment system, may experience lower payments.

c. Proposed Elimination of Recertification Requirement To Estimate How Much Longer Home Health Services Will Be Required

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require, as a condition of payment, that a physician must certify (and recertify, when home health services are furnished over a period of time) that the individual is eligible for home health services. The regulations at § 424.22(b)(2) set forth the content and basis for recertification requirements and states that the recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. This requirement has been longstanding policy that predates the Paperwork Reduction Act of 1995 requirements. Therefore, there is no corresponding Collection of Information that was submitted to the Office of Management and Budget (OMB) for review and approval for the burden estimate for the recertification requirement that the certifying physician must estimate how much longer home health services will be required.

In section III.G. of this proposed rule, we are proposing to eliminate the regulatory requirement as set forth at 42 CFR 424.22(b)(1), that the certifying physician, as part of the recertification process, include an estimate of how much longer home health services will be required at each home health recertification. While all other recertification content requirements under § 424.22 will remain unchanged, the certifying physician would not be required to provide his/her estimation as to how much longer the patient will require home health services on recertifications on and after January 1, 2019. Therefore, we believe this would result in a reduction of burden for certifying physicians by reducing the amount of time physicians spend on the recertification process and we are providing an estimate on the reduction in burden in this proposed rule. All salary information is based on the May 2017 wage data for physicians and surgeons from the Bureau of Labor Statistics (BLS) website at (*https://www.bls.gov/oes/current/oes291069.htm*) and includes a fringe benefits and overhead worth 100 percent of the base salary.

Using CY 2017 claims, we estimate that of the total number of Medicare home health claims (5.8 million), 37 percent were recertifications (2.1 million) completed by 284,615

certifying physicians.[111] Of those 2.1 million recertifications, we estimate that the time needed to recertify patient eligibility will decrease by 2 minutes per recertification with a total reduction of 69,930 physician hours for all recertifications as a result of eliminating the time estimation statement. Based on the physician's hourly wage of $203.26 as described previously ($101.63 with 100 percent fringe benefits and overhead), this results in an overall annualized cost savings of $14.2 million beginning in CY 2019.

2. HHVBP Model

Under the HHVBP Model, the first payment adjustment applies in CY 2018 based on PY1 (2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (2020) data. In the CY 2016 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately $380 million (80 FR 68716). In the CY 2017 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately $378 million (81 FR 76795). We do not believe the changes proposed in this rule would affect the prior estimates.

3. Home Infusion Therapy

a. Health and Safety Standards

Section 5012 of the Cures Act (Pub. L. 114–255), which amended section 1861(s)(2) of the Social Security Act (the Act), established a new Medicare home infusion therapy benefit. Section 1861(iii) of the Act, as added by section 5012 of the Cures Act defines, the Medicare home infusion therapy benefit and covers professional services including nursing services, training and education, and remote monitoring and monitoring services associated with administering certain infusion drugs in a patient's home. This benefit would ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries. Section 1861(iii) of the Act, as added by the Cures Act, sets forth elements for home infusion therapy suppliers in three areas: (1) Ensuring 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, (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided, and (3) having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home.

We propose to implement the following requirements for home infusion therapy suppliers—

- Ensure that all patients must have a plan of care established by a physician that prescribes the type, amount and duration of infusion therapy services that are furnished. The plan of care would specify the care and services necessary to meet the patient specific needs.
- Ensure that the plan of care for each patient is periodically reviewed by the physician.
- Ensure that patients have infusion therapy support services at all times through the provision of professional services, including nursing services, furnished in accordance with the plan of care on a 7-day-a-week, 24-hour-a-day schedule.
- Provide patient training and education.
- Provide remote monitoring and monitoring services for the provision of home infusion therapy and home infusion drugs.

All current standards established by AOs already address the proposed requirements set forth in this rule. Furthermore, all existing home infusion therapy suppliers are already accredited by an existing AO for home infusion therapy to meet requirements established by private insurers and Medicare Advantage plans. Therefore, we assume that there would be no new burden imposed on home infusion therapy suppliers in order to meet the proposed health and safety standards. Additionally, we assume that these proposed health and safety provisions would not impose a new burden on home infusion therapy AOs that are likely to apply to be Medicare approved AOs for home infusion therapy because their existing standards would already meet or exceed those that would be established in this rule.

b. Home Infusion Therapy Payment

We estimate that the net impact of the policies in this rule is approximately $60 million in increased Medicare payments to home infusion suppliers in CY 2019. This increase reflects the cost of providing infusion therapy services to existing DME home infusion therapy beneficiaries (at a 4-hour rate), as the temporary transitional payment applies only to existing Medicare qualified home infusion suppliers (that is, DME suppliers that are enrolled as pharmacies that provide external infusion pumps and supplies are considered eligible home infusion suppliers, as are potential pharmacy suppliers that enroll and comply with the Medicare program's supplier standards (found at 42 CFR 424.57(c)) and quality standards to become accredited for furnishing external infusion pumps and supplies). Prior to the implementation of the temporary transitional payment, home infusion suppliers have not been separately reimbursed for providing these services under the DME benefit. For the temporary transitional payment we do not anticipate an increase in beneficiaries receiving home infusion therapy services as referral patterns are not likely to change significantly due to the inability for other provider types (for example, physicians, HHAs) to become home infusion therapy suppliers prior to CY 2021 and given that existing DME suppliers already provide home infusion therapy services without separate reimbursement.

c. Accreditation of Quality Home Infusion Therapy Suppliers

The requirement for accreditation of home infusion therapy suppliers will cause both the home infusion therapy AOs and the home infusion therapy suppliers to incur costs related to the accreditation process. This section provides a discussion of the estimated time and cost burdens that home infusion therapy suppliers may incur as part of the accreditation process. It also discusses the estimated time and cost burdens that may be incurred by the home infusion therapy AOs to comply with the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050. As the following discussion demonstrates, we have estimated that each home infusion therapy AO would incur an estimated cost burden in the amount of $23,258 for compliance with the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050.

(1) Burden Incurred by Home Infusion Therapy AOs

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit suppliers furnishing home infusion therapy not later than January 1, 2021. To date, we have not solicited nor approved any AOs to accredit home infusion therapy suppliers as required by section 1834(u)(5)(B) of the Act. Therefore, in this rule we have proposed to publish a solicitation notice in the **Federal Register** seeking national AOs to accredit home infusion therapy suppliers. We propose to publish this

[111] CY 2017 OASIS assessments matched to Medicare FFS claims (as of March 2, 2018).

solicitation after the publication of the final rule.

The AOs that respond to the solicitation notice would be required to submit an application to CMS requesting CMS-approval of a home infusion therapy accreditation program for Medicare. If CMS approves the AOs application, the home infusion therapy AO would also be required to meet, on an ongoing basis, the requirements set forth in proposed §§ 488.1010 through 488.1050. The following is a discussion of the burden associated with specific sections of the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050.

(a) Burden for Home Infusion Therapy AOs Associated With Proposed § 488.1010

The AOs that accredit home infusion therapy suppliers would incur time and costs burdens associated with the preparation of the application they submit to CMS requesting approval of their home infusion therapy accreditation program. This would include the preparation, gathering or obtaining of all the documentation required in proposed § 488.1010(a)(1) through (24).

If the AO has never submitted an application to CMS, we estimate that it would take approximately 70 hours of time to gather, obtain or prepare all documentation required by proposed § 488.1010(a)(1) through (23). However, for an existing AO that has previously submitted an application to CMS for any type of accreditation program, we estimate that it would take approximately 45 hours to gather, obtain or prepare all required documentation. We believe that it would take less time for an AO that has previously submitted an application to CMS to prepare an application requesting approval of a home infusion therapy accreditation program because this AO would already be familiar with the application process and requirements. The proposed application requirements for home infusion therapy AOs, set forth at § 488.1010(a)(1) through (23), are consistent with those for Medicare-certified providers and suppliers which are set forth at § 488.5.

The home infusion therapy AO would incur costs associated with the preparation and submission of the home infusion therapy accreditation program application. The home infusion therapy AO would incur costs for the wages of all AO staff that work on the preparation of the application. We estimate that the AO would have 2 staff work on the preparation of the application. We believe that the AO staff that works on the AOs application would be clinicians such as registered nurses or medical or health services manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*) and the mean hourly wage for a medical or health services manager is $53.69 (*https://www.bls.gov/oes/current/oes119111.htm*)). Therefore, we estimate that the home infusion therapy AO would incur wages for 45 hours of time by a registered nurse and wages for 45 hours of time by a medical or health services manager in the amount of $8,014.50 (45 hours × $35.36 per hour = $1,591.20) + (45 hours × $53.69 = $2,416.05 per hour) + ($4,007.25 for fringe benefits and overhead).

As stated previously, we estimate that it would take approximately 70 hours for an AO that has never submitted an application before to prepare and submit their home infusion therapy accreditation program application to CMS. We estimate that the home infusion therapy AO would incur wages for 70 hours of time by a registered nurse and 70 hours of time by a medical or health services manager in the amount of $12,453 (70 hours × $35.36 per hour = $2,475.20) + (70 hours × $53.59 = $3,751.30 + ($6,226,50 for fringe benefits and overhead).

In addition, AOs are required to submit 2 hard copies of their application to CMS in notebooks with dividers and an electronic copy of their application on a thumb drive. Because of this requirement, the home infusion therapy AO would incur costs for the notebooks, dividers, thumb drive, photocopying, paper and ink, and postage costs for mailing the notebooks with the hard copies of the application to the CMS Central Office. We estimate that these costs would be no more than $250.

At this time, there are six AOs that accredit home infusion therapy suppliers (that is—The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA), and National Association of Boards of Pharmacy). The home infusion therapy accreditation offered by these AOs is offered as part of the deeming accreditation of a home health accreditation program and has not been approved under the requirements of section 1834(u)(5)(A) of the Act. Therefore, we are proposing that, in order for the home infusion therapy suppliers accredited by these AOs to continue to receive payment for the home infusion therapy services furnished to Medicare beneficiaries, these AOs must obtain Medicare approval for a home infusion therapy accreditation program. If all of these six AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, the cost incurred across all of these potential home infusion therapy AOs for the preparation and submission of their applications would be $48,087 ($4,007.25 × 6 AOs = $24,043.50) + ($24,043.50 for fringe benefits and overhead).

To obtain this CMS approval, we are proposing that these AOs would be required to submit an application to CMS seeking approval of a home infusion therapy accreditation program that meets the requirements set forth in the proposed new home infusion therapy AO approval and oversight regulations set forth at §§ 488.1010.1 through 488.1010.24 and the proposed new home infusion therapy health and safety regulations at 42 CFR part 466, subpart I. We have further proposed that the home infusion therapy accreditation programs submitted to CMS for approval by the existing home infusion therapy AOs be consistent with the requirements of section 5102 of the 21st Century CURES Act and section 1861(iii) of the Act. We would also require that the home infusion therapy programs submitted by these AOs be separate and distinct from the AOs home health deeming accreditation program.

The AOs that currently provide home infusion therapy accreditation would incur the time and costs associated with the preparation of the CMS application and required supporting documentation. We estimate that it would take these AOs approximately 45 hours to prepare their applications and supporting documentation because they have previously submitted applications for approval of their home health accreditation programs. The existing AOs that accredit home infusion therapy suppliers would also incur costs for the wages for all AO staff involved with the preparation and submission of the application. The AO would also incur costs for printing the hard copies of the application, ink and paper, notebooks and dividers, and postage.

(b) Burden for Home Infusion Therapy AOs Associated With Proposed § 488.1030

In accordance with proposed § 488.1030(b) CMS would perform a comparability review if CMS makes

changes to the home infusion therapy AO approval and oversight regulations or home infusion therapy health and safety regulation. The purpose of the comparability review is to allow CMS to assess the equivalency of a home infusion therapy AO's accreditation standards with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare home infusion therapy accreditation requirements.

Proposed § 488.1030(b)(1) would provide that if CMS were to make changes to the home infusion therapy AO approval and oversight accreditation regulations or the home infusion therapy health and safety regulations, CMS would send a written notice of the changes to the home infusion therapy AOs. Proposed § 488.1030(b)(2) would provide that CMS would provide a deadline of not less than 30 day by which the AO must submit its revised home infusion therapy accreditation program standards to CMS.

Proposed § 488.1030(b)(2) would require the home infusion therapy AOs to revise their home infusion therapy accreditation standards so as to incorporate the changes made by CMS. The AO must submit their revised home infusion therapy accreditation program standards to CMS by the deadline specified in CMS' written notice. The AO may submit a request for an extension of the submission deadline, so long as the request is submitted prior to the original submission deadline.

The home infusion therapy AOs would incur a time burden associated with the time required for the AO staff to review CMS' notice of the revisions to the home infusion therapy AO approval and oversight accreditation standards or home infusion therapy health and safety standards. We estimate that it would take no more than 1 hour for the AO to review the notice from CMS notifying the AO of the changes to the AO approval and oversight regulations or health and safety regulation.

The home infusion therapy AOs would incur a cost burden for the wages of the AO staff that are involved with reviewing the CMS notice and the preparation of the home infusion therapy AO's revised accreditation program standards. We believe that the AO staff that would review the notice from CMS regarding changes to the CMS home infusion therapy regulations would be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the home infusion therapy AO would incur a cost burden in the amount of $70.72 for the preparation of the response to CMS (1 hour × $35.36 per hour = $35.36) + ($35.36 for fringe benefits and overhead).

The home infusion therapy would also incur a cost burden for the wages of the AO staff for the time spent preparing the AOs revised home infusion therapy accreditation standards. However, we are unable to accurately estimate this cost because the amount of wages incurred would be dependent on the amount of time spent by the AO staff preparing the AOs revised accreditation standards.

We believe that the AO staff that would prepare the home infusion therapy AOs revised home infusion therapy accreditation standards would be a clinician such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). If we were to estimate that it would take 5 hours for the home infusion therapy AO to prepare the revised home infusion therapy accreditation standards, the estimated cost burden to the AO would be $353.60 (5 hours × $35.36 per hour = $176.80) + ($176.80 for fringe benefits and overhead).

At this time, there are six AOs that accredit home infusion therapy suppliers (that is—The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA), and National Association of Boards of Pharmacy). The home infusion therapy accreditation offered by these AOs is offered as part of the deeming accreditation of a home health accreditation program and has not been approved under the requirements of section 1834(u)(5)(A) of the Act. If all of these six AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, the cost incurred across all of these AOs for the preparation of revised accreditation standards would be $2,121.60 ($176.80 × 6 AOs = $1,060.80) + ($1,060.80 for fringe benefits and overhead).

As provided by proposed § 488.1030(b)(4), a home infusion therapy AO may request an extension of the deadline by which they must submit their revised accreditation home infusion therapy standards, so long as the extension request is submitted prior to the submission deadline. If the home infusion therapy AO requested an extension of the submission deadline, the AO would incur burden for the time required to prepare and submit the deadline extension request, however, we believe this burden would be minimal. We believe that the extension request could be sent in the form of an email to CMS, would consist of no more than a few paragraphs and would take no more than 15 minutes to prepare and send.

The AO would incur a cost burden for the wages for the AO staff who prepares the extension request. We believe that this email would be sent by an administrative assistant. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an executive administrative assistant is $28.56 (*https://www.bls.gov/oes/current/oes436011.htm*). We estimate that the AO would incur a cost burden for wages related to the preparation and sending of the extension request to CMS in the amount of $14.28. ($28.56 × 15 minutes = $7.14) + ($7.14 for fringe benefits and overhead).

At this time, there are six AOs that accredit home infusion therapy suppliers (that is—The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA), and National Association of Boards of Pharmacy). If all of these six AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, they could become CMS-approved home infusion therapy AOs. It is unlikely that all of the AOs would submit a request for an extension of the deadline to submit their revised accreditation standards to CMS. However, if this were to occur, the cost incurred across all of these AOs for the preparation of the extension requests by each home infusion therapy AO would be $85.68 ($7.14 × 6 AOs = $42.84) + ($42.84 for fringe benefits and overhead).

Proposed § 488.1030(b)(7) would provide that if CMS were to make significant substantial changes to the home infusion therapy AO approval and oversight accreditation standards or the home infusion therapy health and safety standards, we may require the home infusion therapy AOs to submit a new application for approval of their revised home infusion therapy accreditation programs. If this were to occur, the home infusion therapy AOs would incur a time burden for the time associated

the preparation of the AOs new application.

We estimate that it would take the home infusion therapy AO approximately 45 hours to prepare and submit their new application to CMS. This would include the time and costs required to gather and prepare the required supporting documentation to go with the application. We believe that the home infusion therapy AOs would already be familiar with the CMS application process and would be able to use their previous application and supporting documentation with updates, therefore, the reapplication process would be less burdensome.

The home infusion therapy AO would also incur costs associated with the preparation and submission of a new application. The home infusion therapy AO would incur costs for the wages of all AO staff that work on the preparation of the application. We estimate that the AO would have 2 staff persons work on the preparation of the application. Furthermore, we believe that the AO staff that works on the AOs application would be clinicians such as a registered nurse and a medical or health services manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 ((*https://www.bls.gov/oes/current/oes291141.htm*). and the mean hourly wage for a medical or health services manager is $53.69 ((*https://www.bls.gov/oes/current/oes119111.htm*). Therefore, we estimate that the home infusion therapy AO would incur wages for 45 hours of time by a registered nurse and 45 hours of time by a medical or health services manager in the amount of $$8,014.50 (45 hours × $35.36 per hour = $1,591.20) + (45 hours × $53.69 = $2,416.05 per hour) + ($4,007.25 for fringe benefits and overhead). The cost across all the 6 potential home infusion therapy AOs would be $48,087 ($4007.25 × 6 AOs = $24,043.50) + ($24,043.50 for fringe benefits and overhead).

In addition, AOs are required to submit 2 hard copies of their application to CMS in notebooks with dividers and an electronic copy of their application on a thumb drive. Because of this requirement, the home infusion therapy AO would incur costs for the notebooks, dividers, thumb drive, photocopying, paper and ink, and postage costs for mailing the notebooks with the hard copies of the application to the CMS Central Office. We estimate that these costs would be no more than $250.

In accordance with proposed § 488.1030(c), CMS will perform a standards review when the home infusion therapy AO makes updates to its accreditation standards and surveys processes. Proposed § 488.1030(c)(1) would require that when a home infusion therapy AO proposes to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy AO must submit its revised accreditation standards and survey processes to CMS for review, at least 60 days prior to the proposed implementation date of the revised standards. Proposed § 488.1030(c)(3) would require that the home infusion therapy AO provide CMS with a detailed description of the changes that are to be made to the AO's home infusion therapy accreditation standards, requirements and survey processes and a detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each. Proposed § 488.1030(c)(4) would provide that CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of receipt of the home infusion therapy accrediting organization's proposed changes. Proposed § 488.1030(c)(5) would provide that if a home infusion therapy AO implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with proposed § 488.1030(c)(d).

The burden to the home infusion therapy AO associated with the standards review includes the time required for the home infusion therapy AO to prepare its revised accreditation standards and detailed crosswalk for submission to CMS and submit them to CMS for review. This burden would also include the time required for the AO staff to read and respond to CMS' written response. It is important to note that we do not include in our burden estimate the time that would be spent by the home infusion therapy AO in making voluntary revisions to their accreditation standards that are not required by CMS nor prompted by a regulatory change.

The home infusion therapy AO would also incur costs for the wages of the AO staff involved with the preparation of the AO's revised home infusion therapy accreditation standards and the detailed crosswalk for submission to CMS. The AO would also incur costs for wages for the time the AO staff spent reviewing CMS' response. However, the AO could send their revised accreditation standards to CMS via email, therefore the AO would not incur costs for postage.

We are not able to accurately estimate the total time and cost burden associated with the standards review because the time required for the home infusion therapy AO to prepare its revised home infusion therapy accreditation standards and detailed crosswalk would depend on the extent of the revision the AO has made to its home infusion therapy accreditation standards or survey processes. The burden would also depend of the content and length of CMS' response letter. However, we do estimate that the preparation of the home infusion therapy AOs revised accreditation standard and detailed crosswalk for submission to CMS would take no less than 5 hours.

We believe that the AO staff that would prepare the home infusion therapy AOs revised home infusion therapy accreditation standards and detailed crosswalk for submission to CMS would be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, if we were to estimate that this task would take 5 hours to complete, the cost burden to the home infusion therapy would be $353.60 (5 hours × $35.36 per hour = $176.80) + ($176.80 for fringe benefits and overhead).

We further estimate that it would take the home infusion therapy AO approximately 30 minutes for the home infusion therapy AO to review the CMS response to their submission of the revised home infusion therapy accreditation standards and detailed crosswalk. We believe that a clinician such as a registered nurse would review the CMS response letter. Therefore, the cost burden to the home infusion therapy AO associated with this task would be $ 53.04 (45 minutes × $35.36 per hour = $26.52) + ($26.52 for fringe benefits and overhead).

It is important to note that we have not calculated this burden across all of the potential home infusion therapy AOs. We have not done so because the submission of revised home infusion therapy accreditation standards by a home infusion therapy AO would only

occur on an occasional basis and would never be done by all 6 potential AOs at the same time.

In accordance with proposed § 488.1030(d), CMS may perform a home infusion therapy accreditation program review if a comparability, 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 the proposed home infusion therapy AO approval and oversight regulation at 42 CFR part 488, subpart L. If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy AO indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice would provide all of the following information:

- A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.
- A description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy accrediting organization to offer factual information related to CMS' findings.
- A description of the possible actions that may be imposed by CMS based on the findings of the home infusion therapy accreditation program review.
- The actions the home infusion therapy accrediting organization must take to address the identified deficiencies.
- A timeline for implementation of the home infusion therapy accrediting organization's corrective action plan, not to exceed 180 calendar days after receipt of the notice that CMS is initiating a home infusion therapy accreditation program review.

Proposed § 488.1030(d)(3) would provide that CMS will monitor the performance of the AO's home infusion therapy and the implementation of the corrective action plan during a probation period of up to 180 days. Proposed § 488.1030(d)(4) would provide that if CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of the proposed regulations at §§ 488.1010 through 488.1050, CMS may place the home infusion therapy AO's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the period described in § 488.1030(d)(1)(iv).

The time burden associated with the home infusion therapy accreditation program review includes the time burden associated with the AO's review of CMS' written notice which indicates that the home infusion therapy AO's CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The time required for the review of the CMS letter will depend on the length of CMS' finding. However, we estimate it would take no more than 60 minutes to review this letter.

The AO would incur costs for the wages of the AO staff who performs the review of the CMS letter. We believe that an AO staff person with a clinical background such as a registered nurse would review the CMS letter. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, we estimate that the cost burden to the home infusion therapy AO associated with the review of the CMS letter would be approximately $70.72 (1 hour × $35.36 = $35.36) + ($35.36 for fringe benefits and overhead).

There is further burden associated with the requirement that the AO prepare and submit a written response to the CMS letter and a corrective action plan. However, we are unable to accurately estimate the time burden associated with this task because the amount of time required for the home infusion therapy AO to prepare the response letter and corrective plan would be dependent on the number and type of findings identified in CMS' letter.

However, we believe that an AO staff person with a clinical background such as a registered nurse would prepare the home infusion therapy AO's written response to the CMS letter and a corrective action plan. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). If we were to estimate that it would take the home infusion therapy AO 3 hours to prepare and submit a written response to the CMS letter and a corrective action plan, the estimated cost burden to the home infusion therapy AO associated with this task would be $212.16 (3 hours × $35.36 = $106.08) + ($106.08 for fringe benefits and overhead). Proposed § 488.1030(d)(2) provides that CMS would review and approve the AO's plan of correction within 30 days of receipt. If CMS requires the home infusion therapy AO to make changes to their corrective action plan as a condition of approval, the AO would incur burden for the time required to make the required revisions to their plan of correction and resubmit it to CMS.

The home infusion therapy AO would incur a time burden for the time spent by the AO staff making corrections to the AOs corrective action plan. We are unable to accurately estimate how long it would take for the AO to revise its corrective action plan because the revision to be made to the corrective action plan would be dependent on the extent of the correction requested by CMS.

However, we believe that an AO staff person with a clinical background such as a registered nurse would make the corrections to the AOs corrective action plan. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). So, if we were to estimate that it would take the home infusion therapy AO 2 hours to prepare and submit a written response to the CMS letter and make any necessary revision to the corrective action plan, the estimated cost burden to the home infusion therapy AO associated with this task would be $141.44 (2 hours × $35.36 per hour = $70.72) + ($70.72 for fringe benefits and overhead). During the 180 day probationary period, CMS is likely to require the home infusion therapy AO to submit periodic progress reports and participate in periodic telephone to monitor the home infusion therapy AOs progress. The home infusion therapy AO would incur burden for the time required to prepare and submit an initial progress report. We estimate that the initial progress report would take approximately one hour to prepare. We further estimate that the burden associated with the preparation and submission of subsequent progress reports would be less than that for the initial progress report because the AO would be able to modify or update their initial or previous progress report. We estimate that it would take approximately 1 hour for the AO staff to prepare the initial progress report and 30 minutes for the AO staff to prepare subsequent progress reports. If CMS were to require the AO to submit one progress report per month during the entire 180 day probation period (6 months), the AO would have

to submit 1 initial progress report and 5 subsequent progress reports. Therefore, we estimate that the AO would incur a time burden in the amount of 3.5 hours for the submission of all progress reports during the 180 day probation period. The AO would also incur a cost burden for the wages of the AO staff person who is involved in the preparation and submission of the progress reports. We believe that the initial and subsequent progress reports would be prepared by person with a clinical background such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). We estimate that the home infusion therapy AO would incur a cost burden in the amount of $247.52 for the preparation of the progress reports during the 180 day probation period ($3.5 hours × 35.36 per hour = $123.76) + ($123.76 for fringe benefits and overhead).

The home infusion therapy AO would also incur burden associated with the time required to participate in the periodic phone calls with CMS. We are not able to accurately estimate the amount of time that would be required for these periodic phone calls because we do not know how often the AO would be required to participate in phone calls with CMS or how long these phone calls would last. However, we do not believe that these phone calls would be held more often that monthly or last more than one hour. The AO would incur costs for the wages of all AO staff that participate in the periodic telephone calls. We are not able to accurately estimate the total cost burden for wages that would be incurred by the home infusion therapy AO at this time, because we do not know who from the AO would be attending these meetings.

If we were to estimate that these phone calls were to be held on a monthly basis during the 180 day probation period for a period of one hour period per call, the home infusion therapy AO would incur a time burden in the amount of 6 hours per each staff member that participates in these phone calls. We believe that the AO would have a minimum of 3 staff that are clinicians, such as registered nurses, participate on the call. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/ooh/healthcare/registered-nurses.htm*). Therefore, the cost burden to the home infusion therapy AO for participation in the monthly telephone calls would be $1,272.96 ((3 AO staff × $35.36 per hour = $106.08 per call per all staff/$106.08 per call per all staff × 6 calls = $636.48 total wages per all staff per all calls) + ($636.48 for fringe benefits and overhead)).

At or near the end of the first 180 day probationary period, CMS will make a decision as to whether the home infusion therapy AO has successfully come into compliance with the home infusion therapy regulations, or whether the AO has failed to do so. Proposed § 488.1030(d)(4) would provide that if CMS finds that the home infusion therapy AO has failed to properly implement the plan of correction and come into compliance with the requirements of the proposed home infusion therapy AO approval and oversight regulation or the proposed home infusion therapy health and safety regulations, CMS may place the home infusion therapy AO's on an additional probation period of up to 180 calendar days. If this were to occur, the AO would incur the same or similar time and cost burdens as in the initial 180 day probationary period. (See previous estimates for the estimated time and cost burden associated with the 180-day probationary period).

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1030(d) across all of the potential home infusion therapy AOs. We have not done so because the act of CMS placing a home infusion therapy AO on an accreditation program review would only occur on a sporadic and as needed basis. There would never be a situation in which all 6 potential AOs would be under an accreditation program review at the same time.

(c) Burden for Home Infusion Therapy AOs Associated With Proposed § 488.1035

Proposed § 488.1035 titled ''Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization'' would require that the home infusion therapy AO carry out certain activities and submit certain documents to CMS on an ongoing basis. Proposed § 488.1035(a) would require the home infusion therapy AO to submit the following documents to CMS: (1) 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); (2) notice of all accreditation decisions; (3) notice of all complaints related to providers or suppliers; (4) 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; (5) the home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends; (6) notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process.

We believe that there would be little burden associated with this requirements for several reasons. First, while the home infusion therapy AOs would be required to provide copies of all survey reports and any survey-related information that CMS may require, the AOs would only be required to provide this information upon request. CMS may not request the home infusion therapy AO to submit this information if there are no compliance concerns. Second, we believe the home infusion therapy AO would keep these records in the normal course of their business as a home infusion therapy AO and would store the survey records in electronic format. As the AO already has this information prepared and stored in an electronic format, it would place little if any burden on the home infusion therapy AO to provide this information to CMS. We believe that the AO could send this information to CMS via email and attach the survey record electronic files to the email.

We estimate that it would take approximately 30 minutes to locate the required survey information files and approximately 15 minutes for the AO staff to prepare an email to CMS and attach the electronic files to the email. We believe that the person at the AO that would prepare the email sending the survey information to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/ooh/healthcare/registered-nurses.htm*). Therefore, the cost burden to the home infusion therapy AO associated with the preparation and submission of the survey reports and information to CMS would be $53.04 (30 minutes to locate information requested by CMS × $35.36 per hour = $17.68) + (15 minutes × $35.36 = $8.84) + ($26.52 for fringe benefits and overhead). The estimated cost across the potential 6 home infusion therapy AOs for these tasks would be $318.24 ($53.04 × 6 home infusion therapy AOs = $318.24).

Proposed § 488.1035(a)(2) would require the home infusion therapy AO to provide CMS with notice of all accreditation decisions made for each home infusion therapy supplier that files an application for accreditation. This would consist of a list of each home infusion therapy supplier that had filed an application with the home infusion therapy AO for accreditation and the accreditation decision made by the AO.

We believe that these accreditation decisions would be made by the AO in the normal course of the AOs business of performing accreditation of home infusion therapy suppliers. We further believe that there would be little burden associated with the requirement that the AO provide CMS with a list of the accreditation decisions made by the AO as this is information that would be readily available to the AO and that could quickly and easily be provided to CMS via email. We estimate that it would take approximately 15 minutes for the home infusion AO to gather the required accreditation decision information in preparation for sending it to CMS.

We believe that this information can be sent to CMS via email and estimate that it would take an additional 15 minutes for the AO staff to prepare an email to CMS and attach the electronic files containing the accreditation decision information to the email. We believe that the person at the AO who would prepare the accreditation decision information and prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation and submission of the survey reports and information to CMS would be $35.36 (15 minutes × $35.36 per hour = $8.84) and (15 minutes × $35.36 = $8.84) + ($17.68 for fringe benefits and overhead). The estimated cost across the potential 6 home infusion therapy AOs for these tasks would be $212.16 ($35.36 × 6 home infusion therapy AOs = $212.16).

Section 488.1035(a)(3) would require the AO to report complaint information to CMS. Complaint information is typically reported to CMS by other AOs by email on a monthly basis for the previous month. The contents of the complaint information reported to CMS would depend on whether the AO had received any complaints during the previous month. For example, if the AO received no complaint during the previous month, this email could consist of a sentence stating that the AO had received no complaints. If the AO had received one or more complaints during the previous month, the AO would be required to provide information about the nature of each complaint, a description of the investigation performed, a description of how the complaint was resolved and the date resolved.

We believe that there would be little burden associated with the reporting of complaint information by the home infusion therapy AO to CMS for several reasons. First, we estimate that the home infusion therapy AOs will rarely receive complaints about their accredited home infusion therapy suppliers. Second, we believe that the home infusion therapy AO will store information about any complaints received in an electronic format. Therefore, complaint information can be reported by the home infusion therapy AO to CMS via email. We estimate that the preparation of the complaint information email would take only no more than 15 minutes to prepare and send.

We believe that the person at the AO who would prepare the complaint information email and sent it to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*) Therefore, the estimated monthly cost burden to the home infusion therapy AO associated with the submission of complaint information to CMS would be $17.68 (15 minutes × $35.36 per hour = $8.84) + ($8.84 for fringe benefits and overhead). The estimated yearly burden to the home infusion therapy AO for this task would be $212.16 ($17.68 per month × 12 months per year = $212.16 per year).

The estimated monthly cost across the potential 6 home infusion therapy AOs for these tasks would be $106.08 ($17.68 × 6 home infusion therapy AOs = $106.08). The estimated yearly cost across the 6 potential home infusion therapy AOs would be $1,272.96 ($17.68 × 6 AOs = $106.08 per all AOs per month/$106.08 per year × 12 months per year = $1,272.96. Proposed § 488.1035(a)(4) would require the AO to provide CMS with 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 providers or suppliers accreditation. The information to be sent to CMS would simply consist of a list of the home infusion therapy suppliers and the type of remedial or adverse action taken.

We expect that when a home infusion therapy AO takes remedial or adverse action against its accredited supplier, the AO would prepare documentation which states the action taken and the reason this action was taken. We further believe that the AO would store this information electronically. This would enable the AO to send the required information to CMS via email. Therefore, we believe that there would be little burden associated with this requirement.

We believe that the home infusion therapy AOs could send information about adverse or remedial actions they have taken against their accredited suppliers via email. We estimate that it would take approximately 30 minutes for a home infusion therapy AO to prepare a report about the adverse or remedial actions taken against its accredited suppliers and approximately 15 minutes to prepare an email to CMS, attach the electronic file with the required information and send it to CMS. The home infusion therapy AOs would be required to report this information to CMS on a monthly basis.

The AO would incur a cost burden for the wages of the AO staff for the time spent preparing the report of the adverse or remedial action taken against the AO's accredited home infusion therapy suppliers and the time spent preparing the email to CMS. We believe that the person at the AO who would prepare the report of adverse or remedial action taken and prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost monthly cost burden to the home infusion therapy AO associated with the submission of information about the adverse or remedial action taken by the home infusion therapy AO against its accredited home infusion therapy suppliers to CMS would be $53.04 (30 minutes × $35.36 per hour = $17.68 + (15 minutes × $35.36 per hour = $8.84) + ($26.52 for fringe benefits and overhead). The estimated yearly cost burden to the home infusion therapy AO for this task would be $636.48 ($53.04 per month × 12 months per year = $636.48 per year).

The estimated monthly cost across the potential 6 home infusion therapy AOs for these tasks would be $318.24 ($53.04 × 6 home infusion therapy AOs =

$318.24). The estimated yearly cost across the 6 potential home infusion therapy AOs would be $3,818.88 ($53.04 × 6 AOs = $318.24 per all AOs per month/$318.24 per year × 12 months per year = $3,818.88.

Proposed § 488.1035(a)(5) would require the home infusion therapy accrediting organization to provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditation activities and trends. This summary data might include information such as the total number of complaints received during the year, the total number of immediate jeopardy situations found during the year, and the total number of deficiencies cited. We believe this is information that the AO would collect and document throughout the year in the normal course of business. We further believe that the home infusion therapy AO would prepare this year end summary data for their own informational, quality improvement, and research purposes.

We believe that there would be little, if any time burden associated with the submission of the documents and information required by proposed § 488.1035(a)(5) by the home infusion therapy AOs to CMS, because these are documents which the AO would keep in the normal course of business, therefore these documents would be easily accessible to the home infusion therapy AO. Title 5 CFR 1320.3(b)(2) states that the time, effort, and financial resources necessary to comply with a collection of information that would be incurred in the normal course of their activities (for example in compiling and maintaining business records) will be excluded from the burden if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary. Further, we believe that most, if not all of the home infusion therapy AOs would store these documents electronically and would be able to send them electronically to CMS via email.

The home infusion therapy AO would incur a time burden for the preparation and submission of the annual summary data to CMS. We estimate that it would take approximately 60 minutes for the home infusion therapy AO to locate the required annual summary data information and prepare it for submission to CMS. We further estimate that it would take an additional 15 minutes to prepare an email to CMS and attach the electronic files containing the summary data.

The home infusion therapy AO would incur a cost burden for the wages of the AO staff who prepares that summary data for submission to CMS and prepares the email to in which the annual summary data are submitted to CMS. We believe that the person at the AO who would prepare the summary data for submission to CMS and also prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the submission of summary data to CMS would be $88.40 (60 minutes × $35.36 per hour = $35.36) + (15 minutes × $35.36 per hour = $8.84) + ($44.20 for fringe benefits and overhead). The estimate cost burden across the 6 potential home infusion therapy AOs for this task would be $530.40 ($88.40 × 6 potential home infusion therapy AOs = $530.40).

Proposed § 488.1035(b) would require that within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS. The time burden associated with this requirement would be the time required for an AO staff person to review the notification from CMS about the change in home infusion therapy accreditation program requirements and the time required for the AO staff person to compose and send an acknowledgement email to CMS.

We estimate the time required for the AO staff to review the notice of a change in CMS requirements would be 1 hour. We further estimate that the time that would be required to prepare and submit the acknowledgement of receipt of the CMS notice would be approximately 15 minutes because this notice could be sent to CMS via email and would only consist of 1–2 paragraphs.

The home infusion therapy AO would incur a cost burden for the wages of the staff for the time required to review the notice from CMS of the change in CMS requirements. The home infusion therapy AO would incur a cost burden for the wages of the staff for the time required to prepare the acknowledgement and submits it to CMS. We believe that the person at the AO who would prepare the email to CMS acknowledging receipt of the CMS notice would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*).

The estimated cost burden to the home infusion therapy AO associated with the review of the notice from CMS of changes to the CMS requirements would be $70.72 (1 hour × $35.36 per hour) + ($35.36 for fringe benefits and overhead). The estimated cost burden associated with the preparation and submission of the acknowledgement by the home infusion therapy AO would be $17.68 (15 minutes × $35.36 per hour = $8.84) + ($8.84 for fringe benefits and overhead). The estimates cost across the 6 potential home infusion therapy AOs would be $530.40 ($70.72 × 6 = $424.32) + ($17.68 × 6 = $106.08).

It is important to note that the home infusion therapy AOs would only have to perform these tasks if CMS were to make a change to the home infusion therapy standards. We believe that this would occur on an infrequent basis, therefore, the home infusion therapy AOs would incur these time and cost burdens on an infrequent basis.

Proposed § 488.1035(c) would require that the home infusion therapy AO permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. An example in which a surveyor would be needed to testify as a witness would be if there was litigation about CMS' termination of a home infusion therapy supplier's participation in the Medicare program and the surveyor that had performed a survey of that home infusion therapy supplier was needed to testify about the survey findings. The burden associated with this requirement would be the time the surveyor spent providing testimony, any travel expenses the home infusion therapy AO would be responsible to pay, and the wages paid to the surveyor during the time spent giving testimony.

The home infusion therapy AO would incur a time burden for the time required for the AO's surveyor to serve as a witness. This would include travel time to and from the location where the hearing is being held. The AO would also incur cost burdens for the wages paid to the surveyor during the time they are serving as a witness and also for any travel expenses the AO may be required to pay, that are not reimbursed.

It is important to note that the home infusion therapy AO surveyors would rarely, if ever, be required to act as a witness. Therefore, this is a burden that the home infusion therapy AOs would not be likely to incur.

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 AO. The burden associated with this requirement is the time required to provide notice to CMS of the immediate jeopardy situation and the wages for the AO staff person for the time spent preparing and submitting this notice.

We believe that the AO would keep this information in the normal course of their business of providing home infusion therapy accreditation. Therefore, the AO should have these readily available. We further believe that the home infusion therapy AOs would keep records related to immediate jeopardy findings in an electronic format.

The AO would incur a time burden for the time required to report the immediate jeopardy information to CMS. We estimate that it would take the AO no more than 20 minutes to prepare an email to CMS in which they provide the required information about the immediate jeopardy situation that has been discovered. The AO can attach electronic files to the email that contain the required information. It is important to note that we do not count, as a burden, the time spent by the home infusion therapy AO in finding the immediate jeopardy situation or resolving it, because it is the duty of any CMS-approved AO to monitor it's accredited providers or supplier to ensure they are providing care that meets the accreditation standards and that they do not have any situation that put the patients or general public in imminent danger of harm. The home infusion therapy AO would incur a cost burden for the wages of the AO staff that prepares the email to CMS which notified CMS of the immediate jeopardy situation. We believe that the person at the AO who would prepare the immediate jeopardy notification email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation and submission of the acknowledgement by the home infusion therapy AO would be $23.60 ($35.36 divided by 60 minutes per hour = $0.59 per minute/20 minutes × $0.59 per minute = $11.80) + ($11.80 for fringe benefits and overhead).

The home infusion therapy AOs would have to perform these tasks and incur these time and costs burdens only if they discover an immediate jeopardy situation with an accredited home infusion therapy supplier. We would like to point out that this would not be a regular time and cost burden that would be incurred by the home infusion therapy AOs, as the discovery of immediate jeopardy situations by AOs do not occur frequently.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1035(d) across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to report an immediate jeopardy situation to CMS would only occur on a sporadic basis. We do not believe that there would ever be a situation in which all 6 potential AOs would be required to report an immediate jeopardy situation simultaneously. Proposed § 488.1035(e) would require that within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy AO that CMS intends to withdraw approval of the AO's home infusion therapy accreditation program, the home infusion therapy AO must provide written notice of the withdrawal to all of the home infusion therapy AO's accredited suppliers. The time burden associated with this requirement would be the time spent by the AO staff to prepare the required notice that must be sent to all of the AOs accredited home infusion therapy suppliers and the time required for the AO to send this notice out to all of its accredited suppliers.

We estimate that it would take that home infusion therapy AO approximately 45 minutes to prepare the notice that they must send out to their accredited suppliers. We believe it would take an additional 2 minutes per letter to be sent by the home infusion therapy AO to its accredited suppliers to prepare these letters for mailing (that is—fold letter, place in envelope, affix correct amount of postage and place the letter into the outgoing mail). We are not able to accurately estimate the amount of time it would take for the AO to send this notice out to all of its accredited suppliers because this would be dependent on the number of accredited suppliers the AO has at the time. However, if were to assume that a home infusion therapy AO had 50 accredited home infusion therapy suppliers, this task would take the AO staff 1.7 hours to complete (2 minutes × 50 letters = 100 minutes/100 minutes divided by 60 minutes per hour = 1.7 hours).

The home infusion therapy AO would incur a cost burden for the wages of the AO staff person that prepares the required notification. We believe that the person at the AO who would prepare the required notification would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be $53.04 (45 minutes × $35.36 per hour = $26.52) + ($26.52 for fringe benefits and overhead)

The home infusion therapy would also incur a cost burden for the wages of the staff person for the time spent preparing the required notices for mailing and mailing them. We are unable to accurately estimate this cost burden because the time required to perform this task would be dependent on the number of accredited home infusion therapy supplier the AO has at the time. However, if were to assume that a home infusion therapy AO had 50 accredited home infusion therapy suppliers, this task would take the AO staff 1.7 hours to complete (2 minutes × 50 letters = 100 minutes/100 minutes divided by 60 minutes per hour = 1.7 hours). We believe that the person that would perform this task would be an Administrative Assistant. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an executive administrative Assistant is $28.56 (*https://www.bls.gov/oes/current/oes436011.htm*). Therefore, the home infusion therapy AO would incur a cost burden in the amount of $97.92 for the completion of this task ($28.56 per hour divided by 60 minutes per hour = $0.48 per minute/60 minutes per hour divided by 10 = 6 minutes per 0.1 hour/6 minutes × 7 = 42 minutes = 0.7 hour/60 minutes + 42 minutes = 102 minutes or 1.7 hours/$0.48 per minute × 102 minutes = $48.96) + ($48.96 for fringe benefits and overhead). The home infusion therapy AO would incur an additional cost burden for miscellaneous costs. These costs would include the cost of the paper used to print the notices on, the printer ink used, the cost of the envelopes used, and the postage required to mail all the notices. We are unable to accurately estimate these costs as they are dependent on the number of notices that would be sent. We believe that these costs would not exceed $250.

It is important to note that the home infusion therapy AO surveyors would rarely, if ever, be required to perform the tasks required by proposed § 488.1035(e) because we would rarely withdraw the CMS approval of a home

infusion therapy AO. We would do so if there were serious, unresolved compliance concerns that the AO was unable or unwilling to rectify, even after being placed on an accreditation program probationary period. We do not believe that it would be possible that all of the home infusion therapy AOs would incur these cost and time burdens at the same time.

(d) Burden for Home Infusion Therapy AOs Related to Proposed § 488.1040

Proposed § 488.1040 would require that as part of the application review process, the ongoing review process, or the continuing oversight of an home infusion therapy AO's performance, CMS may conduct onsite inspections of the home infusion therapy AO's operations and offices at any time to verify the home infusion therapy AO's representations and to assess the home infusion therapy AO's compliance with its own policies and procedures. Proposed § 488.1040(b) provides that the activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following: (1) Interviews with various AO staff; (2) review of documents, survey files, audit tools, and related records; (3) observation of meetings concerning the home infusion therapy accreditation process; (4) auditing meetings concerning the accreditation process; (5) observation of in-progress surveys and audits; and (6) evaluation of the AO's survey results and accreditation decision-making process.

We believe that there would be little burden associated with the onsite visits made by CMS to the home infusion therapy AO's operations and offices because most of the activities related to the onsite visit involve work performed by the CMS staff, which would not impose burden on the AO staff (such as review of records or observation of meeting held at the AOs offices). We estimate that the time burden to the home infusion therapy AO associated with these onsite visits would include the time required for the AO staff to greet the CMS team upon arrival and show them to the conference room, the time required to locate the records the CMS team requests for review, and the time required for CMS to conduct interviews of AO staff members. If the home infusion therapy AOs records are electronic, an AO staff member may need to remain with the CMS team during their record review to assist them with access to the AO's records.

We are not able to accurately estimate the total time that would be required for these activities because we have not yet accredited any home infusion therapy AOs, nor have we had an opportunity to perform an onsite visit to a home infusion therapy AO. We do not yet know what type of accreditation standards and surveys processes the home infusion therapy AOs would use. Also, we do not know the amount and type of records we would seek to review during an onsite visit to a home infusion therapy AO or approximately how much time we would need to review these records. Likewise, we do not yet know how much interaction we would need to have with the home infusion therapy AO staff or which AO staff members we would choose to interview. The onsite AO visits we have performed for other types of AOs have lasted 1 to 2 days depending on the type of AO.

However, if we estimate that it would take 1 hour for the CMS team entrance conference, 8 hours for the CMS team to perform their records review and 1 hour for the CMS team conduct the exit conference, the home infusion therapy AO would incur a time burden in the amount of 1 hour for each AO staff person that attends the entrance conference, 8 hours for any staff that remains with the CMS team to assist them with the record review and 1 hour of time for each AO staff person that attends the exit conference. We believe that the AO staff that would be attending the entrance and exit conferences and assisting the CMS staff with their records review would most likely be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). We estimate that approximately 4 AO staff persons would attend the entrance and exit conferences and that one AO staff person would assist the CMS team with their record review.

Based on the a previously stated time estimate, we estimate that the home infusion therapy AO would incur a cost burden in the amount of $282.88 for wages for four AO staff for attendance at the entrance conference. ($35.36 per hour per each AO staff × 1 hour = $35.36/$35.36 per hour × 4 AO staff = $141.44) + ($141.44 for fringe benefits and overhead).

We further estimate that the AO would incur a cost burden in the amount of $282.88 for the wages of the four AO staff for attendance at the exit conference. ($35.36 per hour per each AO staff × 1 hour = $35.36/$35.36 per hour × 4 AO staff = $141.44) + ($141.44 for fringe benefits and overhead).

We also estimate that the AO would incur a cost burden in the amount of $565.76 for the wages of the AO staff person that would remain with the CMS team to assist them with their record review. (8 hours × $35.36 = $282.88) + ($282.88 for fringe benefits and overhead).

The total estimated cost burden to the home infusion therapy AO associated with the CMS onsite visit is $1,131.52 ($282.88 for entrance conference + $282.88 for exit conference + $565.76 for assisting CMS staff with record review = $1,131.52). The estimated cost burden across all of the potential six home infusion therapy AOs would be $6,789.12.

In this proposed rule, we have proposed that the six AOs that currently provide accreditation to home infusion therapy suppliers must submit an application to CMS for approval of a separate and distinct home infusion therapy accreditation program. A corporate onsite visit to the home infusion therapy AOs office is a part of the application review and approval process. Therefore, each of the AOs that submit an application to CMS for approval of a home infusion therapy program would incur the previously stated estimated burden related to the corporate onsite visit. However, after the initial application process has been completed, CMS would only make additional corporate onsite visits every 6 years when the home infusion therapy AOs submit their renewal application. Therefore, this would not be is a frequent or ongoing burden incurred by the home infusion therapy AOs.

(e) Burden for Home Infusion Therapy AOs Related to Proposed § 488.1045

Proposed § 488.1045 contains regulations related to the voluntary and involuntary termination of the CMS approval of a home infusion therapy AO's home infusion therapy accreditation program. Proposed § 488.1045(a) would provide that a home infusion therapy accrediting organization that decides to voluntarily terminate its CMS-approved home infusion therapy accreditation program must provide written notice at least 90 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

The requirement that the home infusion therapy AO provide notice of its decision to voluntarily terminate its CMS approved home infusion therapy accreditation program to CMS and all of its accredited home infusion therapy suppliers would cause the AO to incur the following time burdens: (1) The time required to prepare and send the required notice to CMS; and (2) the time required to prepare and send the

required notice to all of the AOs accredited home infusion therapy suppliers. We would require that the AO send the required notice of their decision to voluntarily terminate its CMS-approved accreditation program to CMS by U.S. mail. We would also require the AO to send the required notice to all of its accredited home infusion therapy suppliers by U.S. mail. We estimate that it would take approximately 60 minutes for the AO staff person to prepare the letter to CMS in which the AO notified CMS that the AO wishes to voluntarily terminate its CMS-approved home infusion therapy accreditation program, print the letter and mail it.

We further estimate that it would take the AO staff person another 4 hours to perform the following tasks: (1) Draft a letter its accredited home infusion therapy suppliers, giving notice that the AO is voluntarily terminating its CMS approved home infusion therapy accreditation program; (2) perform a mail merge to prepare a copy of the letter addressed to each accredited home infusion therapy supplier; (3) print out a letter to each accredited supplier and envelope; put the letters into the envelopes; (4) affix the correct amount of postage; and (5) put the envelopes in the outgoing mail. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be $35.36 (60 minutes × $35.36 per hour = $35.36).

The home infusion therapy AO would also incur a cost burden for the wages of the staff person for the time spent preparing and mailing the required notices to be sent to the AO's accredited home infusion therapy suppliers. As stated previously, we estimate that it would take approximately 4 hours of time for an AO staff person to prepare the required notification letter to the AOs accredited providers, print out a copy of the letter for each accredited home infusion therapy supplier and put these letters into the mail. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice for mailing would be $353.60 (4 hours × $35.36 per hour = $176.80) + ($176.80 for fringe benefits and overhead).

The home infusion therapy AO would incur an additional burden for miscellaneous costs associated with the preparation of the required notices to be sent to CMS and the AOs accredited home infusion therapy suppliers, including the cost of the paper on which the notices are printed, the printer ink used, the cost of the envelopes used, and the postage required to mail all of the notices. We are unable to accurately estimate these costs as they are dependent on the number of notices that would need to be sent. However we believe these costs would not exceed $200. We seek comment on how to estimate this burden.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1045 across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks only arise if a home infusion therapy AO voluntarily decides to terminate its CMS approved home infusion therapy accreditation program. This would occur rarely, if ever.

We do not believe that there would ever be a situation in which all six of the potential home infusion therapy AOs would decide to terminate their CMS approved accreditation programs simultaneously.

Proposed § 488.1045(b) states that once CMS publishes a notice in the **Federal Register** announcing the decision to involuntarily terminate the home infusion therapy AO's home infusion therapy accreditation program, the home infusion therapy AO must provide written notification to all suppliers accredited under its CMS-approved home infusion therapy accreditation program by no later than 30 calendar days after the notice is published in the **Federal Register**. This notice would announce that CMS is withdrawing its approval of the AOs home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in accordance with the requirements at § 488.1010(f) once their current term of accreditation expires.

The time burden associated with proposed § 488.1045(b) would be the time it takes for the home infusion therapy AO to prepare and send the required written notification to all accredited home infusion therapy suppliers which states that CMS is withdrawing the AOs approval of the home infusion therapy accreditation program and which also states the implications for the home infusion therapy suppliers payment status. We estimate that it would take no more than 4 hours for an AO staff person to perform the following tasks: (1) Draft the required notification letter; (2) perform a mail merge to prepare a copy of the letter that is addressed to each home infusion therapy supplier accredited by the AO; (3) print copies of the notification letters for each of the AOs accredited home infusion therapy suppliers; (4) put each notifications letter into an envelope; (5) affix the correct amount of postage to the envelope and (6) put the envelopes into the outgoing mail.

The home infusion therapy AO would incur a cost burden for the wages for the AO staff who performs the previously stated tasks. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be $282.88 (4 hours × $35.36 per hour = $141.44) + ($141.44 for fringe benefits and overhead).

The home infusion therapy AO would incur an additional burden for miscellaneous costs associated with the preparation of the required notices to be sent to the AOs accredited home infusion therapy suppliers, including the cost of the paper on which the notices are printed, the printer ink used, the cost of the envelopes used, and the postage required to mail all of the notices. We believe that these costs would not exceed $200.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1045 across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks required by § 488.1045(b) would only arise if CMS decides to involuntarily terminate the CMS approval of the AO's home infusion therapy accreditation program. This would occur rarely, if ever. Also, we do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would decide to terminate their

CMS approved accreditation programs simultaneously.

Proposed § 488.1045(c)(3) would require that for both voluntary and involuntary terminations of a home infusion therapy AOs CMS approved home infusion therapy accreditation program, the home infusion therapy AO must provide a second written notification to all of its accredited home infusion therapy suppliers ten calendar days prior to the AO's accreditation program termination effective date. We estimate that the time and cost burdens associated with this requirement would be the same as our estimated burden for proposed § 488.1045(b) set forth previously.

Proposed § 488.1045(d) sets forth the required steps that a home infusion therapy AO must take when one of its accredited home infusion therapy suppliers has requested a voluntary withdrawal from accreditation. The withdrawal from accreditation by the home infusion therapy supplier may not become effective until the AO completes all of the following 3 steps: (1) The home infusion therapy AO must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program; (2) the home infusion therapy AO must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status; (3) the home infusion therapy AO must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to CMS by no later than 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

The burden associated with the requirement that the home infusion therapy AO contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program would include the time required for the AO to contact the home infusion therapy supplier to request written confirmation that the home infusion therapy supplier does indeed want to terminate their home infusion therapy accreditation. We estimate that the AO would most likely contact the home infusion therapy supplier to make this request by telephone or email. We estimate this would take no more than 15 minutes.

The AO would incur a cost burden for the wages of the AO staff person for the time spent contacting the home infusion therapy supplier to confirm they intend to voluntarily withdraw from the home infusion therapy accreditation program. We believe that the person at the AO who would perform this task would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with contacting the home infusion therapy supplier to confirm that they do want to voluntarily terminate would be $17.68 (15 minutes × $35.36 per hour = $8.84) + ($8.84 for fringe benefits and overhead).

The home infusion therapy AO would also incur a time burden associated with the requirement that they send a written notice to the home infusion therapy supplier that is voluntarily terminating their home infusion therapy accreditation, which provides notice of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status. We estimate that it would take the home infusion therapy no more than 60 minutes to prepare the written notification.

We believe that the person at the AO who would prepare the required written notice to be sent to the home infusion therapy supplier that is voluntarily terminating its home infusion therapy accreditation would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required written notice would be $70.72 (1 hours × $35.36 per hour = $35.36) + ($35.36 for fringe benefits and overhead). We further estimate that the AO would incur postage costs in the amount of $0.50 for each letter sent.

Finally, we estimate the burden associated with § 488.1045(d)(3) would include the time required for the home infusion therapy AO staff to prepare a final notice of voluntary withdrawal of accreditation by the home infusion therapy supplier and the time required to send this notice to CMS. We estimate that it would only take the AO staff 15 minutes or less to prepare the required notice for CMS, because this notice could be sent to CMS by email. We estimate it would take an additional 10 minutes of time for the AO staff to prepare the email and attach the written notice to the email.

The AO would incur a cost burden for the wages of the AO staff for the time spent preparing the notice and sending it to CMS. We believe that the person at the AO who would prepare the required written notice to be sent to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required written notice to be sent to CMS would be $29.48 (15 minutes × $35.36 per hour = $8.84) + (10 minutes × $35.36 per hour = $5.90) + ($14.74 for fringe benefits and overhead).

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1045(d) across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks would only arise if a home infusion therapy supplier would decide to voluntarily terminate its accreditation with the home infusion therapy AO. This would occur on an infrequent basis. We do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would have a home infusion therapy supplier decide to voluntarily terminate the accreditation with their home infusion therapy AOs simultaneously.

(f) Burden for Home Infusion Therapy AOs Associated With Proposed § 488.1050

Proposed § 488.1050(a) would provide that a home infusion therapy AO that is dissatisfied with a determination, made by CMS, that its home infusion therapy accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy AO meet the applicable quality standards is entitled to reconsideration.

Proposed § 488.1050(b)(1) would require that a written request for reconsideration be filed within 30 calendar days of the receipt of CMS' notice of an adverse determination or non-renewal. Proposed § 488.1050(b)(2) would provide that the written request for reconsideration must specify the findings or issues with which the home infusion therapy AO disagrees and the reasons for the disagreement. Proposed

§ 488.1050(c)(1) provides the opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and proposed § 488.1050(c)(2) provides that written notice of the time and place of the hearing will be provided at least 10 business days before the scheduled date.

We estimate that it would take approximately 2 hours for a home infusion therapy AO to prepare its request for reconsideration. We believe that the person at the AO who would prepare the request for reconsideration would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the request for reconsideration would be $141.44 (2 hours × $35.36 per hour = $70.72) + ($70.72 for fringe benefits and overhead).

The remaining information that would be submitted in connection with a request for reconsideration or a reconsideration hearing, including any evidence or testimony provided is not considered ''information'' in accordance with 5 CFR 1320.3(h)(8), which excludes as ''information'' any ''facts or opinions obtained or solicited at or in connection with public hearings.''

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1050 across all of the potential home infusion therapy AOs. We have not done so because we believe that the filing of a request for reconsideration by a home infusion therapy AO would occur rarely, if ever. Further, we do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would decide to file a request for reconsideration at the same time. Therefore, there would never be an occurrence where all the home infusion therapy AOs would incur the previously stated burden simultaneously.

(g) Burdens for Home Infusion Therapy AOs Related to Survey Activities and Accreditation of Home Infusion Therapy Suppliers

The home infusion therapy AO would incur time and cost associated the accreditation of home infusion therapy suppliers. These would include the time and costs required to perform an onsite survey, offsite survey or other type of survey activity for each home infusion therapy supplier that has hired that AO to provide accreditation. However, as we have not approved any home infusion therapy AOs, we do not yet know what type of home infusion therapy accreditation standards they will use, or what the home infusion therapy accreditation survey process will consist of. Therefore, we are unable to accurately estimate the time and cost burden associated with the survey of home infusion therapy suppliers.

However, we can state that if the home infusion therapy AO were to perform an onsite survey, it would incur wages for each of the surveyors that are sent to perform the survey for the amount of time spent performing the survey. The AO would also incur wages for the time spent by the surveyors or other home infusion therapy AO staff in reviewing the survey documents, making a decision about whether to grant accreditation to the home infusion therapy supplier that was surveyed and preparing the decision letter to the home infusion therapy supplier. The AO would also incur travel costs for the AO staff to travel to the home infusion therapy supplier's location to perform the survey.

If the home infusion therapy AO were to do an offsite records audit survey, the AO would request that the home infusion therapy supply the AO with specific records. The AO would incur costs for the wages of the AO staff that performed the audit of the documents provided by the home infusion therapy supplier. The AO would also incur wages for the time spent by the surveyors or other home infusion therapy AO staff in making a decision about whether to grant accreditation to the home infusion therapy supplier that was audited and preparing the decision letter to the home infusion therapy supplier.

We seek comment on how to estimate this burden.

2. Burden to Home Infusion Therapy Suppliers Related to Home Infusion Therapy Health and Safety Standards

All existing home infusion therapy suppliers are already accredited by existing home infusion therapy AOs to meet requirements established by private insurers and Medicare Advantage plans. We are proposing that, in order for the existing home infusion therapy suppliers accredited by these AOs to continue to receive payment for the home infusion therapy services provided, these AOs must obtain Medicare approval for a home infusion therapy accreditation program. To obtain this CMS approval, we are proposing that these AOs would be required to submit an application to CMS seeking approval of a home infusion therapy accreditation program that meets the requirements set forth in the proposed new home infusion therapy AO approval and oversight regulations and proposed new home infusion therapy health and safety regulations. We would also require that the home infusion therapy program submitted by these AOs be separate and distinct from the AOs home health deeming accreditation program.

It is likely that the home infusion therapy suppliers would need to be resurveyed after their home infusion therapy AO obtains CMS approval of a home infusion therapy accreditation program, under section 1861(iii)(3)(D)(i)(III) of the Act. We believe this resurvey would be necessary because the AOs would have to determine if the home infusion therapy suppliers they accredit meet their new Medicare-approved home infusion therapy accreditation program accreditation standards. However, if a current home infusion therapy AOs current home infusion therapy standards already meet or exceed the proposed home infusion therapy health and safety standards, so that a revision of that AOs home infusion therapy accreditation standards is not required, then a resurvey of that AO's accredited home infusion therapy suppliers may not be necessary.

The home infusion therapy supplier would incur some time burden in order to come into compliance with the home infusion therapy AOs new home infusion therapy accreditation program requirements initially and thus prepare for the accreditation survey. However, all existing home infusion therapy suppliers are already accredited by existing home infusion therapy AOs to meet requirements established by private insurers and Medicare Advantage plans. Therefore, we assume that there would be little, is any new burden imposed on home infusion therapy suppliers in order to implement the proposed new health and safety standards.

The home infusion therapy supplier would be charged a fee by the AO for providing accreditation services. Fees for the home infusion therapy accreditation currently offered by the six AOs listed previously accreditation programs offered by the six AOs listed previously vary between $5,950 and $12,500 and, in general, currently cover all of the following items: Application fee, manuals, initial accreditation fee, onsite surveys or other auditing (generally once every 3 years), and travel, when necessary for survey

personnel. Accreditation costs also vary by the size of the provider or supplier seeking accreditation, its number of locations, and the number of services it provides.

We recognize that cost and time burdens associated with becoming accredited may be a barrier for small suppliers such as home infusion therapy suppliers. We propose to implement the following to minimize the burden of accreditation on suppliers, including small businesses:

- Multiple accreditation organizations—We expect that more than one AO would submit an application to become a designated Home Infusion Therapy AO. We believe that selection of more than one home infusion therapy AO would introduce competition resulting in reductions in accreditation costs.
- Required plan for small businesses—During the application process we would require prospective home infusion therapy AOs to include a plan that details their methodology to reduce accreditation fees and burden for small or specialty suppliers. This would need to include that the AO's fees are based on the size of the organization.
- Reasonable quality standards—The quality standards that would be used to evaluate the services rendered by each home infusion therapy supplier are being proposed in this rule. Many home infusion therapy suppliers already comply with the standards and have incorporated these practices into their daily operations. It is our belief that compliance with the quality standards would result in more efficient and effective business practices and would assist suppliers in reducing overall costs.

There are at least two important sources of uncertainty in estimating the impact of accreditation on home infusion therapy suppliers. First, our estimates assume that all home infusion therapy suppliers with positive Medicare payments would seek accreditation. We assume that home infusion therapy suppliers who currently receive no Medicare allowed charges would choose not to seek accreditation. It is also possible that many of the home infusion therapy suppliers with allowed charges between $1 and $1,000 may decide not to incur the costs of accreditation.

Second, it is difficult to predict what accreditation fees would be in the future. Our experience with other accreditation programs has lead us to believe that the accreditation rates would go up, due to factors such as wage increases, and increased travel costs. To monitor accreditation fees, we propose to require the AOs for home infusion therapy suppliers to submit their proposed fees to CMS for review for reasonableness. We would require home infusion therapy AOs to notify CMS anytime there is an increase in accreditation fees.

(d) Medicare-Certified Accreditation Organizations—Proposed Changes to 42 CFR 488.5

We have proposed to modify the AO approval and oversight regulations for Medicare-certified providers and suppliers by adding two new requirements. The first proposed new requirement is to added to 42 CFR 488.5(a)(7) and is a requirement that in their application for CMS approval, the AOs that accredited Medicare-certified providers and suppliers must include a statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program specific CMS online trainings established for state surveyors, initially, and thereafter. The second requirement is to be added as § 488.5(a)(18)(iii) and would require that the AOs for Medicare-certified providers and suppliers include a written statement in their application for CMS approval agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

(1) Burden Associated With the Online Training Requirement for AO Surveyors

CMS provides a number of online surveyor training modules that are available to the State Survey Agency surveyors. We have proposed to require the AO surveyors to take this training in an attempt to decrease the historically high disparity rate between the AOs survey results and those of the validation surveys performed by the State Survey Agency surveyors.

CMS offers 168 online surveyor training programs that are available for the State Survey Agency surveyors. This website provides courses that are general in nature such as ''Principles of Documentation Learning Activity—Long Term Care'', ''Basic Writing Skills for Surveyor Staff'', Infection Control, Patient Safety, and Emergency Preparedness. The CMS Surveyor Training website also offers courses related to specific healthcare settings, services, and regulations, such as hospitals, CAHs, ASCs, CLIA, CMHCs, EMTALA, FQHCs, HHAs and OASIS, Hospices, Nursing Homes and the MDS, Outpatient Physical Therapy/Outpatient Speech Therapy (OPT/OST). These courses are self-paced and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training course varies depending on the pace preferred by the trainee.

We estimate that each SA surveyor takes approximately 10 courses on the CMS Surveyor Training website. We estimate that it would take approximately 3–5 hours to complete each of these courses. We believe that the surveyors for AOs that accredit Medicare-certified providers should take the same number and type of surveyor training courses as the SA surveyors (that is—approximately 10 courses). This means that each of the AOs surveyors that takes this training would incur a time burden in the amount of 30 to 50 hours.

The AOs that accredit Medicare-certified providers and suppliers would incur a cost burden for the wages of the surveyor for the time they spend taking these online surveyor training courses. Most surveyors are clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). As noted previously, we estimated that it would take approximately 30–50 hours for each AO surveyor to complete 10 online surveyor courses. Therefore, the AO would incur wages in the amount of $1,060.80 to $1,768 per each surveyor that completes the CMS online surveyor training (($35.36 × 30 hours = $1,060.80) and ($35.36 × 50 hours = $1,768)). The AO would also incur additional costs for fringe benefits and overhead in the amount of $1,060.80 to $1,768.00 per each surveyor that completes the CMS online surveyor training.

We are not able to accurately estimate to total time and cost burden to each AO for the wages incurred for the time spent by all surveyors of that AO that take the CMS online surveyor training courses, because we do not know exactly how many surveyors each AO has. However, if we estimate that each AO has 15 surveyors, the estimated time burden to each AO associated with this requirement would be 450 to 750 hours ((30 hours × 15 surveyors = 450 hours per all surveyors) and (50 hours × 15 surveyors = 750 hours per all surveyors)). The estimated cost burden to each AO for Medicare-certified providers and supplies associated with

this requirement would be $31,824 to $53,040 (($1,060.80 × 15 = $15,912) and ($1,768.00 × 15 = $26,520) and ($15,912 to $26,520 for fringe benefits and overhead)).

There are currently 9 AOs that accredit Medicare-certified providers and suppliers. We estimate that the time burden across all of these AOs associated with the requirement that their surveyors take the CMS online surveyor training would be 4,050 to 6,750 ((450 hours per all surveyors/AO × 9 AOs = 4,050 hours across all AOs) and (750 hours per all surveyors/AO × 9 AOs = 6,750 hours across all AOs)). The estimated cost across all AOs that accredit Medicare-certified providers and suppliers would be $143,208 to $238,680 (($15,912 × 9 AOs = $143,208) and ($26,520 × 9 AOs = $238,680)). The cost for fringe benefits and overhead on these estimated wages across all AOs would be $143,208 to 238,680.

(2) Burden Associated With the Statement Requirement for AOs

We are proposing that AOs approved in accordance with section 1865 of the Act, and regulated under part 488 subpart A, provide a written statement in their application in which they agree to continue a provider's or supplier's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

Proposed § 488.5(a)(18)(iii) would require the AOs for Medicare-certified providers and suppliers to include a written statement in their application for CMS approval of their accreditation program, agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

We believe that the AOs that accredit Medicare-certified providers and suppliers would incur limited burden associated with this requirement, because this proposed regulation simply requires that the AOs to include a statement in their application stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider of supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program. We believe that this written statement to be provided by the AO would consist of only 1 to 2 paragraphs and would take no more than 15 minutes to prepare.

We believe that a clinicians such as registered nurses would prepare the required statement to be included in the AOs application. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (*https://www.bls.gov/oes/current/oes291141.htm*). Therefore, the estimated cost burden to the AOs that accredit Medicare-certified providers and suppliers associated with the preparation of the required statement would be approximately $17.68 ((15 minutes × $35.36 per hour = $8.84) + ($8.84 for fringe benefits and overhead)).

There are nine AOs that accredit Medicare-certified providers and suppliers. The cost across all AOs for the completion of this task would be $158.12 (($8.84 × 9 AOs = $79.56) + ($79.56 for fringe benefits and overhead. However, AOs for Medicare-certified providers and suppliers are required to submit a renewal application only every six years. Therefore, the existing AOs would be required to submit the statement stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider of supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program with their next renewal application which is submitted after the publication of the final rule. While we have calculated the cost for the performance of this task across all AOs that accredit Medicare-certified providers and suppliers, it is important to note that the existing AOs are scheduled to submit their renewal applications at varying dates and times over a period of several years. Therefore there will be no time period in which all of these AOs will incur these expenses simultaneously.

D. Detailed Economic Analysis

1. HH PPS

This rule proposes updates for the CY 2019 HH PPS rates contained in the CY 2018 HH PPS final rule (82 FR 51676 through 51752). The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2017. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

a. HH PPS for CY 2019

Table 59 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2019. For this analysis, we used an analytic file with linked CY 2017 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2017. The first column of Table 59 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2019 wage index and revised labor share. The fourth column shows the payment effects of the CY 2019 case-mix weights. The fifth column shows the effects of the new rural add-on payment provision in statute. The sixth column shows the effects of the revised FDL ratio used to calculate outlier payments, and the seventh column shows the effects of the CY 2019 home health payment update percentage.

The last column shows the combined effects of all the policies proposed in this rule. Overall, it is projected that aggregate payments in CY 2019 would increase by 2.1 percent. As illustrated in Table 59, the combined effects of all of the changes vary by specific types of

providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2019 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2019 relative to CY 2018, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

TABLE 59—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2019

	Number of agencies	CY 2019 wage index and labor share [1] (%)	CY 2019 case-mix weights [2] (%)	Rural add-on revisions (%)	Updated outlier FDL ratio 0.51 (%)	CY 2019 HH payment update percentage [3]	Total (%)
All Agencies	10,547	0.0	0.0	−0.1	0.1	2.1	2.1
Facility Type and Control							
Free-Standing/Other Vol/NP	1,065	−0.3	−0.1	0.0	0.2	2.1	1.9
Free-Standing/Other Proprietary	8,366	0.1	0.0	−0.1	0.1	2.1	2.2
Free-Standing/Other Government	260	0.3	0.1	−0.1	0.2	2.1	2.6
Facility-Based Vol/NP	604	0.0	0.0	0.0	0.2	2.1	2.3
Facility-Based Proprietary	76	−0.3	0.1	−0.2	0.2	2.1	1.9
Facility-Based Government	176	−0.1	0.0	−0.3	0.2	2.1	1.9
Subtotal: Freestanding	9,691	0.0	0.0	−0.1	0.1	2.1	2.1
Subtotal: Facility-based	856	−0.1	0.0	−0.1	0.2	2.1	2.1
Subtotal: Vol/NP	1,669	−0.2	−0.1	0.0	0.2	2.1	2.0
Subtotal: Proprietary	8,442	0.1	0.0	−0.1	0.1	2.1	2.2
Subtotal: Government	436	0.1	0.0	−0.2	0.2	2.1	2.2
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	253	0.1	0.1	−0.3	0.2	2.1	2.2
Free-Standing/Other Proprietary	821	0.6	0.0	−0.7	0.1	2.1	2.1
Free-Standing/Other Government	176	0.5	0.1	−0.2	0.2	2.1	2.7
Facility-Based Vol/NP	273	0.2	0.1	−0.3	0.2	2.1	2.3
Facility-Based Proprietary	41	0.1	0.2	−0.5	0.1	2.1	2.0
Facility-Based Government	134	0.2	0.1	−0.4	0.2	2.1	2.2
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	812	−0.4	−0.1	0.0	0.2	2.1	1.8
Free-Standing/Other Proprietary	7,545	0.0	0.0	0.0	0.1	2.1	2.2
Free-Standing/Other Government	84	0.1	0.1	0.0	0.2	2.1	2.5
Facility-Based Vol/NP	331	−0.1	−0.1	0.0	0.2	2.1	2.1
Facility-Based Proprietary	35	−0.6	0.1	0.0	0.2	2.1	1.8
Facility-Based Government	42	−0.4	−0.1	−0.1	0.1	2.1	1.6
Facility Location: Urban or Rural							
Rural	1,698	0.4	0.0	−0.6	0.1	2.1	2.0
Urban	8,849	0.0	0.0	0.0	0.1	2.1	2.2
Facility Location: Region of the Country (Census Region)							
New England	363	−0.9	0.0	0.0	0.2	2.1	1.4
Mid Atlantic	482	−0.3	−0.2	0.0	0.2	2.1	1.8
East North Central	2,031	−0.3	0.1	0.0	0.1	2.1	2.0
West North Central	705	0.0	0.1	0.0	0.2	2.1	2.4
South Atlantic	1,647	0.0	−0.2	0.0	0.1	2.1	2.0
East South Central	423	0.1	−0.1	−0.5	0.1	2.1	1.7
West South Central	2,774	0.6	0.1	−0.3	0.1	2.1	2.6
Mountain	678	−0.3	0.1	0.1	0.2	2.1	2.2
Pacific	1,403	0.3	0.2	0.0	0.1	2.1	2.7
Other	41	0.9	−0.9	0.0	0.2	2.1	2.3
Facility Size (Number of First Episodes)							
<100 episodes	2,907	0.0	0.3	0.0	0.2	2.1	2.6
100 to 249	2,301	0.1	0.4	−0.1	0.1	2.1	2.6
250 to 499	2,218	0.1	0.3	−0.1	0.1	2.1	2.5
500 to 999	1,637	0.1	0.1	−0.1	0.1	2.1	2.3
1,000 or More	1,484	0.0	−0.1	−0.1	0.1	2.1	2.0

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment.

[1] The impact of the CY 2019 home health wage index is offset by the wage index budget neutrality factor described in section III.C.4 of this proposed rule.

[2] The impact of the CY 2019 home health case-mix weights reflects the recalibration of the case-mix weights offset by the case-mix weights budget neutrality factor described in section III.B of this proposed rule.

[3] The CY 2019 home health payment update percentage reflects the home health payment update of 2.1 percent as described in section III.C.2 of this proposed rule.

Region Key:

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

b. HH PPS for CY 2020 (Proposed PDGM)

Table 60 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2020. For this analysis, we used an analytic file with linked CY 2017 OASIS assessments and CY 2017 HH claims data (as of March 2, 2018) for dates of service that ended on or before December 31, 2017. The first column of Table 60 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of HHAs in the impact analysis. The PDGM, as required by Section 51001(a)(2)(A) of the BBA of 2018, will be implemented in a budget neutral manner and the third column shows the total impact of the proposed PDGM as outlined in section III.F of this proposed rule. As illustrated in Table 60, the effect of the proposed PDGM varies by specific types of providers and location. We note that some individual HHAs within the same group may experience different impacts on payments than others. This is due to distributional differences among HHAs with regards to the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, the degree of Medicare utilization, and the ratio of overall visits that were provided as therapy versus skilled nursing.

As outlined in section III.F of this proposed rule, several OASIS items would no longer be needed to case-mix adjust the 30-day payment under the PDGM; therefore, we would make 19 current OASIS items (48 data elements) optional at the FU time point starting January 1, 2020. As also discussed in section III.F. of this proposed rule, in order to calculate the case-mix adjusted payment amount for the PDGM, we would add the collection of two current OASIS items (10 data elements) at the FU time point starting January 1, 2020. Section VII of this proposed rule provides a detailed description of the net decrease in burden associated with these proposed changes in conjunction with the changes in burden that result from OASIS item collection changes due to the proposed removal of certain measures required under HH QRP, also effective for January 1, 2020 as outlined in section V.E of this rule. We estimate that the burden associated with OASIS item collection as a result of this proposed rule results in a net $60 million in annualized cost savings to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

TABLE 60—IMPACTS OF PDGM, CY 2020

	Number of agencies	PDGM (%)
All Agencies	10,480	0.0%
Facility Type and Control		
Free-Standing/Other Vol/NP	1,055	2.6
Free-Standing/Other Proprietary	8,309	−1.2
Free-Standing/Other Government	260	1.1
Free-Based Vol/NP	604	3.8
Free-Based Proprietary	76	4.4
Free-Based Government	176	4.6
Subtotal: Freestanding	9,624	−0.4
Subtotal: Free-based	856	3.9
Subtotal: Vol/NP	1,659	2.9
Subtotal: Proprietary	8,385	−1.2
Subtotal: Government	436	2.9
Facility Type and Control: Rural		
Free-Standing/Other Vol/NP	253	3.8
Free-Standing/Other Proprietary	820	3.9
Free-Standing/Other Government	176	1.9
Free-Based Vol/NP	273	4.1
Free-Based Proprietary	41	11.3
Free-Based Government	134	5.9
Facility Type and Control: Urban		
Free-Standing/Other Vol/NP	802	2.4
Free-Standing/Other Proprietary	7,489	−1.8
Free-Standing/Other Government	84	0.3
Free-Based Vol/NP	331	3.7
Free-Based Proprietary	35	0.1

TABLE 60—IMPACTS OF PDGM, CY 2020—Continued

	Number of agencies	PDGM (%)
Free-Based Government	42	3.4
Facility Location: Urban or Rural		
Rural	1,697	4.0
Urban	8,783	−0.6
Facility Location: Region of the Country (Census Region)		
New England	354	2.5
Mid Atlantic	479	3.1
East North Central	2,012	−1.1
West North Central	703	−3.9
South Atlantic	1,643	−5.3
East South Central	423	0.9
West South Central	2,750	4.1
Mountain	675	−5.2
Pacific	1,400	3.8
Other	41	11.0
Facility Size (Number of 1st Episodes)		
< 100 episodes	2,841	1.9
100 to 249	2,301	1.1
250 to 499	2,218	0.6
500 to 999	1,636	−0.3
1,000 or More	1,484	−0.2
Nursing/Therapy Visits Ratio		
1st Quartile (Lowest 25 Nursing)	2,620	−9.9
2nd Quartile	2,620	−0.8
3rd Quartile	2,620	6.5
4th Quartile (Top 25 Nursing)	2,620	17.0

Source: CY 2017 Medicare claims data (as of March 2, 2018) for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment.

Note(s): The ''PDGM'' is the 30-day version of the model with no behavioral assumptions applied. From the impact file, this analysis omits 354,099 60-day episodes not grouped under the PDGM (either due to a missing SOC OASIS, because they could be assigned to a clinical grouping, or had missing therapy/nursing visits). After converting 60-day episodes to 30-day periods for the PDGM, a further 26 periods were excluded with missing NRS weights, and 2,386 periods with a missing urban/rural indicator. These excluded episodes results overall in 67 fewer HHAs being represented than in the standard impact tables.

Region Key:

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

In response to the CY 2019 case-mix adjustment methodology refinements proposed in the CY 2018 HH PPS proposed rule (82 FR 35270), a few commenters requested that CMS include more information in the impact table for the proposed PDGM, specifically how payments are impacted for patients with selected clinical conditions as was included in the Technical Report which is available at: *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.* Therefore, we are including Table 61 which provides more information on the impact of the PDGM case-mix adjustment methodology for patients with selected clinical conditions.

TABLE 61—IMPACT OF THE PDGM FOR SELECTED PATIENT CHARACTERISTICS

	Ratio of average PDGM payment to average current (30-day equivalent) payment
All Episodes (60-Day Count)	1.00
Clinical Group	
Behavioral Health	0.85
Complex	1.13

TABLE 61—IMPACT OF THE PDGM FOR SELECTED PATIENT CHARACTERISTICS—Continued

	Ratio of average PDGM payment to average current (30-day equivalent) payment
MMTA	1.00
MS Rehab	0.96
Neuro Rehab	0.93
Wound	1.27
Functional Level	
Low	0.95
Medium	1.00
High	1.05
Admission Source	
Community	0.89
Institutional	1.30
Timing	
Early	1.25
Late	0.87
Comorbidity Group	
No adjustment	0.97
Single Comorbidity	1.02
Comorbidity Interaction	1.22
Dual Status	
Not (Full) Dual Eligible	0.99
Yes (Full) Dual Eligible	1.03
Parenteral Nutrition	
No Parenteral Nutrition	1.00
Yes Parenteral Nutrition	1.18
Surgical Wounds	
No Known Surgical Wound	0.98
Yes Known Surgical Wound	1.11
Ulcers	
No Ulcers Recorded	0.99
Positive Number of Ulcers Recorded	1.16
Bathing	
Able to Bathe with some independence	0.97
Cannot bathe independently	1.08
Poorly-Controlled Cardiac Dysrhythmia	
No Poorly-Controlled Cardiac Dysrhythmia	1.00
Yes Poorly-Controlled Cardiac Dysrhythmia	1.04
Poorly-Controlled Diabetes	
No Poorly-Controlled Diabetes	0.99
Yes Poorly-Controlled Diabetes	1.06
Poorly-Controlled Peripheral Vascular Disease	
No Poorly-Controlled Peripheral Vascular Disease	1.00
Yes Poorly-Controlled Peripheral Vascular Disease	1.07
Poorly-Controlled Pulmonary Disorder	
No Poorly-Controlled Pulmonary Disorder	1.00

TABLE 61—IMPACT OF THE PDGM FOR SELECTED PATIENT CHARACTERISTICS—Continued

	Ratio of average PDGM payment to average current (30-day equivalent) payment
Yes Poorly-Controlled Pulmonary Disorder	1.03
Open Wound/Lesion	
No Open Wound/Lesion	0.98
Yes Open Wound/Lesion	1.10
Temporary Health Risk	
No Temporary Health Risk	0.99
Yes Temporary Health Risk	1.02
Fragile/Serious Health Risk	
Yes Fragile/Serious Health Risk	0.98
No Fragile/Serious Health Risk	1.04

Note(s): **For this table only**, payments are for normal episodes and do not include outlier payments. For comparability with the 30-day PDGM, current payments have been halved from 60-day amounts to simulate 30-day payments. PDGM payments have been normalized so that national average 30-day payments equaled the 30-day current system equivalent payment to facilitate an understanding of reallocation of payments from the current system. For the ratio of PDGM to current payments in the right-hand column, a value greater than one signifies that characteristic would receive increased payment and a value less than one would signify that characteristic would receive lesser payment, all else equal, in the PDGM. To be classified as Poorly Controlled Cardiac Dysrhythmia, Diabetes, Peripheral Vascular Disease, or Pulmonary Disorder required one of the following respective primary or secondary diagnosis codes with an accompanying recorded ''poorly-controlled'' degree of symptom control: Cardiac Dysthymia: ICD–10 I–21–I22.9 & I47–I49; Diabetes: E08.0–E08.8, E09.0–E09.8, & E10–E14; Peripheral Vascular Disease: ICD–10 I73; and Pulmonary Disorder: (I40–47, J84.01, J84.02, J84.03, J84.10, J96.0–J96.92, & J98.01–J98.3).

2. HHVBP Model

Table 62 displays our analysis of the distribution for possible payment adjustments at the maximum 7-percent, and 8-percent rates that will be used in Years 4 and 5 of the Model. These analyses use performance year data from 2016, the first year of HHVBP, the most recent year for which complete performance year data are available. The estimated impacts are for the following proposed changes, each of which would take effect beginning with PY4 (2019):

- Remove two OASIS-based measures (Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received);
- Replace three OASIS-based measures (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion) with two composite measures (Total Change in Self Care, Total Change in Mobility). The two composite measures would have a maximum score of 15 points;
- Reduce the maximum possible improvement points from 10 to 9 (13.5 for the two composite measures); and,
- Change the weights given to the performance measures used in the Model so that the OASIS and claims-based measures each count for 35 percent and the HHCAHPS measures count for 30 percent of the 90 percent of the Total Performance Score (TPS) that is based on performance 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. The weight of the unplanned hospitalization measure would also be increased so that it has three times the weight of the ED use without hospitalization measure.

We analyzed the payment adjustment percentage and the number of eligible HHAs under current policy to determine the impacts if the proposed changes in this rule were finalized. We used PY1 (CY2016) data to measure the impacts. The data sources for these analyses are data from the QIES system for the existing OASIS and claims-based measures, OASIS assessments for the two composite measures, HHCAHPS data received from the HHCAHPS contractor, and New Measure data submitted by Model participants. HHAs are classified as being in the smaller or larger volume cohort using the 2016 Quality Episode File, which is created using OASIS assessments. We note that this impact analysis is based on the aggregate value across all nine Model states.

Table 63 displays our analysis of the estimated impact of the proposals in this rule on the number of eligible HHAs and the distribution of percentage change in payment adjustment percentage based on the same PY1 (CY2016) data used to calculate Table 62. We note that this impact analysis is based on the aggregate value across all nine Model states. Note that all Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee are required to compete in this Model. The analysis is calculated at the state and size cohort level. It is expected that a certain number of HHAs would not have a payment adjustment because they may be servicing too small of a population to report an adequate number of measures to calculate a TPS. Table 63 shows that there would be a reduction in the number of HHAs that would have a sufficient number of measures to receive a payment adjustment for performance year 4 of 31 HHAs (Change column), a decrease from 1,610 HHAs (Current column) to 1,579 HHAs (Simulated column) across the nine selected states.

This analysis reflects only HHAs that would have data for at least five measures that meet the requirements of § 484.305 and would be included in the LEF and would have a payment adjustment calculated. Value-based incentive payment adjustments for the estimated eligible 1,579 HHAs in the selected states that would compete in the HHVBP Model are stratified by size as described in section IV.B. of the CY 2017 HH PPS final rule. As finalized in

section IV.B. of the CY 2017 final rule, there must be a minimum of eight HHAs in any cohort.

Those HHAs that are in states that do not have at least eight smaller-volume HHAs will not have a separate smaller-volume cohort and thus there will only be one cohort that will include all the HHAs in that state. As indicated in Table 63, Maryland, North Carolina, Tennessee, Washington, and Arizona would have only one cohort while Florida, Iowa, Massachusetts, and Nebraska would have both a smaller-volume cohort and a larger-volume cohort. For example, Iowa would have 17 HHAs eligible to be exempt from being required to have their beneficiaries' complete HHCAHPS surveys because they provide HHA services to less than 60 beneficiaries. Therefore, those 17 HHAs would be competing in Iowa's smaller-volume cohort for CY 2019 (PY4) under the Model.

Table 63 shows the distribution of percentage change in payment adjustment percentage resulting from the proposals in this rule. Using 2016 data and the maximum payment adjustment for performance year 4 of 7 percent (as applied in CY 2021), based on the six proposed OASIS quality measures and two claims-based measures in QIES, the five HHCAHPS measures, and the three New Measures, we see that, across all nine states, 31 HHAs would no longer be eligible for a payment adjustment for PY4 because they would not have data on at least five measures that meet the requirements of § 484.305. The distribution of scores by percentile shows the distribution of the change in percent payment adjustment. For example, the distribution for HHAs in Florida in the smaller-volume cohort ranges from −2.5 percent at the 10th percentile to +2.9 percent at the 90th percentile. This means that, for 7 of the 77 HHAs in the smaller-volume cohort in Florida, the proposed changes would decrease their payment adjustment percentage by −2.5 percent or more while, for another 7 HHAs these proposed changes would increase their payment adjustment percentage by 2.9 percent or more. For half of the HHAs in Florida's smaller volume cohort, the impact of these proposed changes on their payment adjustment percentage would be between −1.1 percent and +1.3 percent. These impact analyses suggest that, for most participating HHAs, the impacts of the proposed changes would be modest.

Table 64 provides the payment adjustment distribution based on agency size, proportion of dually-eligible beneficiaries, average case mix (using the average case-mix for non-LUPA episodes), the proportion of the HHA's beneficiaries that reside in rural areas and HHA organizational status. HHAs with a higher proportion of dually-eligible beneficiaries and HHAs whose beneficiaries have higher acuity tend to have a more negative impact associated with the proposals in this rule based on the 50th percentile of the impact of the changes on payment adjustment percentage.

Table 65 shows the current and proposed weights for individual performance measures by measure category and possible applicable measure category scenarios to demonstrate the weight of the individual measures when an HHA has scores on All Measures or if an HHA is missing all measures in a measure category. For example, for an HHA that has quality measure scores on All Measures in all the measure categories (OASIS-based, claims-based and HHCAHPS) under the current weighting method, the individual measures are weighted equally. The Proposed Weights columns show the proposed weights for the individual performance measures based on the changes to the weighting methodology proposed in this rule. For example, for HHAs with scores on All Measures, the OASIS-based measures account for 35 percent of the TPS, with equal weighting given to the Improvement in Oral Medications, Improvement in Dyspnea, Improvement in Pain, and Discharge to Community measures. The proposed Composite Self-Care and Composite Mobility measures would be weighted 1.5 times more than the other OASIS-based measures so that the maximum score for the two composite measures is the same as for the three functional OASIS-based measures that they would replace (Improvement in Ambulation, Bathing and Bed Transferring). Under the proposed weights, the two claims-based measures, which would collectively account for 35 percent of an HHA's TPS, would not be weighted equally. We are proposing that the weight of the acute care hospitalization measure would be three times higher than that of the ED Use measure. Thus, its weight would be 26.25 percent while the weight of the ED Use measure would be 8.75 percent for an HHA that reported on all measures. The HHCAHPS measures would account for 30 percent of an HHA's TPS and each measure would be weighted equally.

Table 65 also shows the number of HHAs that would have enough measures to receive a payment adjustment under each possible scoring scenario under both the current and proposed weighting methodologies. Most of the HHAs that would no longer receive a payment adjustment with the proposed changes in this rule are those with no claims or HHCAHPS measures. With only OASIS measures, these HHAs are more impacted by the proposal to remove the two immunization measures and the proposal to replace three OASIS functional measures with the two composite measures. The number of HHAs without claims or HHCAHPS measures that do not have enough measures to receive a payment adjustment would drop from 99 to 73 (a decrease of 26 HHAs), and the majority of the HHAs that would no longer have a payment adjustment would be smaller HHAs (16 of the 26 HHAs).

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TABLE 62: ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES (PERCENTAGE)

		Percentile								
Payment Adj. Distribution	**Maximum Payment Adjustment Percentage**	**10%**	**20%**	**30%**	**40%**	**Median**	**60%**	**70%**	**80%**	**90%**
7% Payment Adj. For PY4 of the Model	7%	-3.3%	-2.4%	-1.7%	-0.9%	-0.2%	0.5%	1.2%	2.2%	3.7%
8% Payment Adj. For PY5 of the Model	8%	-3.8%	-2.8%	-1.9%	-1.0%	-0.3%	0.5%	1.4%	2.5%	4.2%

TABLE 63: HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT
[Based on a 7-percent payment adjustment]

		Number of Eligible HHAs			Distribution of Percentage Change in Payment Adjustment Percentage Resulting From Proposed Changes				
State	**Cohort**	**Current**	**Simulated**	**Change**	**10th Percentile**	**25th Percentile**	**50th Percentile**	**75th Percentile**	**90th Percentile**
	All	1610	1579	31	-2.1%	-1.0%	-0.1%	0.9%	1.9%
HHAs with no separate small HHA cohort									
AZ	All	113	112	1	-2.7%	-1.4%	-0.1%	0.7%	1.8%
MD	All	51	50	1	-1.7%	-0.6%	-0.3%	0.9%	1.6%
NC	All	163	163	0	-1.6%	-0.8%	0.0%	0.7%	1.9%
TN	All	122	122	0	-1.2%	-0.7%	0.2%	0.8%	1.7%
WA	All	57	57	0	-1.3%	-0.8%	0.0%	0.8%	2.0%
Large-volume HHA Cohort in states with small cohort									
FL	Large	706	703	3	-2.3%	-1.2%	-0.2%	1.0%	2.0%
IA	Large	99	97	2	-1.9%	-1.2%	-0.2%	0.8%	1.5%
MA	Large	123	119	4	-2.0%	-1.1%	-0.4%	0.5%	1.4%
NE	Large	45	45	0	-2.8%	-0.9%	-0.3%	0.6%	1.8%
Small-volume HHA Cohort in states with small cohort									
FL	Small	77	68	9	-2.5%	-1.1%	0.1%	1.3%	2.9%
IA	Small	25	17	8	0.1%	1.3%	2.9%	4.4%	6.4%
MA	Small	15	12	3	-1.4%	-0.5%	0.3%	1.5%	2.2%
NE	Small	14	14	0	-3.0%	-1.0%	0.0%	1.2%	2.2%

TABLE 64: PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS FOR THE HHVBP MODEL
[Based on a 7-percent payment adjustment [1, 2]]

	Number of Eligible HHAs			Distribution of Percentage Change in Payment Adjustment Percentage Resulting From Proposed Changes				
Cohort	**Current**	**Simulated**	**Change**	**10th Percentile**	**25th Percentile**	**50th Percentile**	**75th Percentile**	**90th Percentile**
Facility size (# of patients)								
Small HHA	136	117	19	-3.2%	-1.6%	-0.2%	1.1%	3.1%
Large HHA	1474	1462	12	-2.0%	-1.0%	-0.1%	0.9%	1.9%
Percentage of Medicaid patients								
No Medicaid	749	743	6	-2.2%	-1.1%	-0.1%	0.9%	2.0%
>0 and < 30% Medicaid	661	653	8	-1.7%	-0.9%	0.0%	0.9%	1.9%
30%+ Medicaid	200	183	17	-2.6%	-1.4%	-0.4%	0.6%	1.8%
Patient acuity								
Low Acuity	403	384	19	-2.2%	-1.0%	-0.1%	1.0%	2.0%
Medium Acuity	805	798	7	-1.8%	-0.9%	0.0%	0.9%	1.9%
High Acuity	402	397	5	-2.3%	-1.3%	-0.3%	0.9%	2.0%
Percentage of rural beneficiaries								
None	1482	1458	24	-2.1%	-1.1%	-0.1%	0.9%	1.9%
> 0 and < 90%	11	10	1	-4.1%	-1.1%	-0.4%	0.3%	1.7%
>=90%	117	111	6	-1.7%	-0.9%	0.2%	1.5%	2.7%
Facility type and control								
Non-profit	310	308	2	-1.4%	-0.8%	0.2%	1.0%	1.9%
For profit	1191	1169	22	-2.2%	-1.1%	-0.2%	0.8%	1.9%
Government	109	102	7	-1.9%	-0.9%	0.0%	1.2%	2.7%
Freestanding	1448	1419	29	-2.1%	-1.1%	-0.2%	0.9%	1.9%
Facility-based	162	160	2	-1.2%	-0.5%	0.2%	1.1%	2.0%

[1] Rural beneficiaries identified based on the CBSA code reported on the claim.

[2] Acuity is based on the average case-mx weight for non-LUPA episodes. Low acuity is defined as the bottom 25% (among HHVBP model participants); mid-acuity is the middle 50% and high acuity is the highest 25%.

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TABLE 65: CURRENT AND PROPOSED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES FOR THE HHVBP MODEL [1234]

	Current Weights				Proposed Weights: All Changes				Proposed Weights: Reweighting Changes Only			
	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)	All Measures (n=1,026)	No HHCAHPS (n=460)	No claims (n=20)	No claims or HHCAHPS (n=73)
Large HHAs	*1023*	*382*	*20*	*49*	*1023*	*380*	*20*	*39*				
Small HHAs	*3*	*83*	*0*	*50*	*3*	*80*	*0*	*34*				
OASIS (35% weight)*												
Flu vaccine ever received**	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Pneumococcal vaccine**	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Bathing***	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Bed Transfer***	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Ambulation***	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Oral Meds	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Improve Dyspnea	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Improve Pain	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Discharge to Community	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Composite self-care	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%	0.00%	0.00%	0.00%	0.00%
Composite mobility	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%	0.00%	0.00%	0.00%	0.00%
Total weight for OASIS measures	*56.25%*	*81.82%*	*64.26%*	*100.00%*	*35.00%*	*49.98%*	*53.82%*	*99.96%*	*35.00%*	*50.00%*	*53.85%*	*100.00%*
Claims (35% weight)												
Hospitalizations	6.25%	9.09%	0.00%	0.00%	26.25%	37.50%	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%	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%*	*35.00%*	*50.00%*	*0.00%*	*0.00%*
HHCAHPS (30% weight)												
Care of patients	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	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%	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%	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%	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%	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%*	*30.00%*	*0.00%*	*46.15%*	*0.00%*

[1] Under the proposal if individual OASIS items are missing, the weight of the non-missing OASIS items would be increased.

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

[3] Improvement in Bathing, Bed Transfer and Ambulation measures are proposed to be removed if proposed composite measures are added to the applicable measure set beginning in CY 2019/PY4.

[4] The proposed composite measures (Composite Self-Care and Composite Mobility) would replace three functional OASIS-based measures (Improvement in Bathing, Improvement in Bed Transfer, Improvement in Ambulation), thus they would be weighted 1.5 times more than the other OASIS-based measures so that the total weight for the functional-based OASIS measures is unchanged.

3. HH QRP

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a calendar year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to a HHA for that calendar year by 2 percentage points. For the CY 2018 annual payment update determination, 1,311 of the 11,776 active Medicare-certified HHAs, or approximately 11.1 percent, did not receive the full annual percentage increase. Information is not available to determine the precise number of HHAs that would not meet the requirements to receive the full annual percentage increase for the CY 2019 payment determination.

As discussed in section V.E. of this proposed rule, we are proposing to remove seven measures from the HH QRP: Depression Assessment Conducted, Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care, Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537), Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in the Status of Surgical Wounds, Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505), Rehospitalization during the First 30 Days of HH (NQF #2380). All seven of these measures are proposed for removal starting with the CY 2021 HH QRP. As noted previously, section VII. of this proposed rule provides a detailed description of the net decrease in burden associated with these proposed changes in conjunction with the changes in burden that result from the proposed implementation of the PDGM for CY 2020. We estimate that the burden associated with OASIS item collection as a result of this proposed rule results in a net $60 million in annualized cost savings to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

4. Home Infusion Therapy Payment

The following analysis applies to the Temporary Transitional Payment for Home Infusion Therapy as set forth in section 1834(u)(7) of the Act, as added by section 50401 of the BBA of 2018 (Pub. L 115–123), and accordingly, describes the impact for CY 2019 only. Table 66 represents the estimated increased costs of existing DME users currently using home infusion therapy services. We used CY 2017 data to identify beneficiaries with DME claims containing 1 of the 37 HCPCS codes identified in section 1834(u)(7)(C) of the Act, which are shown in column 2. In column 3, 2017 claims were again used to determine the total weeks of care, which is the sum of weeks of care across all beneficiaries found in each category. Weeks of care for payment categories 1 and 3 are defined as the week of the last infusion drug or pump claim minus the week of the first infusion drug or pump claim plus one. For Category 2, we used the median number of weeks of care, 47, as many patients use immune globulin for the whole year. Column four assumes the initial week of care requires two nurse visits, and all subsequent weeks only require one visit, in order to estimate the total visits of care per category. In general, nursing visits for payment category 2, subcutaneous immune globulin (SCIG) administration, occur once per month; therefore, we assume the estimated number of visits for these patients is 12. The fifth column multiplies the volume of nurse visits across beneficiaries by the payment rate (using the 2018 Physician Fee Schedule amounts) in order to estimate the increased cost per each of the three infusion drug categories.[112] In the CY 2019 HH PPS final rule, we will update this impact analysis using more complete 2017 claims data (as of June 30, 2018 or later) and the CY 2019 Physician Fee Schedule amounts.

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

Payment category	Number of beneficiaries	Total weeks of care	Estimated total visits of care	2018 Payment rate	Estimated cost
1	5,885	130,896	136,781	$141.12	$19,302,535
2	6,315	236,470	75,780	224.28	16,995,938
3	5,774	87,260	93,034	239.76	22,305,832
Total	17,974	.....	.....	.....	58,604,305

Table 67 displays the estimated regional impacts using the beneficiary enrollment address reported in the Medicare Master Beneficiary Summary File. Table 68 displays impacts based on rural or urban designations. All beneficiaries identified had at least one applicable home infusion claim (claims with 1 of the 37 drug codes listed in section 1834(u)(7)(C) of the Act) in CY 2017. Unknown beneficiaries were those without valid state and county information in the Master Beneficiary Summary File. Additionally, the tables provide the estimated impacts by drug category.

TABLE 67—ESTIMATED IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES BY REGION, CY 2019

Census Region	Number of home infusion patients	Category 1	Category 2	Category 3	Total
New England	719	$1,030,740.48	$866,617.92	$$263,496.24	$2,160,854.64
Mid Atlantic	3,503	2,699,343.36	1,582,519.68	8,670,920.40	12,952,783.44
East North Central	2,493	3,204,976.32	1,733,235.84	3,346,330.32	8,284,542.48
West North Central	1,296	1,192,605.12	1,351,062.72	1,644,034.32	4,187,702.16
South Atlantic	4,396	4,367,805.12	4,849,830.72	4,516,359.12	13,733,994.96
East South Central	1,201	1,330,761.60	1,544,840.64	668,690.64	3,544,292.88

[112] Based on the 2018 Medicare PFS these rates are $141.12 ($74.16 + 3 * $22.32) for Category 1, $224.28 ($176.76 + 3 * $15.84) for Category 2, and $239.76 ($144.72 + 3 * $31.68) for Category 3.

TABLE 67—ESTIMATED IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES BY REGION, CY 2019—Continued

Census Region	Number of home infusion patients	Category 1	Category 2	Category 3	Total
West South Central	1,729	2,546,228.16	1,824,742.08	942,256.80	5,313,227.04
Mountain	847	978,949.44	1,404,889.92	281,957.76	2,665,797.12
Pacific	1,727	1,928,969.28	1,800,519.84	1,882,595.52	5,612,084.64
Other	63	22,155.84	37,679.04	89,190.72	149,025.60
Total	17,974	19,302,534.72	16,995,938.40	22,305,831.84	58,604,304.96

TABLE 68—ESTIMATED URBAN/RURAL IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES, CY 2019

CBSA Urban/rural	Number of home infusion patients	Category 1	Category 2	Category 3	Total
Urban	14,692	$15,906,058.56	$14,495,664.96	$17,419,762.80	$47,821,486.32
Rural	3,239	3,384,057.60	2,462,594.40	4,863,052.08	10,709,704.08
Unknown	43	12,418.56	37,679.04	23,016.96	73,114.56
Total	17,974	19,302,534.72	16,995,938.40	22,305,831.84	58,604,304.96

E. Alternatives Considered

1. HH PPS

a. HH PPS for CY 2019

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2019 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. For CY 2019, Section 1895(b)(3)(B)(vi) of the Act requires that the market basket update under the HHA prospective payment system be annually adjusted by changes in economy-wide productivity. The proposed 0.7 percentage point multifactor productivity adjustment to the proposed CY 2019 home health market basket update of 2.8 percent, is discussed in the preamble of this rule and is not discretionary as it is a requirement in section 1895(b)(3)(B)(vi)(I) of the Act.

We considered not rebasing the home health market basket. However, we believe that it is desirable to rebase the home health market basket periodically so that the cost category weights reflect changes in the mix of goods and services that HHAs purchase in furnishing home health care. In addition, we considered not implementing the proposed revision to the labor-related share of 76.1 percent in a budget neutral manner. However, we believe it is more prudent to implement the revision to the labor-related share in a manner that does not increase or decrease budgetary expenditures.

With regards to payments made under the HH PPS for high-cost outlier episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care), we did not consider maintaining the current FDL ratio of 0.55. As discussed in section III.E.3. of this proposed rule, we propose to revise the FDL ratio to 0.51. Simulations using CY 2017 claims data and the proposed CY 2019 HH PPS payment rates resulted in an estimated 2.32 percent of total HH PPS payments being paid as outlier payments using the existing methodology for calculating the cost of an episode of care. The FDL ratio and the loss-sharing ratio must be selected so that the estimated outlier payments do not exceed the 2.5 percent of total HH PPS payments (as required by section 1895(b)(5)(A) of the Act). We did not consider proposing a change to the loss sharing ratio (0.80) in order for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.)

b. HH PPS for CY 2020 (PDGM)

For CY 2020, we did not consider alternatives to changing the unit of payment from 60 days to 30 days, eliminating the use of therapy thresholds for the case-mix adjustment, and requiring the revised payments to be budget neutral. Section 51001 of the BBA of 2018 requires the change in the unit of payment from 60 days to 30 days to be made in a budget neutral manner and mandates the elimination of the use of therapy thresholds for case-mix adjustment purposes. The BBA of 2018 also requires these measures to be implemented on January 1, 2020 and that we make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and as a result of the case-mix adjustment factors that are implemented in CY 2020 in calculating a 30-day payment amount for CY 2020 in a budget neutral manner.

Alternatives to making 19 current OASIS items (48 data elements) optional at the FU time point as outlined in section VII. of this proposed rule, would be to either not implement the case-mix adjustment methodology changes proposed under the PDGM or to continue collecting the 19 current OASIS items at the FU time point, even though they would not be used to case-mix adjust payments under the PDGM. Similarly, an alternative to adding collection of two current OASIS items (10 data elements) at the FU time point as discussed in section VII. of this proposed rule would be to either not adopt the PDGM or not to include the two current OASIS items (M1800 and M1033) as part of the case-mix adjustment methodology under the proposed PDGM. As noted previously, we did not consider not implementing the case-mix methodology changes under the proposed PDGM as a new case-mix adjustment methodology is required to be implemented in accordance with section 51001 of the BBA of 2018, which mandates the elimination of the use of therapy thresholds for case-mix adjustment purposes by January 1, 2020. We believe that continuing to require HHAs to report responses for the 19 current OASIS items at the FU time point that are no longer needed for case-mix adjustment purposes under the PDGM results in unnecessary burden for HHAs.

While requiring HHAs to report responses for two current OASIS items at the FU time point results in a small increase in burden if CMS were to not make 19 current OASIS items optional at the FU time point, those two OASIS items (M1800 and M1033) are correlated with increases in resource use and are used to determine the patient's functional impairment level under the HHGM, thus they are important for case-mix adjustment purposes in order to ensure accurate payments to HHAs under the proposed PDGM.

We considered whether to continue using the wage-weighted minutes of care (WWMC) approach to estimate resource use under the PDGM, as described in section III.F.2. of this proposed rule. Although the relationship in relative costs between the WWMC approach and the proposed cost-per-minute plus non-routine supplies (CPM + NRS) approach is very similar (correlation coefficient equal to 0.8512), the WWMC approach does not as evenly weight skilled nursing costs relative to therapy costs as evidenced in the cost report data and would require us to maintain a separate case-mix adjustment mechanism for NRS. If we were to maintain the current WWMC approach, skilled nursing and therapy costs would not be as evenly weighted and a certain level of complexity in calculating payments under the HH PPS would persist as we would need to continue with the current method of case-mix adjusting NRS payments separate from service costs (that is, skilled nursing, physical therapy, occupational therapy, speech-language pathology, home health aide, and medical social services) under the HH PPS.

In this proposed rule and to begin in CY 2020, we considered proposing a phase-out of the split percentage payment approach by reducing the percentage of the upfront payment over a period of time and requiring a notice of admission (NOA) to be submitted upon full elimination of the split-percentage payment. However, we wanted to take the opportunity in this year's rule to more clearly signal our intent to potentially eliminate the split percentage payment approach over time as a reduced timeframe for the unit of payment (30 days rather than 60 days) is now required in statute. Given that existing HHAs (certified with effective dates prior to January 1, 2019) would need to adapt to changes in cash flow with the elimination of the split percentage payment approach, we hope to receive additional feedback on the timeframes for a phase-out of the split percentage payment approach and whether there is a need for an NOA upon completion of a phase-out of the split percentage payment approach that we can take into consideration for potential future rulemaking.

2. HHVBP Model

An alternative to our proposal to remove the two vaccination measures beginning with PY 4 would be to continue to include them in the applicable measure set.

An alternative to our proposal to replace three OASIS-based measures with two proposed composite measures would be to make no changes to the OASIS-based measures category.

Another alternative to this proposal would be to finalize one but not both composite measures. All three of the ADL measures that would be replaced (Improvement in Bathing, Improvement in Bed Transferring, Improvement in Ambulation-Locomotion) relate to the normalized change in self-care measure, so, if only the self-care measure were adopted it would replace the three individual ADL items and count for 30 points. If only the mobility composite measure were adopted, however, it would count for 15 points and the three individual measures (which would not be dropped) would count for 5 points each. That would keep the relative points for the ADL measures at 30 no matter which option were adopted.

An alternative to rescoring the maximum improvement points from 10 points to 9 points would be to keep the current scoring methodology.

An alternative to reweighting the OASIS-based, claims-based and HHCAHPS measure categories would be to keep the current equally weighted methodology.

3. HH QRP

An alternative to removing seven measures from the HH QRP (Depression Assessment Conducted, Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care, Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537), Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in the Status of Surgical Wounds, Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505), Rehospitalization during the First 30 Days of HH (NQF #2380)), as discussed in section V.E. of this proposed rule would be to retain these measures in the HH QRP.

4. Home Infusion Therapy

a. Health and Safety Standards

We considered establishing additional requirements related to patient assessment, infection control and quality improvement. However, according to the home infusion therapy supplier industry, and our research, we believe there are already AO standards that include requirements related to 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 basic patient health and safety.

b. Payment

We did not consider alternatives to implementing the home infusion therapy benefit for CY 2019 and 2020 because section 1834(u)(7) of the Act requires the Secretary to provide a temporary transitional payment to eligible home infusion therapy suppliers for items and services associated with the furnishing of transitional home infusion drugs.

c. Accreditation of Qualified Home Infusion Therapy Suppliers

AOs that accredit home infusion therapy suppliers must become accredited by an AO designated by the Secretary. In these options, we have attempted to minimize the burden of accreditation on home infusion therapy suppliers, which include approving home infusion therapy AOs that consider the unique needs of small home infusion therapy suppliers. Also, it is likely that the surveys of home infusion therapy suppliers would be performed as a desk review instead of an onsite survey. Doing a desk audit survey would prevent the travel time and cost that is required when the AO has to send a survey team to the home infusion therapy supplier's location to perform an onsite survey.

F. Accounting Statement and Tables

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 69, we have prepared an accounting statement showing the classification of the transfers and costs associated with the CY 2019 HH PPS provisions of this rule. For CY 2020, due to the section 51001(a) of the BBA of 2018 requirement that the transition to the 30-day unit of payment be budget neutral, Table 70 displays a transfer of zero. Table 71 provides our best estimates of the changes to OASIS item collection as a result of the proposed implementation of the PDGM

and proposed changes to the HH QRP. Table 72 provides our best estimate of the increase in Medicare payments to home infusion therapy suppliers related to the temporary transitional payment for home infusion therapy in CY 2019. Table 73 provides our best estimate of cost of AO compliance with our proposed home infusion the Infusion Therapy requirements.

TABLE 69—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers.	$400 million.
From Whom to Whom?	Federal Government to HHAs.

TABLE 70—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS DUE TO THE PDGM PROPOSALS, FROM CY 2019 TO 2020 PDGM

Category	Transfers
Annualized Monetized Transfers.	$0 million.
From Whom to Whom?	HHAs to Federal Government.

TABLE 71—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS OF OASIS ITEM COLLECTION, FROM CY 2019 TO CY 2020

Category	Costs
Annualized Monetized Net Burden for HHAs' Submission of the OASIS.	−$60 million

TABLE 72—ACCOUNTING STATEMENT: TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSTION THERAPY CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers.	$60 million.
From Whom to Whom?	Federal Government to Home Infusion Therapy Suppliers.

TABLE 73—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS FOR HOME INFUSION THERAPY ACCREDITATION ORGANIZATIONS, FROM CY 2019 TO CY 2020

Category	Costs
Annualized Monetized Net Burden to Each Home Infusion Therapy AO for Compliance with the Proposed Regulations at §§ 488.1010 through 488.1050	$23,258.

G. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' Details on the estimated costs of this proposed rule, including limitations on the ability thus far to quantify some categories of impacts, can be found in the rule's economic analysis. The determination of this proposed rule's status as a regulatory or deregulatory action for the purposes of Executive Order 13771 will be informed by comments received in response to this proposed rulemaking.

H. Conclusion

1. HH PPS

a. HH PPS for CY 2019

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is an increase of 2.1 percent, or $400 million, in Medicare payments to HHAs for CY 2019. The $400 million increase reflects the effects of the CY 2019 home health payment update of 2.1 percent ($400 million increase), a 0.1 percent increase in payments due to decreasing the FDL ratio in order to target to pay no more than 2.5 percent of total payments as outlier payments ($20 million increase), and a −0.1 percent decrease in CY 2019 payments due to the new rural add-on policy mandated by the BBA of 2018 ($20 million decrease).

b. HH PPS for CY 2020 (PDGM)

In conclusion, we estimate that Medicare payments to HHAs for CY 2020 will remain the same compared to CY 2019 as a result of the implementation of the PDGM. Section 51001(a) of the BBA of 2018 requires the Secretary to implement the 30-day unit of payment in a budget-neutral manner.

2. OASIS Changes Related to the HH QRP and HH PPS (PDGM) for CY 2020

In conclusion, we estimate that the changes to OASIS item collection as a result of the proposed changes to the HH QRP and the proposed changes to the HH PPS (PDGM), both effective on and after January 1, 2020, would result in a net $60 million in annualized cost savings, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

3. HHVBP Model

In conclusion, we estimate there would be no net impact (to include either a net increase or reduction in payments) in this proposed rule in Medicare payments to HHAs competing in the HHVBP Model for CY 2019. However, the overall economic impact of the HHVBP Model is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model. We do not believe the changes proposed in this rule would affect the prior estimates.

4. Home Infusion Therapy

a. Health and Safety Standards

In summary, the proposed health and safety standards would not have any economic impact on home infusion therapy suppliers or accreditation organizations.

b. Payment

In conclusion, we estimate that the net impact of the temporary transitional payment to eligible home infusion suppliers for items and services associated with the furnishing of transitional home infusion drugs would result in approximately $60 million in additional Medicare payments to home infusion suppliers in CY 2019.

c. Accreditation of Qualified Home Infusion Therapy Suppliers

In summary, AOs that accredit HIT suppliers must become accredited by an AO designated by the Secretary. In these options, we have attempted to minimize the burden of accreditation on HIT suppliers, which include approving AOs that consider the unique needs of small HIT suppliers. Also, it is likely that the surveys of HIT suppliers will be performed as a desk review instead of an onsite survey. Doing a desk audit survey would prevent the travel time and cost that is required when the AO has to send a survey team to the HIT

supplier's location to perform an onsite survey.

This analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 409.43 [Amended]

■ 2. Section 409.43 is amended—
■ a. By removing paragraph (c)(2);
■ b. By resignating paragraphs (c)(3) and (4) as paragraphs (c)(2) and (3);
■ c. In newly redesignated paragraph (c)(2)(ii) by removing the phrase ''for services is submitted for the final percentage prospective payment'' and adding in its place the phrase ''(for episodes beginning on or before December 31, 2019) or 30-day period (for periods beginning on or after January 1, 2020) is submitted''; and
■ d. In paragraph (e)(1)(iii) by removing the phrase ''during the 60-day episode'' and adding in its place the phrase ''within 60 days''.
■ 3. Section 409.46 is amended by adding paragraph (e) to read as follows:

§ 409.46 Allowable administrative costs.

* * * * *

(e) *Remote patient monitoring.* Remote patient monitoring is defined as the collection of physiologic data (for example, ECG, blood pressure, or glucose monitoring) digitally stored and transmitted by the patient or caregiver or both to the home health agency. If remote patient monitoring is used by the home health agency to augment the care planning process, the costs of the equipment and service related to this system are allowable administrative costs.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 4. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. Section 424.22 is amended by revising paragraphs (b)(2) and (c) to read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(b) * * *

(2) *Content and basis of recertification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, if there is a continuing need for home health services, a physician must recertify the patient's continued eligibility for the home health benefit as outlined in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as set forth in paragraph (a)(1) of this section, and as specified in paragraphs (b)(2)(i) and (ii) of this section.

(i) Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy.

(ii) If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician must include a brief narrative describing the clinical justification of this need. If the narrative—

(A) Is part of the recertification form, then the narrative must be located immediately prior to the physician's signature.

(B) Exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately following the narrative in the addendum.

(c) *Determining patient eligibility for Medicare home health services.* (1) Documentation in the certifying physician's medical records or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) or both must be used as the basis for certification of the patient's eligibility for home health as described in paragraphs (a)(1) and (b) of this section. Documentation from the HHA may also be used to support-the basis for certification of home health eligibility, but only if the following requirements are met:

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

(ii)(A) 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.

(B) HHA documentation can include, but is not limited to, the patient's plan of care required under § 409.43 of this chapter and the initial or comprehensive assessment of the patient required under § 484.55 of this chapter.

(2) The documentation must be provided upon request to review entities or CMS or both. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment is not rendered for home health services provided.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 6. The authority citation for part 484 continues to read as follows:

Authority: Secs 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 7. Section 484.202 is amended by revising the definitions of ''Rural area'' and ''Urban area'' to read as follows:

§ 484.202 Definitions.

* * * * *

Rural area means an area defined in § 412.64(b)(1)(ii)(C) of this chapter.

Urban area means an area defined in § 412.64(b)(1)(ii)(A) and (B) of this chapter.

■ 8. Section 484.205 is revised to read as follows:

§ 484.205 Basis of payment.

(a) *Method of payment.* An HHA receives a national, standardized prospective payment amount for home health services previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national, standardized prospective payment is determined in accordance with § 484.215.

(b) *Unit of payment*—(1) *Episodes before December 31, 2019.* For episodes beginning on or before December 31, 2019, an HHA receives a unit of payment equal to a national, standardized prospective 60-day episode payment amount.

(2) *Periods on or after January 1, 2020.* For periods beginning on or after January 1, 2020, a HHA receives a unit of payment equal to a national, standardized prospective 30-day payment amount.

(c) *OASIS data.* A HHA must submit to CMS the OASIS data described at § 484.55(b) and (d) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484. 230, 484.235, and 484.240.

(d) *Payment adjustments.* The national, standardized prospective payment amount represents payment in full for all costs associated with furnishing home health services and is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in § 484.230.

(2) A partial payment adjustment as specified in § 484.235.

(3) An outlier payment as specified in § 484.240.

(e) *Medical review.* All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Medical necessity determinations.

(3) Case-mix group assignment.

(f) *Durable medical equipment (DME) and disposable devices.* DME provided as a home health service as defined in section 1861(m) of the Act is paid the fee schedule amount. Separate payment is made for ''furnishing NPWT using a disposable device,'' as that term is defined in § 484.202, and is not included in the national, standardized prospective payment.

(g) *Split percentage payments.* Normally, there are two payments (initial and final) paid for an HH PPS unit of payment. The initial payment is made in response to a request for anticipated payment (RAP) as described in paragraph (h) of this section, and the residual final payment is made in response to the submission of a final claim. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(1) *Split percentage payments for episodes beginning on or before December 31, 2019*—(i) *Initial and residual final payments for initial episodes on or before December 31, 2019.* (A) The initial payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage-adjusted 60-day episode rate.

(ii) *Initial and residual final payments for subsequent episodes before December 31, 2019.* (A) The initial payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(2) *Split percentage payments for periods beginning on or after January 1, 2020*—(i) *Initial and residual final payments for initial periods beginning on or after January 1, 2020.* (A) The initial payment for initial 30-day periods is paid to an HHA at 60 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for initial 30-day periods is paid at 40 percent of the case-mix and wage-adjusted 30-day payment rate.

(ii) *Initial and residual final payments for subsequent periods beginning on or after January 1, 2020.* (A) The initial payment for subsequent 30-day periods is paid to an HHA at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for subsequent 30-day periods is paid at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

(iii) *Split percentage payments on or after January 1, 2019.* Split percentage payments are not made to HHAs that are certified for participation in Medicare effective on or after January 1, 2019. An HHA that is certified for participation in Medicare effective on or after January 1, 2019 receives a single payment for a 30-day period of care after the final claim is submitted.

(h) *Requests for anticipated payment (RAP).* (1) HHAs that are certified for participation in Medicare effective by December 31, 2018 submit requests for anticipated payment (RAPs) to request the initial split percentage payment as specified in paragraph (g) of this section. HHAs that are certified for participation in Medicare effective on or after January 1, 2019 are still required to submit RAPs although no split percentage payments are made in response to these RAP submissions. The HHA can submit a RAP when all of the following conditions are met:

(i) After the OASIS assessment required at § 484.55(b)(1) and (d) is complete, locked or export ready, or there is an agency-wide internal policy establishing the OASIS data is finalized for transmission to the national assessment system.

(ii) Once a physician's verbal orders for home care have been received and documented as required at §§ 484.60(b) and 409.43(d) of this chapter.

(iii) A plan of care has been established and sent to the physician as required at § 409.43(c) of this chapter.

(iv) The first service visit under that plan has been delivered.

(2) A RAP is based on the physician signature requirements in § 409.43(c) of this chapter and is not a Medicare claim for purposes of the Act (although it is a ''claim'' for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the following:

(i) Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a(i)(2)).

(ii) The Civil False Claims Act (as defined in 31 U.S.C. 3729(c)).

(iii) The Criminal False Claims Act (18 U.S.C. 287)).

(iv) The RAP is canceled and recovered unless the claim is submitted within the greater of 60 days from the end date of the appropriate unit of payment, as defined in paragraph (b) of this section, or 60 days from the issuance of the RAP.

(3) CMS has the authority to reduce, disprove, or cancel a RAP in situations when protecting Medicare program integrity warrants this action.

§ 484.210 [Removed and Reserved]

■ 9. Section 484.210 is removed and reserved.

■ 10. Section 484.215 is amended—

■ a. By revising the section heading;

■ b. In paragraph (d) introductory text by removing the phrase ''CMS calculates the'' and adding in its place the phrase ''For episodes beginning on or before December 31, 2019, CMS calculates the''; and

■ c. By adding paragraph (f).

The revisions and addition reads as follows:

§ 484.215 Initial establishment of the calculation of the national, standardized prospective payment rates.

* * * * *

(f) *For periods beginning on or after January 1, 2020, a national, standardized prospective 30-day payment rate applies.* The national, standardized prospective 30-day payment rate is an amount determined by the Secretary, as subsequently adjusted in accordance with § 484.225.

■ 11. Section 484.220 is amended—

■ a. By revising the section heading and introductory text; and

■ b. In paragraph (a) introductory text by removing the phrase ''national prospective 60-day episode'' and adding in its place the phrase ''national, standardized prospective''.

The revisions read as follows:

§ 484.220 Calculation of the case-mix and wage area adjusted prospective payment rates.

CMS adjusts the national, standardized prospective payment rates as referenced in § 484.215 to account for the following:

* * * * *

■ 12. Section 484.225 is amended—

■ a. By revising the section heading and paragraph (a);

■ b. In paragraphs (b) and (c) by removing the phrase ''national prospective 60-day episode'' and adding in its place the phrase ''national, standardized prospective''; and

■ c. By adding paragraph (d).

The revisions and addition reads as follows:

§ 484.225 Annual update of the unadjusted national, standardized prospective payment rates.

(a) CMS annually updates the unadjusted national, standardized prospective payment rate on a calendar year basis (in accordance with section 1895(b)(1)(B) of the Act).

* * * * *

(d) For CY 2020, the national, standardized prospective 30-day payment amount is an amount determined by the Secretary. CMS annually updates this amount on a calendar year basis in accordance with paragraphs (a) through (c) of this section.

■ 13. Section 484.230 is revised to read as follows:

§ 484.230 Low-utilization payment adjustments.

(a) For episodes beginning on or before December 31, 2019, an episode with four or fewer visits is paid the national per-visit amount by discipline determined in accordance with § 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(1) The national per-visit amount is adjusted by the appropriate wage index based on the site of service of the beneficiary.

(2) An amount is added to the low-utilization payment adjustments for low-utilization episodes that occur as the beneficiary's only episode or initial episode in a sequence of adjacent episodes.

(3) For purposes of the home health PPS, a sequence of adjacent episodes for a beneficiary is a series of claims with no more than 60 days without home care between the end of one episode, which is the 60th day (except for episodes that have been PEP-adjusted), and the beginning of the next episode.

(b) For periods beginning on or after January 1, 2020, an HHA receives a national 30-day payment of a predetermined rate for home health services, unless CMS determines at the end of the 30-day period that the HHA furnished minimal services to a patient during the 30-day period.

(1) For each payment group used to case-mix adjust the 30-day payment rate, the 10th percentile value of total visits during a 30-day period of care is used to create payment group specific thresholds with a minimum threshold of at least 2 visits for each case-mix group.

(2) A 30-day period with a total number of visits less than the threshold is paid the national per-visit amount by discipline determined in accordance with § 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(3) The national per-visit amount is adjusted by the appropriate wage index based on the site of service for the beneficiary.

(c) An amount is added to low-utilization payment adjustments for low-utilization periods that occur as the beneficiary's only 30-day period or initial 30-day period in a sequence of adjacent periods of care. For purposes of the home health PPS, a sequence of adjacent periods of care for a beneficiary is a series of claims with no more than 60 days without home care between the end of one period, which is the 30th day (except for episodes that have been partial payment adjusted), and the beginning of the next episode.

■ 14. Section 484.235 is revised to read as follows:

§ 484.235 Partial payment adjustments.

(a) *Partial episode payments (PEPs) for episodes beginning on or before December 31, 2019.* (1) An HHA receives a national, standardized 60-day payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 60-day episode, warrants a new 60-day episode for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required.

(2) The PEP adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode.

(ii) The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 60-day payment and a new physician certification and a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The PEP is calculated by determining the actual days served as a proportion of 60 multiplied by the initial 60-day payment amount.

(b) *Partial payment adjustments for periods beginning on or after January 1, 2020.* (1) An HHA receives a national, standardized 30-day payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 30-day period, warrants a new 30-day period for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required.

(2) The partial payment adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on

behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 30-day period.

(ii) The common ownership exception to the transfer partial payment adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 30-day period before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 30-day payment and a new physician certification and a new plan of care, the initial HHA receives a partial payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The partial payment is calculated by determining the actual days served as a proportion of 30 multiplied by the initial 30-day payment amount.

■ 15. Section 484.240 is revised to read as follows:

§ 484.240 Outlier payments.

(a) For episodes beginning on or before December 31, 2019, an HHA receives an outlier payment for an episode whose estimated costs exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the episode payment amount for that group, or the PEP adjustment amount for the episode, plus a fixed dollar loss amount that is the same for all case-mix groups.

(b) For periods beginning on or after January 1, 2020, an HHA receives an outlier payment for a 30-day period whose estimated cost exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the 30-day payment amount for that group, or the partial payment adjustment amount for the 30-day period, plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of imputed cost beyond the threshold.

(d) CMS imputes the cost for each claim by multiplying the national per-15 minute unit amount of each discipline by the number of 15 minute units in the discipline and computing the total imputed cost for all disciplines.

■ 16. Section 484.250 is amended by revising paragraph (a)(1) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) Such OASIS data described at § 484.55(b) and (d) as is necessary for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240; and such OASIS data described at § 484.55(b) and (d) as is necessary to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

■ 17. Section 484.320 is amended by revising paragraph (c) to read as follows:

§ 484.320 Calculation of the Total Performance Score.

* * * * *

(c)(1) For performance years 1 through 3, CMS will sum all points awarded for each applicable measure excluding the New Measures, weighted equally at the individual measure level to calculate a value worth 90 percent of the Total Performance Score.

(2) 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 when all three measure categories are reported, to calculate a value worth 90 percent of the Total Performance Score.

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 18. The authority citation for part 486 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1395hh.

■ 19. Add reserved subpart H and subpart I to read as follows:

Subpart H—[Reserved]

Subpart I—Requirements for Home Infusion Therapy Suppliers

General Provisions

Sec.
486.500 Basis and Scope.
486.505 Definitions.

Standards for Home Infusion Therapy

486.520 Plan of care.
486.525 Required services.

Subpart I—Requirements for Home Infusion Therapy Suppliers

General Provisions

§ 486.500 Basis and scope.

Section 1861(s)(2)(iii) of the Act requires the Secretary to establish the conditions that home infusion therapy suppliers must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients.

§ 486.505 Definitions.

Applicable provider means a physician, a nurse provider, and a physician assistant.

Home means a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, CAH, or SNF as defined in section 1861(e)(1), 1861(mm)(1), or 1819(a)(1) of the Act, respectively.

Home infusion drug means a parental 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.

Infusion drug administration calendar day means the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

Qualified home infusion therapy supplier means 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.

(4) Meets such other requirements as the Secretary determines appropriate.

Standards for Home Infusion Therapy

§ 486.520 Plan of care.

The qualified home infusion therapy supplier ensures the following:

(a) All patients must be under the care of an applicable provider.

(b) All patients must have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished.

(c) The plan of care for each patient must be periodically reviewed by the physician.

§ 486.525 Required services.

The qualified home infusion therapy supplier must provide the following services on a 7-day-a-week, 24-hour-a-day basis in accordance with the plan of care:

(a) Professional services, including nursing services.

(b) Patient training and education not otherwise paid for as durable medical equipment as described in § 424.57(c)(12) of this chapter.

(c) Remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 20. The authority citation for part 488 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1395hh.

■ 21. Section 488.5 is amended—

■ a. By redesignating paragraphs (a)(7) through (21) as paragraphs (a)(8) through (22);

■ b. By adding a new paragraph (a)(7);

■ c. In newly redesignated paragraph (a)(18)(i) by removing the word ''and'' at the end of the paragraph;

■ d. In newly redesignated paragraph (a)(18)(ii) by removing the period and adding in its place ''; and''; and

■ e. By adding paragraph (a)(18)(iii).

The additions read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(7) A statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program specific CMS online trainings established for state surveyors, initially, and thereafter.

* * * * *

(18) * * *

(iii) Include a written statement that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

* * * * *

■ 22. Add reserved subpart K and subpart L to read as follows:

Subpart K—[Reserved]

Subpart L—Accreditation of Home Infusion Therapy Suppliers

General Provisions

Sec.

Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations

Subpart L—Accreditation of Home Infusion Therapy Suppliers

General Provisions

§ 488.1000 Basis and scope.

(a) Regulatory basis for home infusion therapy services. The home infusion therapy health and safety regulations are codified at part 486, subpart L, of this chapter.

(b) *Statutory basis for the accreditation of home infusion therapy suppliers.* (1) Sections 1102 and 1871 of the Act require that the Secretary prescribe such regulations as may be necessary to carry out the administration of the Medicare program.

(2) Section 1834(u)(5) of the Act require the Secretary to designate and approve independent organizations for the purposes of accrediting qualified home infusion therapy suppliers.

(c) *Scope.* This subpart sets forth the following:

(1) Application and reapplication procedures for national accrediting organizations seeking approval or re-approval of authority to accredit qualified home infusion therapy suppliers.

(2) Ongoing CMS oversight processes for approved accrediting organizations that accredit qualified home infusion therapy suppliers.

(3) Appeal procedures for accrediting organizations that accredit qualified home infusion therapy suppliers.

§ 488.1005 Definitions.

As used in this subpart—

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.

National accrediting organization means an organization that accredits provider or supplier entities under a specific program and whose accredited provider or supplier entities under each program are widely dispersed geographically across the United States. In addition, the specific program is active, fully implemented, and operational.

National in scope means a program is fully implemented, operational, and widely dispersed geographically throughout the country.

Qualified home infusion therapy supplier means 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.

(4) Meets such other requirements as the Secretary determines appropriate.

Reasonable assurance means an accrediting organization has demonstrated to CMS' satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

Rural 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 qualified home infusion therapy supplier's compliance with the applicable Medicare accreditation requirements.

Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations

§ 488.1010 Application and reapplication procedures for national accrediting organizations.

(a) *Information submitted with application.* A national home infusion therapy accrediting organization applying to CMS for approval or re-approval of a designated home infusion therapy accreditation program must furnish CMS with information and materials that demonstrate that its home infusion therapy accreditation program requirements meet or exceed the applicable Medicare requirements for accrediting organizations, including the following:

(1) Documentation that demonstrates the organization meets the definition of a national accrediting organization under § 488.1005 as it relates to the accreditation program.

(2) The Medicare provider or supplier type for which the organization is requesting approval or re-approval.

(3) Documentation that demonstrates the home infusion therapy accrediting organization's ability to take into account the capacities of rural home infusion therapy suppliers (as required by section 1834(u)(5)(A)(ii) of the Act).

(4) Information that demonstrates the home infusion therapy accrediting organization's knowledge, expertise, and experience in home infusion therapy.

(5) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare requirements, the exact language of the organization's comparable accreditation requirements and standards.

(6) A detailed description of the home infusion therapy accrediting organization's survey processes to confirm that a home infusion therapy supplier's processes are comparable to those of Medicare. This description must include all of the following:

(i) The types and frequency of surveys performed, and a rationale for which accreditation requirements will be evaluated via onsite surveys and which will be evaluated via offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements, including an explanation of how the accrediting organization will maintain the schedule it proposes.

(ii) Copies of the home infusion therapy accrediting organizations survey and audit forms, guidelines, and instructions to surveyors.

(iii) Documentation demonstrating that the home infusion therapy accrediting organization's onsite survey or offsite audit reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare home infusion therapy accreditation requirements, as applicable.

(iv) A description of the home infusion therapy accrediting organization's accreditation survey review process.

(v) A description of the home infusion therapy accrediting organization's procedures and timelines for notifying a surveyed or audited home infusion therapy supplier of non-compliance with the home infusion therapy accreditation program's standards.

(vi) A description of the home infusion therapy accrediting organization's procedures and timelines for monitoring the home infusion therapy supplier's correction of identified non-compliance with the accreditation program's standards.

(vii) The ability of the home infusion therapy accrediting organization to conduct timely reviews of accreditation applications.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the home infusion therapy accrediting organization agrees to provide CMS with information extracted from each home infusion therapy accreditation onsite survey, offsite audit or other evaluation strategies as part of its data submissions required under paragraph (a)(19) of this section, and, upon request from CMS, a copy of the most recent accreditation onsite survey, offsite audit, or other evaluation strategy together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the home infusion therapy accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 488.1005. Using the format specified by CMS, the home infusion therapy accrediting organization must notify CMS within 2 business days from the date the accrediting organization identifies the immediate jeopardy.

(7) Procedures to ensure that—

(i) Unannounced onsite surveys, as appropriate, will be conducted periodically, including procedures that protect against unannounced surveys becoming known to the provider or supplier in advance of the visit; or

(ii) Offsite survey audits are performed to evaluate the quality of services provided which may be followed up with periodic onsite visits.

(8) The criteria for determining the size and composition of the home infusion therapy accrediting organization's survey, audit and other evaluation strategy teams for individual supplier onsite surveys. The home infusion therapy accrediting organization's criteria should include, but not be limited to the following information:

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

(ii) The number of home infusion therapy suppliers to be surveyed using off-site audits.

(iii) A description of other types of home infusion therapy accreditation review activities to be used.

(iv) The reasons for each type of survey (that is, initial accreditation survey, reaccreditation survey, and complaint survey).

(9) The overall adequacy of the number of the home infusion therapy accrediting organization's surveyors, auditors, and other staff available to perform survey related activities, including how the organization will increase the size of the survey, audit, and other evaluation staff to match growth in the number of accredited facilities or programs while maintaining re-accreditation intervals for existing accredited facilities or programs.

(10) Detailed information about the individuals who perform onsite surveys, offsite audits or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements, including all of the following information:

(i) The number and types of professional and technical staff available for conducting onsite surveys, offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements.

(ii) The education, employment, and experience requirements surveyors and auditors must meet.

(iii) The content and length of the orientation program.

(11) The content, frequency and types of in-service training provided to survey and audit personnel.

(12) The evaluation systems used to monitor the performance of individual surveyors, auditors and survey teams.

(13) The home infusion therapy accrediting organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

(14) The policies and procedures used when a home infusion therapy supplier has a dispute regarding survey or audit findings, or an adverse decision.

(15) Procedures for the home infusion therapy supplier to use to notify the home infusion therapy accrediting organization when the accredited home infusion therapy supplier does the either of the following:

(i) Removes or ceases furnishing services for which they are accredited.

(ii) Adds services for which they are not accredited.

(16) The home infusion therapy accrediting organization's procedures for responding to, and investigating complaints against accredited facilities, including policies and procedures regarding referrals, when applicable, to appropriate licensing bodies, ombudsmen offices, and CMS.

(17) A description of the home infusion therapy accrediting organization's accreditation status decision-making process. The home infusion therapy accrediting organization must furnish the following:

(i) Its process for addressing deficiencies identified with accreditation program requirements, and the procedures used to monitor the correction of deficiencies identified during an accreditation survey and audit process.

(ii) 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.

(iii) Its policies and procedures for the granting, withholding or removal of accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements.

(iv) A statement acknowledging that the home infusion therapy accrediting organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, terminate, or revise the accreditation status of a home infusion therapy supplier, within 3 business days from the date the organization takes an action.

(18) A list of all currently accredited home infusion therapy suppliers, the type and category of accreditation, currently held by each, and the expiration date for each home infusion therapy supplier's current accreditation.

(19) A schedule of all survey activity (such as onsite surveys, offsite audits and other types if survey strategies) expected to be conducted by the organization during the 6-month period following submission of an initial or renewal application.

(20) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data.

(21) A description of the home infusion therapy accrediting organization's data management and analysis system with respect to its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the home infusion therapy accrediting organization uses its data to assure the compliance of its home infusion therapy accreditation program with the Medicare home infusion therapy accreditation program requirements.

(ii) A written statement acknowledging that the home infusion therapy accrediting organization agrees to submit timely, accurate, and complete data that CMS has determined is both necessary to evaluate the accrediting organization's performance and is not unduly burdensome for the accrediting organization to submit.

(A) The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(B) Data to be submitted includes the following:

(*1*) Accredited home infusion therapy supplier identifying information.

(*2*) Survey findings.

(*3*) Quality measures.

(*4*) Notices of accreditation decisions.

(22) The three most recent annual audited financial statements of the home infusion therapy accrediting organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys, audits, and related activities to maintain the accreditation program.

(23) A written statement acknowledging that, as a condition for approval, the home infusion therapy accrediting organization agrees to the following:

(i) *Voluntary termination.* Provide written notification to CMS and all home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program at least 90 calendar days in advance of the effective date of a decision by the home infusion therapy accrediting organization to voluntarily terminate its CMS-approved home infusion therapy accreditation program and the implications for the suppliers' payment status once their current term of accreditation expires in accordance with the requirements at § 488.1045(a).

(ii) *Involuntary termination.* Provide written notification to all accredited home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of its accreditation program and the implications for the home infusion therapy supplier's payment status in accordance with the requirements at § 488.1045(b) once their current term of accreditation expires.

(A) For both voluntary and involuntary terminations, provide a second written notification to all accredited home infusion therapy suppliers 10 calendar days prior to the organization's accreditation program effective date of termination.

(B) Notify CMS, in writing (electronically or hard copy), within 2 business days of a deficiency identified in any accredited home infusion therapy supplier from any source where the deficiency poses an immediate jeopardy to the home infusion therapy supplier's beneficiaries or a hazard to the general public.

(iii) Provide, on an annual basis, summary accreditation activity data and trends including the following:

(A) Deficiencies.

(B) Complaints.

(C) Terminations.

(D) Withdrawals.

(E) Denials.

(F) Accreditation decisions.

(G) Other survey-related activities as specified by CMS.

(iv) If CMS terminates a home infusion therapy accrediting organization's approved status, the home infusion therapy accrediting organization must work collaboratively with CMS to direct its accredited home infusion therapy suppliers to the remaining CMS-approved accrediting organizations within a reasonable period of time.

(v) Notify CMS at least 60 days in advance of the implementation date of any significant proposed changes in its CMS-approved home infusion therapy accreditation program and that it agrees not to implement the proposed changes

without prior written notice of continued program approval from CMS, except as provided for at § 488.1040(b)(2).

(vi) A statement acknowledging that, in response to a written notice from CMS to the home infusion therapy accrediting organization of a change in the applicable home infusion therapy accreditation requirements or survey process, the organization will provide CMS with proposed corresponding changes in the accrediting organization's home infusion therapy accreditation requirements for its CMS-approved home infusion therapy accreditation program to ensure that its accreditation standards continue to meet or exceed those of Medicare, or survey process remains comparable with that of Medicare. The home infusion therapy accrediting organization must comply with the following requirements:

(A) The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the home infusion therapy accrediting organization or by a date specified in the notice, whichever is later. CMS gives due consideration to a home infusion therapy accrediting organization's request for an extension of the deadline as long as it is submitted prior to the due date.

(B) The proposed changes are not to be implemented without prior written notice of continued program approval from CMS, except as provided for at § 488.1040(b)(2)(ii).

(24) The organization's proposed fees for accreditation, including any plans for reducing the burden and cost of accreditation to small and rural suppliers.

(b) *Additional information needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the home infusion therapy accrediting organization's initial application or re-application for CMS-approval of an accreditation program, CMS requires that the home infusion therapy accrediting organization submit any specific documentation requirements and attestations as a condition of approval of accreditation status. CMS notifies the home infusion therapy accrediting organization and afford it an opportunity to provide the additional information.

(c) *Withdrawing an application.* A home infusion therapy accrediting organization may withdraw its initial application for CMS' approval of its home infusion therapy accreditation program at any time before CMS publishes the final notice described in § 488.1025(b).

(d) *Notice of approval or disapproval of application.* CMS sends a notice of its decision to approve or disapprove the home infusion therapy accrediting organization's application within 210 calendar days from the date CMS determines the home infusion therapy accrediting organization's application is complete. The final notice specifies the following:

(1) The basis for the decision.

(2) The effective date.

(3) The term of the approval (not exceed 6 years).

§ 488.1015 Resubmitting a request for reapproval.

(a) Except as provided in paragraph (b) of this section, a home infusion therapy accrediting organization whose request for CMS's approval or re-approval of an accreditation program has been denied, or a home infusion therapy accrediting organization that has voluntarily withdrawn an initial application, may resubmit its application if the home infusion therapy accrediting organization satisfies all of the following requirements:

(1) Revises its home infusion therapy accreditation program to address the issues related to the denial of its previous request or its voluntary withdrawal.

(2) Resubmits the application in its entirety.

(b) If a home infusion therapy accrediting organization has requested, in accordance with § 488.1050, a reconsideration of CMS's disapproval, it may not submit a new application for approval of a home infusion therapy accreditation program until such reconsideration is administratively final.

§ 488.1020 Public notice and comment.

CMS publishes a notice in the **Federal Register** when the following conditions are met:

(a) *Proposed notice.* CMS publishes a notice after the receipt of a completed application from a national home infusion therapy accrediting organization seeking CMS's approval of a home infusion therapy accreditation program. The notice identifies the home infusion therapy accrediting organization, the type of suppliers covered by the home infusion therapy accreditation program, and provides at least a 30 day public comment period (beginning on the date of publication).

(b) *Final notice.* The final notice announces CMS decision to approve or deny a national accrediting organization application. The notice specifies the basis for the CMS decision.

(1) *Approval or re-approval.* If CMS approves or re-approves the home infusion therapy accrediting organization's home infusion therapy accreditation program, the final notice at a minimum includes the following information:

(i) A description of how the home infusion therapy accreditation program meets or exceeds Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of approval (no later than the publication date of the notice).

(iii) The term of the approval (6 years or less).

(2) *Denial.* If CMS does not approve the home infusion therapy accrediting organization's accreditation program, the final notice describes the following:

(i) How the home infusion therapy accrediting organization fails to meet Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of the decision.

§ 488.1025 Release and use of home infusion therapy accreditation surveys.

The home infusion therapy accrediting organization must include, in its accreditation agreement with each supplier, an acknowledgement that the 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, corrective action plans.

(a) 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.

(b) With the exception of home health agency surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

§ 488.1030 Ongoing review of home infusion therapy accrediting organizations.

(a) *Performance review.* CMS evaluates the performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis. This review includes the review of the following:

(1) The home infusion therapy accrediting organization's survey activity.

(2) The home infusion therapy accrediting organization's continued

fulfillment of the requirements at §§ 488.1010 and 488.1035.

(b) *Comparability review.* CMS assesses the equivalency of a home infusion therapy accrediting organization's CMS-approved program requirements with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare accreditation requirements. When this occurs, the following takes place:

(1) CMS provides the home infusion therapy accrediting organizations with written notice of the changes to the to the Medicare home infusion therapy accreditation requirements.

(2) The home infusion therapy accrediting organization must make revisions to its home infusion therapy accreditation standards or survey processes which incorporate the new or revised Medicare accreditation requirements.

(3) In the written notice, CMS specifies the deadline (no less than 30 calendar days) by which the home infusion therapy accrediting organization must submit its proposed revised home infusion therapy accreditation standard or survey process revisions, and the timeframe(s) for implementation of these revised home infusion therapy accreditation standards.

(4) CMS may extend the submission deadline by which the accrediting organization must submit its proposed revised home infusion therapy accreditation standards and survey processes, if both of the following occur:

(i) The accrediting organization submits a written request for an extension of the submission deadline.

(ii) The request for extension is submitted prior to the original submission deadline.

(5) After completing the comparability review of the home infusion therapy accrediting organizations revised home infusion therapy accreditation standards and survey processes, CMS shall provide written notification to the home infusion therapy accrediting organization regarding whether or not its home infusion therapy accreditation program, including the proposed revised home infusion therapy accreditation standards and implementation timeframe(s), continues to meet or exceed all applicable Medicare requirements.

(6) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide the written notice to the home infusion therapy accrediting organization required, then the revised home infusion therapy accreditation standards and program is deemed to meet or exceed all applicable Medicare requirements and to have continued CMS-approval.

(7) If a home infusion therapy accrediting organization is required to submit a new application because CMS imposes new home infusion therapy regulations or makes significant substantive revisions to the existing home infusion therapy regulations, CMS provides notice of the decision to approve or disapprove the new application submitted by the home infusion therapy accrediting organization within the time period specified in § 488.1010(d).

(8) If a home infusion therapy accrediting organization fails to submit its proposed changes to its home infusion therapy accreditation standards and survey processes within the required timeframe, or fails to implement the proposed changes that have been determined or deemed by CMS to be comparable, CMS may open an accreditation program review in accordance with paragraph (d) of this section.

(c) *Review of revised home infusion therapy accreditation standards submitted to CMS by an accrediting organization.* When a home infusion therapy accrediting organization proposes to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy accrediting organization must do the following:

(1) Provide CMS with written notice of any proposed changes in home infusion therapy accreditation standards, requirements or survey process at least 60 days prior to the proposed implementation date of the proposed changes.

(2) Not implement any of the proposed changes before receiving CMS's approval, except as provided in paragraph (c)(4) of this section.

(3) Provide written notice to CMS that includes all of the following:

(i) A detailed description of the changes that are to be made to the organization's home infusion therapy accreditation standards, requirements and survey processes.

(ii) A detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each.

(4) CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of receipt of the home infusion therapy accrediting organization's proposed changes. If CMS has made a finding that the home infusion therapy accrediting organization's home infusion therapy accreditation program, accreditation requirements and survey processes, including the proposed revisions does not continue to meet or exceed all applicable Medicare home infusion therapy requirements. CMS must state the reasons for these findings.

(5) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide written notice to the home infusion therapy accrediting organization that the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements, then the revised home infusion therapy accreditation program is deemed to meet or exceed all applicable Medicare home infusion therapy requirements and to have continued CMS approval.

(6) If a home infusion therapy accrediting organization implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with paragraph (d) of this section.

(d) *CMS-approved home infusion therapy accreditation program review.* If a comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program with the requirements of this subpart, CMS may initiate a home infusion therapy accreditation program review.

(1) If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy accrediting organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice will provide all of 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 accrediting organization 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 home infusion therapy accreditation program review.

(iv) The actions the home infusion therapy accrediting organization must take to address the identified deficiencies

(v) The length of the accreditation program review probation period, which will include monitoring of the home infusion therapy accrediting organization's performance and implementation of the corrective action plan. The probation period is not to exceed 180 calendar days from the date that CMS approves the AOs corrective action plan.

(2) CMS will review and approve the home infusion therapy accrediting organization's plan of correction for acceptability within 30 days after receipt.

(3) CMS will monitor the AO's performance and implementation of the plan of correction during the probation period which is not to exceed 180 days from the date of approval of the plan of correction.

(4) If CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the 180-day probation period described in paragraph (d)(1)(v) of this section to implement additional corrective actions or demonstrate sustained compliance, not to exceed the home infusion therapy accrediting organization's current term of approval. In the case of a renewal application where CMS has already placed the home infusion therapy accreditation program on probation, CMS indicates that any approval of the application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the home infusion therapy accrediting organization as to whether or not its CMS-approved home infusion therapy accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS determines that the home infusion therapy accrediting organization does not meet the requirements, CMS may withdraw approval of the CMS-approved home infusion therapy accreditation program. The notice of determination provided to the home infusion therapy accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (d)(4)(iii) of this section.

(iii) CMS publishes in the **Federal Register** a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the reasons for the withdrawal, effective 60 calendar days after the date of publication of the notice.

(e) *Immediate jeopardy.* If at any time CMS determines that the continued approval of a CMS-approved home infusion therapy accreditation program of any home infusion therapy accrediting organization poses an immediate jeopardy to the patients of the suppliers accredited under the program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved home infusion therapy accreditation program of that home infusion therapy accrediting organization and publish a notice of the removal, including the reasons for it, in the **Federal Register**.

(f) *Notification to home infusion therapy suppliers of withdrawal of CMS approval status.* A home infusion therapy accrediting organization whose CMS approval of its home infusion therapy accreditation program has been withdrawn must notify each of its accredited home infusion therapy suppliers, in writing, of the withdrawal of CMS approval status no later than 30 calendar days after the notice is published in the **Federal Register**. The notification to the accredited home infusion therapy suppliers must inform them of the implications for their payment status once their current term of accreditation expires.

§ 488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization.

A home infusion therapy accreditation organization approved by CMS must carry out the following activities on an ongoing basis:

(a) Provide CMS with all of the following in written format (either electronic or hard copy):

(1) 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).

(2) Notice of all accreditation decisions.

(3) Notice of all complaints related to providers or suppliers.

(4) 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.

(5) The home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(6) Notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process. If the home infusion therapy accrediting organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accrediting organization.

(b) Within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(c) The home infusion therapy accrediting organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(d) 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 accrediting organization must provide CMS with written notice of the deficiency and any adverse action implemented by the accrediting organization.

(e) Within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy accrediting organization that CMS intends to withdraw approval of the home infusion therapy accrediting organization, the home infusion therapy accrediting organization must provide written notice of the withdrawal to all of the home infusion therapy accrediting organization's accredited suppliers.

§ 488.1040 Onsite observations of home infusion therapy accrediting organization operations.

(a) As part of the application review process, the ongoing review process, or the continuing oversight of a home infusion therapy accrediting organization's performance, CMS may conduct onsite inspections of the home infusion therapy accrediting organization's operations and offices at any time to verify the home infusion therapy accrediting organization's representations and to assess the home infusion therapy accrediting organization's compliance with its own policies and procedures.

(b) Activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following:

(1) Interviews with various accrediting organization staff.

(2) Review of documents, survey files, audit tools, and related records.

(3) Observation of meetings concerning the home infusion therapy accreditation process.

(4) Auditing meetings concerning the accreditation process.

(5) Observation of in-progress surveys and audits.

(6) Evaluation of the accrediting organization's survey results and accreditation decision-making process.

§ 488.1045 Voluntary and involuntary termination.

(a) *Voluntary termination by a CMS-approved accrediting program.* In accordance with § 488.1010(a)(23), a home infusion therapy accrediting organization that decides to voluntarily terminate its CMS-approved home infusion therapy accreditation program must provide written notice at least 90 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

(b) *Involuntary termination of an accrediting organization's approval by CMS.* Once CMS publishes the notice in the **Federal Register** announcing its decision terminate the home infusion therapy accrediting organization's home infusion therapy accreditation program, the home infusion therapy accrediting organization must provide written notification to all suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of its home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in accordance with the requirements at § 488.1010(f) once their current term of accreditation expires.

(c) *Voluntary and involuntary terminations.* For both voluntary and involuntary terminations—

(1) The accreditation status of affected home infusion therapy suppliers is considered to remain in effect until their current term of accreditation expires;

(2) If the home infusion therapy supplier wishes to avoid a suspension of payment, it must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date that it has submitted an application for home infusion therapy accreditation under another CMS-approved home infusion therapy accreditation program. Failure to comply with this 60-calendar day requirement prior to expiration of their current home infusion therapy accreditation stations within could result in a suspension of payment; and

(3) The home infusion therapy accrediting organization provides a second written notification to all accredited home infusion therapy suppliers ten calendar days prior to the organization's accreditation program effective date of termination.

(d) *Voluntary withdrawal from accreditation requested by a home infusion therapy supplier.* If a voluntary withdrawal from accreditation is requested by the home infusion therapy supplier, the withdrawal may not become effective until the accrediting organization completes all of the following steps:

(1) The accrediting organization must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program.

(2) The home infusion therapy accrediting organization must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status.

(3) The home infusion therapy accrediting organization must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to CMS by 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

§ 488.1050 Reconsideration.

(a) *General rule.* A home infusion therapy accrediting organization dissatisfied with a determination that its home infusion therapy accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy accrediting organization meet the applicable quality standards is entitled to reconsideration.

(b) *Filing requirements.* (1) A written request for reconsideration must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(2) The written request for reconsideration must specify the findings or issues with which the home infusion therapy accrediting organization disagrees and the reasons for the disagreement.

(3) A requestor may withdraw its written request for reconsideration at any time before the issuance of a reconsideration determination.

(c) *CMS response to a request for reconsideration.* In response to a request for reconsideration, CMS provides the accrediting organization with—

(1) The opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accrediting organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(2) Written notice of the time and place of the hearing at least 10 business days before the scheduled date.

(d) *Hearing requirements and rules.* (1) The reconsideration hearing is a public hearing open to all of the following:

(i) Authorized representatives and staff from CMS, including, but not limited to, the following:

(A) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(B) Legal counsel.

(C) Non-technical witnesses with personal knowledge of the facts of the case.

(ii) Representatives from the accrediting organization requesting the reconsideration including, but not limited to, the following:

(A) Authorized representatives and staff from the accrediting organization.

(B) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(C) Legal counsel.

(D) Non-technical witnesses, such as patients and family members that have personal knowledge of the facts of the case.

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(3) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(4) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(5) Within 45 calendar days after the close of the hearing, the hearing officer will present the findings and recommendations to the accrediting organization that requested the reconsideration.

(6) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(7) The hearing officer's decision is final.

Dated: June 25, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: June 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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