DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS–1689–FC]

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: Final rule with comment period.

SUMMARY: This final rule with comment period updates 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. This rule also: Updates 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; finalizes a rebasing of the HH market basket (which includes a decrease in the labor-related share); finalizes 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 (Pub. L. 115–123) hereinafter referred to as the ''BBA of 2018''; finalizes regulations text changes regarding certifying and recertifying patient eligibility for Medicare home health services; and finalizes the definition of ''remote patient monitoring'' and the recognition of the costs associated with it as allowable administrative costs.

This rule also summarizes the case-mix methodology refinements for home health services beginning on or after January 1, 2020, which includes the elimination of therapy thresholds for payment and a change in the unit of payment from a 60-day episode to a 30-day period, as mandated by section 51001 of the Bipartisan Budget Act of 2018. This rule also finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model. In addition, with respect to the Home Health Quality Reporting Program, this rule discusses the Meaningful Measures Initiative; finalizes the removal of seven measures to further the priorities of this initiative; discusses social risk factors and provides an update on implementation efforts for certain provisions of the IMPACT Act; and finalizes a regulatory text change regarding OASIS data.

For the home infusion therapy benefit, this rule finalizes health and safety standards that home infusion therapy suppliers must meet; finalizes an approval and oversight process for accrediting organizations (AOs) that accredit home infusion therapy suppliers; finalizes the implementation of temporary transitional payments for home infusion therapy services for CYs 2019 and 2020; and responds to the comments received regarding payment for home infusion therapy services for CY 2021 and subsequent years.

Lastly, in this rule, we are finalizing only one of the two new requirements we proposed to implement in the regulations for the oversight of AOs that accredit Medicare-certified providers and suppliers. More specifically, for reasons set out more fully in the section X. of this final rule with comment period, we have decided not to finalize our proposal to require that all surveyors for AOs that accredit Medicare-certified providers and suppliers take the same relevant and program-specific CMS online surveyor training that the State Agency surveyors are required to take.

However, we are finalizing our proposal to require that each AO must provide a written statement with their application to CMS, stating that if one of its fully accredited providers or suppliers, 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 provider or supplier'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.

DATES:

Effective Date: This final rule with comment period is effective on January 1, 2019.

Implementation Date: The Patient-Driven Groupings Model (PDGM) case-mix methodology refinements and the change in the unit of payment from 60-day episodes of care to 30-day periods of care will be for home health services (30-day periods of care) beginning on or after January 1, 2020.

Comment Date: To be assured consideration, comments on the definition of ''infusion drug administration calendar day'' at § 486.505 and discussed in section VI.D. of this final rule with comment period must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1689–FC. 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–FC, 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–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850. [*Note:* This zipcode for express mail or courier delivery only. This zipcode specifies the agency's physical location.]

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: CAPT Jacqueline Leach, (410) 786–4282 or Sonia Swancy, (410) 786–8445.

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://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 final rule with comment period updates 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 rule also updates the case-mix weights under sections 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 finalizes case-mix methodology refinements, which eliminate the use of therapy thresholds for case-mix adjustment purposes; and changes 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 (hereinafter referred to as the ''BBA of 2018''). This final rule with comment period also: Finalizes the methodology used to determine rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the BBA of 2018; finalizes 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 finalizes our proposal on how to define ''remote patient monitoring'' under the Medicare home health benefit and include the costs of such monitoring as an allowable administrative costs. Lastly, this rule finalizes 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

a. Payment for Home Infusion Therapy Services

This final rule with comment period establishes 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 finalizes health and safety standards for home infusion therapy and an accreditation and oversight process for qualified home infusion therapy suppliers.

b. Safety Standards for Home Infusion Therapy Services

This final rule with comment period implements health and safety standards for qualified home infusion therapy suppliers as required by section 5012 of the 21st Century Cures Act. These standards provide 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.

c. Accreditation of Home Infusion Therapy Suppliers

This final rule with comment period also implements regulations for the approval and oversight of AOs that accredit home infusion therapy suppliers.

B. Summary of the Major Provisions

1. Home Health Prospective Payment System (HH PPS)

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. of this rule, we are finalizing the rebasing of the home health market basket and updates to the payment rates under the HH PPS by the home health payment update percentage of 2.2 percent (using the 2016-based Home Health Agency (HHA) market basket update of 3.0 percent, minus 0.8 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 final rule with comment period, we are finalizing a reduction in 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 update the CY 2019 home health wage index using FY 2015 hospital cost report data. In section III.D. of this final rule with comment period, we are finalizing a 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 finalizing a reduction to 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 section III.F. of this rule, we are finalizing 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 effective January 1, 2020 and in a budget neutral manner, as required by section 51001 of the BBA of 2018. The ''Patient-Driven Groupings Model'', or 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.

In section III.G. of this rule, we are finalizing 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 finalizing a proposal to align the regulations text at § 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 rule, we are finalizing our proposal to define ''remote patient monitoring'' under the Medicare home health benefit and changes to the regulations at § 409.46 to include costs of remote patient monitoring as allowable administrative costs.

2. Home Health Value Based Purchasing

In section IV. of this final rule with comment period, we are finalizing changes to the Home Health Value Based Purchasing (HHVBP) Model implemented January 1, 2016. Specifically, we are finalizing, beginning with performance year (PY) 4, the following policy changes: removal of 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; replacement of three OASIS-based measures (Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing) with two new composite measures on total normalized composite change in self-care and mobility; changes to how we calculate the Total Performance Scores by changing the weighting methodology for the OASIS-based, claims-based, and HHCAHPS measures; and a change to the scoring methodology by reducing the maximum amount of improvement points an HHA can earn, from 10 points to 9 points. We are also providing an update on the progress towards developing public reporting of performance under the HHVBP Model and providing a summary of public comments received in response to our solicitation of feedback on what information we should consider making publicly available in the future.

3. Home Health Quality Reporting Program

In section V. of this final rule with comment period, we are finalizing updates to our the Home Health (HH) Quality Reporting Program (QRP) by adopting eight measure removal factors, removing seven measures, and updating our regulations to clarify that not all OASIS data are required for the HH QRP. We are also providing an update on the implementation of certain provisions of the IMPACT Act, and are finalizing our proposal 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 final rule with comment period, we discuss general background of home infusion therapy services and how this relates to the implementation of the new home infusion benefit. In section VI.B. of this final rule with comment period, we have finalized the addition of a new subpart I under the regulations at 42 CFR part 486 to incorporate health and safety requirements for home infusion therapy suppliers. These regulations provide a framework for CMS to approve home infusion therapy accreditation organizations. Subpart I includes General Provisions (Scope and Purpose, and Definitions) and Standards for Home Infusion Therapy (Plan of Care and Required Services). Section VI.D. of this final rule with comment period 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, and responds to the comments received regarding issues such as the regulatory definition of ''Infusion Drug Administration Calendar Day.''

In section VI.C. of this final rule with comment period, 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 not later than January 1, 2021. Qualified home infusion therapy suppliers are required to receive accreditation before receiving Medicare payment for services provided to Medicare beneficiaries.

Until now, no regulations have addressed 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. However, this final rule with comment period finalizes a set of regulations that will govern the CMS approval and oversight process for all home infusion therapy AOs.

In this final rule with comment period, we are not finalizing our proposal to modify 42 CFR 488.5 by adding a requirement that all surveyors, that work for AOs that accredit Medicare certified providers and suppliers, must complete the relevant program specific CMS online trainings.

However, in this final rule with comment period, we are finalizing the proposed requirement to be added at § 488.5 which requires the AOs for Medicare certified providers and suppliers to provide a written statement with their application stating that if a fully accredited 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

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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 $420 million (2.2 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 ($48 million in Medicare payments and $12 million in beneficiary cost-sharing).	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 for CY 2018 through 2022 is an estimated $378 million in total savings to Medicare 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 in this final rule with comment period). 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 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.

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 8 home infusion therapy AOs will be $64,116. 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 8 home infusion therapy AOs will be $99,624. We further estimate that each home infusion therapy AO will incur an estimated cost burden in the amount of $23,258 for compliance with the home infusion therapy AO approval and oversight regulations at §§488.1010 through 488.1050 (including the filing of an application). The cost across the 8 potential home infusion therapy AOs will be $186,064.		Accreditation of HIT suppliers will be required in order for HIT suppliers to receive payment from Medicare, effective 01/01/2021. The CMS AO approval and oversight regulations are necessary so that CMS has a process in place for the approval and oversight of the AOs that will be CMS-approved home infusion therapy accrediting organizations available to accredit the home infusion therapy suppliers, so that they can continue to receive payment from Medicare when the permanent benefits go into effect on 01/01/2021.

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D. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

In the CY 2019 HH PPS proposed rule, we stated that 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

[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.*

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, stated in the proposed rule that we had 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.
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 stated our belief 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 also stated the 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. Section 50208(a)(1) of the BBA of 2018 again extended the 3 percent 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 later in this final rule with comment period.

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 multidrug 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, 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.

III. Provisions of the Proposed Rule: Payment Under the Home Health Prospective Payment System (HH PPS) and Responses to Comments

In the July 12, 2018 **Federal Register** (83 FR 32340 through 32522), we published the proposed rule titled ''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''. We received approximately 1,125 timely comments from the public, including comments from home health agencies, home infusion therapy providers, DME suppliers, manufacturers of remote patient monitoring technology, national and state provider associations, patient and other advocacy organizations, physicians, nurses, therapists, pharmacists, and accrediting organizations. In the following sections, we summarize the proposed provisions and the public comments, and provide the responses to comments.

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

In the CY 2019 proposed rule (83 FR 32348), we provided a summary of analysis on fiscal (FY) 2016 HHA cost report data and how such data, if used, would impact our estimate of the percentage difference between Medicare payments and HHA costs. In addition, we presented information on Medicare home health utilization statistics and trends that included HHA claims data through CY 2017. We will continue monitoring the impacts due to the rebasing adjustments and other policy changes and will provide the industry with periodic updates on our analysis in rulemaking and/or announcements on the HHA Center web page at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.*

B. 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 2019, we will use the same methodology finalized in the CY 2008

[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.

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

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 final CY 2019 HH PPS case-mix weights, we used CY 2017 home health claims data (as of June 30, 2018) with linked OASIS data. These data are the most current and complete data available at this time. We noted in the proposed rule that we would 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 for this final rule with comment period. The process we used to calculate the HH PPS case-mix weights is outlined in this section.

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 3. 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 3: CY 2019 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	.	3	.	3
5	Other Diagnosis = Diabetes	1	.	.	.
6	Primary or Other Diagnosis = Dysphagia AND Primary or Other Diagnosis = Neuro 3 – Stroke	2	14	.	10
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	.	3
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	4	1	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	.	4	.	4
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 OR M1860 (Ambulation) = 4 or more	2	6	3	8
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)	1	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	.	.	.	1
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	15	6	15
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	2	15	8	15
29	Primary or Other Diagnosis = Tracheostomy	1	10	.	10
30	Primary or Other Diagnosis = Urostomy/Cystostomy	.	17	.	9
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	.	10	1	10
32	M1030 (Therapy at home) = 3 (Enteral)	.	12	.	6
33	M1200 (Vision) = 1 or more	1	.	.	.
34	M1242 (Pain)= 3 or 4	3	.	2	1
35	M1311 = Two or more pressure ulcers at stage 3 or 4	2	4	2	4
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	4	17	6	16
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	6	27	8	23
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	5	12
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	.	3	.	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	6

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 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 final CY 2019 four-equation model resulted in 119 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 9 variables that were added to the model due to the presence of additional resources associated with those variables and 9 variables that were dropped from the model due to the absence of additional resources associated with those variables. 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 7 variables increased in the CY 2019 four-equation model and the points for 68 variables decreased in the CY 2019 4-equation model. There were 35 variables with the same point values.

Step 2: Redefining 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.

Then, we 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.[5]

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 final CY 2019 four-equation model points are shown in Table 4.

[5] For Step 1, 33.7 percent 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 percent of episodes were in the low functional level (Most with score 0). For Step 3, 46.6 percent of episodes were in the medium functional level (Most with score 9). For Step 4, 33.2 percent of episodes were in the medium functional level (Most with score 6).

TABLE 4: 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 5 shows the regression coefficients for the variables in the payment regression model updated with CY 2017 home health claims data. The R-squared value for the final CY 2019 payment regression model is 0.5429 (an increase from 0.5095 for the CY 2018 recalibration).

TABLE 5: CY 2019 PAYMENT REGRESSION MODEL

	Payment Regression from 4-Equation Model for CY 2019
Step 1, Clinical Score Medium	$20.57
Step 1, Clinical Score High	$56.45
Step 1, Functional Score Medium	$68.66
Step 1, Functional Score High	$96.85
Step 2.1, Clinical Score Medium	$52.45
Step 2.1, Clinical Score High	$126.15
Step 2.1, Functional Score Medium	$20.24
Step 2.1, Functional Score High	$31.91
Step 2.2, Clinical Score Medium	$51.44
Step 2.2, Clinical Score High	$180.61
Step 2.2, Functional Score Medium	$47.44
Step 2.2, Functional Score High	$0.00
Step 3, Clinical Score Medium	$16.38
Step 3, Clinical Score High	$85.55
Step 3, Functional Score Medium	$56.26
Step 3, Functional Score High	$81.57
Step 4, Clinical Score Medium	$70.36
Step 4, Clinical Score High	$246.36
Step 4, Functional Score Medium	$32.71
Step 4, Functional Score High	$38.77
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	$505.27
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	$497.02
Step 3, 3rd+ Episodes, 0-13 Therapy Visits	-$53.16
Step 4, All Episodes, 20+ Therapy Visits	$851.24
Intercept	$373.81

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 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 concerns that the HH PPS over-values therapy episodes and undervalues non-therapy episodes and to better align the case-mix weights with episode costs estimated from cost report data.[6]

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).

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

Step 7: The interpolated weights are then adjusted so that the average case-mix for the weights is equal to 1.0000.[7] This last step creates the CY 2019 case-mix weights shown in Table 6.

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TABLE 6: CY 2019 CASE-MIX PAYMENT WEIGHTS

Pay Group	Description	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2019 Weight
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5468
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.6791
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8115
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9438
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0761
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2085
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3526
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.4968
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.6473
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.7651
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8829
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0007
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1185
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2363
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.3858
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5352
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6885
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8013
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9140
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.0268
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1396
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2523
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.3992
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.5460
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.5769
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7176
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8584
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	0.9991
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1398
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2806
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4321
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.5836
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.6773
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8035
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9298
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0560
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1822
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3084

[7] 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.

Pay Group	Description	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2019 Weight
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4653
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6221
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.7186
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.8397
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9609
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.0821
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2033
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3244
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.4787
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.6329
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6294
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.7799
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9304
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.0809
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2314
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.3819
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.5782
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.7746
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7298
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.8658
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0018
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.1378
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.2737
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4097
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6114
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8130
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7711
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9020
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0329
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.1639
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.2948
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.4258
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.6248
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	1.8238
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4691
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6147
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7603
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9059
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0515
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.1971
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3451
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.4930
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.6409
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5514
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.6936
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8358
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9780

Pay Group	Description	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2019 Weight
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1202
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2624
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4031
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5439
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.6847
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.5884
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7232
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.8580
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	0.9928
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1276
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2624
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4058
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.5493
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.6928
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4930
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6480
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8030
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	0.9579
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1129
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2679
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4236
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.5794
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.7352
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5753
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7269
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8784
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0300
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1815
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3331
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4817
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6303
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.7790
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6123
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7565
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9006
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.0448
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.1889
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3331
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.4844
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.6357
40231	All Episodes, 20+ Therapy Visits	C2F3S1	1.7871
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.5942
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.7644
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9347
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1049
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2752
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4454

Pay Group	Description	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2019 Weight
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6206
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.7957
40311	All Episodes, 20+ Therapy Visits	C3F1S1	1.9709
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.6765
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8433
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0102
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.1770
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3438
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5106
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6787
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8467
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.0147
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7135
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.8729
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0324
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.1918
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.3512
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5106
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.6814
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	1.8521
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.0228

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 CY 2019 national, standardized 60-day episode payment rate (see section III.C.3. of this final rule with comment period). 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 1.0169.

The following is a summary of the comments received and our responses to comments on the CY 2019 HH PPS case-mix weights.

Comment: Some commenters believe that CMS should not recalibrate the case-mix weights for CY 2019 because annual changes are too frequent. Other commenters indicated that CMS should provide more detail on how the recalibration works and why the model is recalibrated every year.

Response: As stated in the CY 2019 HH PPS proposed rule (83 FR 32340), the methodology used to recalibrate the weights is identical to the methodology used in the CY 2012 recalibration except for the minor exceptions as noted in the CY 2015 HH PPS proposed and final rules (79 FR 38366 and 79 FR 66032, respectively). In the CY 2015 HH PPS final rule, we finalized annual recalibration and the methodology to be used for each year's recalibration (79 FR 66072). As stated in the CY 2019 HH PPS proposed rule (83 FR 32353), 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. For more detail, we also encourage commenters to refer to the CY 2012 HH PPS proposed and final rules (76 FR 40988 and 76 FR 68526, respectively) and the November 1, 2011 ''Revision of the Case-Mix Weights for the HH PPS Report'' on our home page at: *https://www.cms.gov/center/provider-Type/home-Health-AgencyHHA-Center.html* for additional information about the recalibration methodology. We note that in comparing the final CY 2019 HH PPS case-mix weights (see Table 6) to the final CY 2018 HH PPS case-mix weights (82 FR 51676), the case-mix weights change very little, with most case-mix weights either increasing or decreasing by 1 to 2 percent with no case-mix weights increasing by more than 3 percent or decreasing by more than 3 percent. Aggregate increases or decreases in the case-mix weights are offset by the case-mix budget neutrality factor, which is applied to the national, standardized 60-day episode payment rate. In other words, although the case-mix weights themselves may increase or decrease from year-to-year, we correspondingly offset any estimated increases or decreases in total payments under the HH PPS, as a result of the case-mix recalibration, by applying a budget neutrality factor to the national, standardized 60-day episode payment rate. For CY 2019, the case-mix budget neutrality factor will be 1.0169 as described previously. The recalibration of the case-mix weights is not intended to increase or decrease overall HH PPS payments, but rather is used to update the relative differences in resource use amongst the 153 groups in the HH PPS case-mix system to reflect current practice patterns.

Comment: Another commenter suggested that CMS should adjust for any nominal case-mix changes observed between 2015 and 2017.

Response: We will continue to monitor real and nominal case-mix growth and may propose additional

reductions for nominal case-mix growth, as needed, in the future.

Final Decision: We are finalizing the recalibrated scores for the case-mix adjustment variables, clinical and functional thresholds, payment regression model, and case-mix weights in Tables 3 through 6. For this final rule with comment period, the CY 2019 scores for the case-mix variables, the clinical and functional thresholds, and the case-mix weights were developed using complete CY 2017 claims data as of June 30, 2018. We note that we finalized the recalibration methodology and the proposal to annually recalibrate the HH PPS case-mix weights in the CY 2015 HH PPS final rule (79 FR 66072). No additional proposals were made with regards to the recalibration methodology in the CY 2019 HH PPS proposed rule.

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 and 10451), the notice with comment period published in the February 14, 1995 **Federal Register** (60 FR 8389 through 8392), and the notice with comment period published in the July 1, 1996 **Federal Register** (61 FR 34344 through 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 final rule with comment period, we are using 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.

Comment: A commenter had concerns that the data used for the market rebasing does not reflect current costs.

Response: For the 2016-based home health market basket, we use the 2016 Medicare cost reports for freestanding HHAs (CMS Form 1728–94) as the primary data source; the 2016 data are the most recent and comprehensive set of cost report data available to CMS at the time of rebasing. As we discussed in the CY 2019 HH PPS proposed rule (83 FR 32361), we use 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. The 2010-based home health market basket was primarily based on the 2010 Medicare cost report data. Therefore, we believe that rebasing the home health market basket alleviates the concerns that the market basket does not reflect the most current costs.

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 proposed 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 moved 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 rebasing and revising, we rebased the detailed wages and salaries and benefits cost weights to reflect 2016 BLS Occupational Employment Statistics (OES) data for HHAs. The 2010-based home health market basket used 2010 BLS OES data for HHAs. We also proposed 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 proposed to eliminate the cost category 'Postage' and include these expenses in the 'All Other Services' cost weight.

Comment: Another commenter supported the rebasing of the home health market basket.

Response: We appreciate the commenter's support.

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

The major cost weights for this 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 referred 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 maintained our policy of using data from freestanding HHAs (77 FR 67081), 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 derived 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 eliminated the cost category 'Postage' and included 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 calculated 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 calculated 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 calculated 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 calculated 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 calculated 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 calculated 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 was 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 calculated 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 was 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 and was 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 maintained our policy 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 5 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. Then, we divided this by the sum of total Medicare allowable costs across all remaining

providers to obtain a cost weight for the 2016-based home health market basket for the given category.

Table 7 shows the major cost categories and their respective cost weights as derived from the Medicare cost reports for this final rule with comment period.

TABLE 7: MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major Cost Categories	2010 Based	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: (1) The employee wages and salaries costs as a percent of the sum of employee wages and salaries costs and employee benefits costs times; and (2) 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 later in this section. This is a similar methodology that was implemented for the 2010-based home health market basket.

We further divided 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 used 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 5 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.[8] 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.

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

Instead of using the less detailed Annual I–O data, we inflated 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. Then, we calculated the cost shares that each cost 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 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 2016-based home health market basket's ''All Other'' cost category (19.0 percent), yielding an Operations and Maintenance cost weight of 1.5 percent in the 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 derived nine detailed cost categories from the 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 proposed to eliminate the stand-alone cost category for Postage and include these expenses in the Other Services cost category.

Table 8 lists the final 2016-based home health market basket cost categories, cost weights, and price proxies.

TABLE 8: COST CATEGORIES, WEIGHTS, AND PRICE PROXIES IN FINAL 2016-BASED HOME HEALTH MARKET BASKET

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

*Figures may not sum due to rounding.

We received no comments on the derivation of the 2016-based Home Health market basket cost categories and weights and therefore are finalizing the categories and weights without modification.

d. 2016-Based Home Health Market Basket Price Proxies

After we computed the CY 2016 cost category weights for the 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 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 would 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 for use in the HH market basket 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 proposed to rebase the home health blended Wages and Salaries index and the home health blended Benefits index. We proposed 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 in this rule.

- *Wages and Salaries:* For measuring price growth in the 2016-based home health market basket, we proposed 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 used a blended wage proxy because there is not a published wage proxy specific to the home health industry.

We proposed 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 proposed 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 9 compares the 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.''

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TABLE 9: 2016 OCCUPATIONAL ASSIGNMENTS COMPARED TO 2010 OCCUPATIONAL ASSIGNMENTS FOR CMS HOME HEALTH WAGES AND SALARIES BLEND

2016 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
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

2016 Occupational Groupings		2010 Occupational Groupings	
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 10 represent the Wages and Salaries blend weights.

TABLE 10: COMPARISON OF THE 2016-BASED HOME HEALTH WAGES AND SALARIES BLEND AND THE 2010-BASED HOME HEALTH WAGES AND SALARIES BLEND

Cost Subcategory	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	CIU1026220000000I
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	CIU2025400000000I
Management	7.6	8.3	ECI for Wages and salaries for Private industry workers in Management, business, and financial	CIU2020000110000I
Administrative	6.7	7.7	ECI for Wages and salaries for Private industry workers in Office and administrative support	CIU2020000220000I
Health and Social Assistance Services	35.3	35.8	ECI for Wages and salaries for All Civilian workers in Health care and social assistance	CIU1026200000000I
Other Service Occupations	14.4	12.6	ECI for Wages and salaries for Private industry workers in Service occupations	CIU2020000300000I
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 2016-based home health Wages and Salaries blend is shown in Table 11. The annual increases in the two price proxies are the same when rounded to one decimal place.

TABLE 11: ANNUAL GROWTH IN 2016 AND 2010 HOME HEALTH WAGES AND SALARIES BLEND

	2016	2017	2018	2019
Wage Blend 2016	2.3	2.5	2.8	3.2
Wage Blend 2010	2.3	2.5	2.8	3.2

Source: IHS Global Insight Inc. 3rd Quarter 2018 forecast with historical data through 2nd Quarter 2018

• *Benefits:* For measuring Benefits price growth in the 2016-based home health market basket, we proposed to apply applicable price proxies to the six occupational subcategories that are used for the Wages and Salaries blend. The six categories in Table 12 are the same as those in the 2010-based home health market basket and include the same occupational mix as listed in Table 12.

TABLE 12: COMPARISON OF THE 2016-BASED HOME HEALTH BENEFITS BLEND AND 2010-BASED HOME HEALTH BENEFITS BLEND

Cost Category	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 used 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 applied this ratio to the 2016 OES weight for wages and salaries for management, 7.6 percent, and then normalized those weights relative to the other 5 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 2016-based home health Benefits 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 THE 2016 HOME HEALTH BENEFITS BLEND AND THE 2010 HOME HEALTH BENEFITS BLEND

	2016	2017	2018	2019
Benefits Blend 2016	1.7	1.9	2.2	3.0
Benefits Blend 2010	1.7	1.9	2.2	3.0

Source: IHS Global Insight Inc. 3rd Quarter 2018 forecast with historical data through 2nd Quarter 2018

- *Operations and Maintenance:* We proposed 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 proposed 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 American Medical Association (AMA) publication, *Physician Characteristics and Distribution in the U.S.*

- *Administrative and Support:* We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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.

Comment: Several commenters stated they do not believe the CY 2019 home health market basket adequately reflects compensation pressures faced by home health providers. A commenter recommended that CMS build into the 2019 market basket update an increase to reflect general health care wage increases.

Response: We believe the CY 2019 market basket update of 3.0 percent reflects the expected compensation price increases that home health agencies will face in CY 2019. The compensation component of the 2016-based Home Health market basket is 76.1 percent. The weight for the ''Wages and Salaries'' cost category is 65.1 percent and the weight for the ''Benefits'' cost category is 10.9 percent. Each of these two respective cost categories are proxied by price indices that reflect the occupational mix of home health staff for the following categories: Health-related professional and technical; non health-related professional and technical; management; administrative; health and social assistance services; and other service occupations. Full details on these price indices can be found in the CY 2019 HH PPS proposed rule (83 FR 32364 through 32366). For CY 2019, the estimated ''Wages and Salaries'' inflation is 3.2 percent and the estimated ''Benefits'' inflation is 3.0 percent. We believe the CY 2019 market basket update adequately reflects these projected price increases associated with wage increases specific to the health and non-health occupations used by the home health industry.

e. Rebasing Results

After consideration of public comments, we are finalizing the proposed 2016-based home health market basket without modification. A comparison of the yearly changes from CY 2014 to CY 2021 for the 2010-based home health market basket and the final 2016-based home health market basket is shown in Table 14.

TABLE 14: COMPARISON OF THE 2010-BASED HOME HEALTH MARKET BASKET AND THE FINAL 2016-BASED HOME HEALTH MARKET BASKET, PERCENT CHANGE, 2014-2021

	Home Health Market Basket, 2010-Based	Home Health Market Basket, 2016-Based	Difference (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
Average CYs 2014-2017	1.9	1.9	0.0
Forecast:			
CY 2018	2.7	2.7	0.0
CY 2019	3.0	3.0	0.0
CY 2020	3.2	3.2	0.0
CY 2021	3.2	3.2	0.0
Average CYs 2018-2021	3.0	3.0	0.0

Source: IHS Global Inc. 3rd Quarter 2018 forecast with historical data through 2nd Quarter 2018.

Table 14 shows that the forecasted rate of growth for CY 2019 for the 2016-based home health market basket is 3.0 percent, the same rate of growth as estimated using the 2010-based home health market basket; 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.

The growth rates in Table 14 are based upon IHS Global Inc.'s (IGI) 3rd quarter 2018 forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. We noted in the proposed rule that if more recent data were 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. In that proposed rule the forecasted rate of growth for CY 2019, based on IGI's 1st quarter 2018 forecast, for the 2016-based home health market basket was 2.8 percent (83 FR 32368).

Comment: A commenter asked if the 2002 through 2018 increases in the market basket represent the percentage increases in consumer health care costs (defined by the commenter as insurance premiums and cost for services) during the same time period. The commenter further stated the inflationary rates used understated what the actual change to costs would have been during this period.

Response: We believe the commenter may be confusing the concept of the CMS market basket, which is an input price index, with the concept of a consumer price index, which is an output price index. An input price index measures the change in the prices of goods and services bought by producers or providers as intermediate inputs. An output price index measures the change in the prices of goods and services sold as output by producers.

The 2016-based HHA market basket, along with its predecessors such as the 2010-based HHA market basket, are fixed-weight indices that are intended to measure the input prices used in providing home health care services. The market basket by definition is a price index rather than a cost index and, therefore, only accounts for changes in prices, holding quantities constant. In order to reflect the changes in the mix of input costs over time, CMS rebases the market basket periodically to ensure that the index is reflecting the most up to date relative cost shares for specific categories of expenses. We have found that the relative cost shares for each category do not change substantially from year to year.

The current CY 2019 market basket update factor of 3.0 percent reflects the projected price growth in the input costs to provide home health services. This forecast is based on the IHS Global Inc. (IGI) third quarter 2018 forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

We also note that according to the Medicare Payment Advisory Committee, Medicare home health revenue has greatly exceeded Medicare home health costs since PPS implementation, with the most recent Medicare margins for 2016 estimated to be 15.5 percent (*http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch9_sec_rev_0518.pdf*)

f. Labor-Related Share

Effective for CY 2019, we revised the labor-related share to reflect the 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 2016-based home health market basket, the labor-related share would be 76.1 percent and the non-labor-related share would be 23.9 percent. The labor-related share for the 2010-based home health market basket was 78.535 percent and the non-labor-related share was 21.465 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 15 details the components of the labor-related share for the 2010-based and 2016-based home health market baskets.

TABLE 15: LABOR-RELATED SHARE OF 2010-BASED and 2016-BASED HOME HEALTH MARKET BASKETS

Cost Category	2010-Based Market Basket Weight	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 Nonlabor-Related	21.5	23.9

There are no changes to the labor-related share in this final rule with comment period compared to the labor related share in the proposed rule (83 FR 32368).

We implemented the 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.

Comment: Several commenters disagreed with CMS' proposal to reduce the labor related share, because such a change could result in less care for patients.

Response: The labor related share is composed of the Wages & Salaries and Benefits cost weights from the 2016-based home health market basket. These cost weights were calculated using the 2016 Medicare cost report data (form CMS–1728–94), which is provided directly by freestanding home health agencies. The 2016 data was the most comprehensive data source available for determining the CY 2019 labor-related share at the time of rulemaking. The CY 2018 labor-related share of 78.535 percent was based on the 2010-based home health market basket Wages and Salaries and Benefit cost weights, which were calculated using the 2010 Medicare cost report data. Therefore, we believe the labor-related share of 76.1 percent is technically appropriate as it is based on more recent Medicare cost report data reported by home health agencies.

Comment: Another commenter agreed with CMS' proposal to reduce the labor related share.

Response: We appreciate the commenter's support and agree that the labor-related share should be reduced from 78.535 percent to 76.1 percent as it reflects the most recent Medicare cost report data for home health agencies available at the time of rebasing.

Final Decision: After consideration of public comments, based on the 2016-based home health market basket, we are finalizing the proposed labor related share of 76.1 percent and the non-labor-related share of 23.9 percent.

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) 3rd quarter 2018 forecast with history through the 2nd quarter of 2018, the projected MFP adjustment (the 10-year moving average of MFP for the period ending December 31, 2019) for CY 2019 is 0.8 percent.

We noted in the proposed rule that if more recent data were 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. For comparison purposes, the proposed MFP adjustment for CY 2019 was 0.7 percent (83 FR 32368), and was based on IGI's 1st quarter 2018 forecast.

2. CY 2019 Market Basket Update for HHAs

Using IGI's third quarter 2018 forecast, the MFP adjustment for CY 2019 is projected to be 0.8 percent. In accordance with section 1895(b)(3)(B)(iii) of the Act, we proposed 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 2016-based home health market basket. Based on IGI's third quarter 2018 forecast with history through the second quarter of 2018, the projected increase of the 2016-based home health market basket for CY 2019 is 3.0 percent. We then reduce this percentage increase by the current estimate of the MFP adjustment for CY 2019 of 0.8 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 2.2 percent (3.0 percent market basket update, less 0.8 percentage point MFP adjustment).

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 would be 0.2 percent (2.2 percent minus 2 percentage points).

Comment: Several commenters agreed with CMS' proposed 2.1 percent payment increase.

Response: We appreciate the commenters' support. The proposed 2.1 percent payment increase was based on IGI Global Inc.'s first quarter 2018 forecast of the 2016-based HHA market basket and the 10-year moving average of annual economy-wide private nonfarm business. As noted in the proposed rule, if a more recent forecast of the market basket and MFP was available, we would use such data to determine the CY 2019 market basket update and MFP adjustment in the final rule. Based on IHS Global Inc.'s (IGI) third quarter 2018 forecast, we determine a payment increase of 2.2 percent for the final update percentage as previously stated.

Based on IGI's third quarter 2018 forecast, we are finalizing the CY 2019 HHA payment update at 2.2 percent (3.0 percent market basket update, less 0.8 percentage point MFP adjustment).

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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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.[9] 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.* 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 following is a summary of the comments received on the proposed CY 2019 home health wage index and our responses:

Comment: Several commenters shared concerns in how the wage index is calculated and implemented for home health agencies compared to other prospective payment systems within the same CBSAs. A commenter commented that hospitals are given the opportunity to appeal their annual wage index and apply for geographic reclassification while HHAs in the same geographic location are not given that same privilege. The commenter believes that this lack of parity between different health care sectors further exemplifies the inadequacy of CMS 'decision to continue to use the pre-floor, pre-reclassified hospital wage index to adjust home health services payment rates. They gave an example of Massachusetts where every hospital in the Worchester CBSA and two hospitals in the Providence-Bristol CBSA have been re-classified to the Boston CBSA, effectively increasing their wage index by approximately 9 percent and 20 percent respectively. They further suggest that CMS use wage index from Critical Access Hospitals in calculating the wage index for HHAs to make the wage index more reflective of actual local wage practices.

Response: We thank the commenters for their comments. We continue to believe that the regulations and statutes that govern the HH PPS do not provide a mechanism for allowing HHAs to seek geographic reclassification or to utilize the rural floor provision that exists for Hospital Inpatient Prospective Payment System (IPPS) hospitals. Section 4410(a) of the Balanced Budget Act of 1997 provides that the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This is the rural floor provision and it is specific to hospitals. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Medicare Geographic Classification Review Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification for purposes of payment under the IPPS. This reclassification provision is only applicable to hospitals as defined in section 1886(d) of the Act. In addition, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals. We continue to believe that using the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates is appropriate and reasonable. Although the pre-floor, pre-classified hospital wage index does not include data from Critical Access Hospitals (CAHs), we believe that it reflects the relative level of wages and wage-related costs applicable to providing HH services. As we stated in the August 1, 2003 IPPS final rule (68 FR 45397), CAHs represent a substantial number of hospitals with significantly different labor costs in many labor market areas where they exist.

Comment: A commenter expressed concerns with CMS using CY 2015 wage index figures for the CY 2019 wage index since there have been shifts in the labor market in New York State.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the cost reports of hospitals in those specific labor market areas. The wage index values are based on data submitted on the inpatient hospital cost reports. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified hospital; wage index, which is calculated based on cost report data submitted from hospitals paid under the IPPS. All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, Medicare contractors perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. We believe that our review processes result in an accurate reflection of the applicable wages for each labor market area. The processes and procedures describing how the inpatient hospital wage index is developed are discussed in the IPPS rule each year, with the most recent discussion provided in the FY 2019 IPPS final rule (83 FR 41362 through 41374 and 83 FR 41380 through 41383). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

Comment: A commenter believes that the CMS decision 10 years ago to switch from Metropolitan Statistical Areas (MSAs) to CBSAs for the wage adjustment to the rates has had negative financial ramifications for HHAs in New York City. The commenter stated that unlike past MSA designations, where all of the counties in the New York City designation were from New York State, the 2006 CBSA wage index designation added Bergen, Hudson, and Passaic counties from New Jersey into the New York City CBSA. The commenter also noted that with the CY 2015 final rule, CMS added three more New Jersey counties (Middlesex, Monmouth, and Ocean) to the CBSA used for New York City.

Response: The MSA delineations as well as the CBSA delineations are determined by the Office of Management and Budget (OMB). The OMB reviews its Metropolitan Area definitions preceding each decennial census to reflect recent population changes. We believe that the OMB's CBSA designations reflect the most recent available geographic classifications and are a reasonable and appropriate way to define geographic areas for purposes of wage index values. Over 10 years ago, in our CY 2006 HH PPS final rule (70 FR 68132), we finalized the adoption of the revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). In the December 27, 2000 **Federal Register** (65 FR 82228 through 82238), the OMB announced its new standards for defining metropolitan and micropolitan statistical areas. According to that notice, the OMB defines a CBSA, beginning in 2003, as ''a geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as

[9] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

measured by commuting ties.'' The general concept of the CBSAs is that of an area containing a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus. The purpose of the standards is to provide nationally consistent definitions for collecting, tabulating, and publishing federal statistics for a set of geographic areas. CBSAs include adjacent counties that have a minimum of 25 percent commuting to the central counties of the area. This is an increase over the minimum commuting threshold for outlying counties applied in the previous MSA definition of 15 percent. Based on the OMB's current delineations, as described in the July 15, 2015 OMB Bulletin 15–01, the New Jersey counties of Bergen, Hudson, Middlesex, Monmouth, Ocean, and Passaic belong in the New York-Jersey City-White Plains, NY-NJ (CBSA 35614). In addition, for the payment systems of other provider types, such as IPPS hospitals, hospices, skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and ESRD facilities, we have used CBSAs to define their labor market areas for more than a decade.

Comment: A commenter questioned the validity of the wage index data, especially in the case of the CBSA for Albany-Schenectady-Troy, noting that in the past 5 years, this CBSA has seen its wage index reduced 6.18 percent, going from 0.8647 in 2013 to a proposed CY 2019 wage index of 0.8179.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the cost reports of hospitals in those specific labor market areas. The area wage index measures differences in hospital wage rates among labor market areas and compares the area wage index of the labor market area to the national average hourly wage. If a hospital or labor market area does not keep pace with the national average hourly wage in a given year, then the labor market area will see a decrease in the area wage index during that year.

Comment: A commenter recommended that providers meeting higher minimum wage standards, such as HHAs, obtain additional supplemental funding to better align payments with cost trends impacting providers.

Response: Regarding minimum wage standards, we note that such increases will be reflected in future data used to create the hospital wage index to the extent that these changes to state minimum wage standards are reflected in increased wages to hospital staff.

Final Decision: After considering the comments received in response to the CY 2019 HH PPS proposed rule, we are finalizing our proposal to continue to use the pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2019, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2014 and before October 1, 2015 (FY 2015 cost report data). The final CY 2019 wage index is available on the CMS website at: *https://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. The labor-related share of the case-mix adjusted 60-day episode is 76.1 percent and the non-labor-related share is 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 is adjusted as described in section III.B of this final rule with comment period. The following are the steps we take to compute the case-mix 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 proposed 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 final rule with comment period; and the home health payment update percentage discussed in section III.C.2. of this final rule with comment period.

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 labor-related share of 76.1 percent and the non-labor-related share of 23.9 percent) applied to CY 2017 utilization (claims) data and compared it to our simulation of total payments for non-LUPA episodes using the CY 2018 wage index (including the application of the current labor-related share of 78.535 percent and the non-labor-related of 21.465) applied to CY 2017 utilization (claims) data. 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 0.9985. We will apply the wage index budget neutrality factor of 0.9985 to the calculation of the CY 2019 national, standardized 60-day episode payment rate.

As discussed in section III.B. of this final rule with comment period, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we proposed 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 1.0169 as described in section III.B. of this final rule with comment period. Next, we apply the payment rates by the CY 2019 home health payment update percentage of 2.2 percent as described in section III.C.2. of this final rule with comment period. The CY 2019 national, standardized 60-day episode payment rate is calculated in Table 16.

TABLE 16: 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	X 0.9985	X 1.0169	X 1.022	$3,154.27

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 2.2 percent minus 2 percentage points and is shown in Table 17.

TABLE 17: 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	X 0.9985	X 1.0169	X 1.002	$3,092.55

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 0.9996. We apply the wage index budget neutrality factor of 0.9996 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 2.2 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 2.2 percent and are shown in Table 18.

TABLE 18: CY 2019 NATIONAL PER-VISIT PAYMENT AMOUNTS

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	X 0.9996	X 1.022	$ 66.34
Medical Social Services	$229.86	X 0.9996	X 1.022	$234.82
Occupational Therapy	$157.83	X 0.9996	X 1.022	$161.24
Physical Therapy	$156.76	X 0.9996	X 1.022	$160.14
Skilled Nursing	$143.40	X 0.9996	X 1.022	$146.50
Speech- Language Pathology	$170.38	X 0.9996	X 1.022	$174.06

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 2.2 percent minus 2 percentage points and are shown in Table 19.

TABLE 19: 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	X 0.9996	X 1.002	$ 65.04
Medical Social Services	$229.86	X 0.9996	X 1.002	$230.23
Occupational Therapy	$157.83	X 0.9996	X 1.002	$158.08
Physical Therapy	$156.76	X 0.9996	X 1.002	$157.01
Skilled Nursing	$143.40	X 0.9996	X 1.002	$143.63
Speech- Language Pathology	$170.38	X 0.9996	X 1.002	$170.65

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 $270.27 (1.8451 multiplied by $146.48), subject to area wage adjustment.

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

All medical supplies (routine and non-routine) 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 2.2 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 NRS conversion factor for CY 2019 is shown in Table 20.

TABLE 20: CY 2019 NRS CONVERSION FACTOR

CY 2018 NRS Conversion Factor	CY 2019 HH Payment Update	CY 2019 NRS Conversion Factor
$53.03	X 1.022	$54.20

Using the CY 2019 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 21.

TABLE 21: CY 2019 NRS PAYMENT AMOUNTS

Severity Level	Points (Scoring)	Relative Weight	CY 2019 NRS Payment Amounts
1	0	0.2698	$ 14.62
2	1 to 14	0.9742	$ 52.80
3	15 to 27	2.6712	$ 144.78
4	28 to 48	3.9686	$ 215.10
5	49 to 98	6.1198	$ 331.69
6	99+	10.5254	$ 570.48

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 2.2 percent minus 2 percentage points. The CY 2019 NRS conversion factor for HHAs that do not submit quality data is shown in Table 22.

TABLE 22: 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	X 1.002	$53.14

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 23.

TABLE 23: 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	$14.34
2	1 to 14	0.9742	$51.77
3	15 to 27	2.6712	$141.95
4	28 to 48	3.9686	$210.89
5	49 to 98	6.1198	$325.21
6	99+	10.5254	$559.32

The following is a summary of the public comments received on the CY 2019 Annual Payment Update and our responses.

Comment: Several commenters expressed concerns with the reduction in the labor-related shares suggesting such a change will result in less care for patients.

Response: We thank the commenters for expressing their concerns. As noted in the proposed rule (83 FR 32368), the decrease in 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. The decreased labor-related share is implemented in a budget neutral manner, which is consistent with the policies for implementing the annual recalibration of the case-mix weights and update of the home health wage index in a budget neutral manner.

Comment: A commenter stated that HHAs have received only one positive inflation update since 2011 and that this has left them behind in their ability to attract and retain medically trained personnel.

Response: The home health market basket growth rate measures input price inflation associated with providing home health services. We disagree with the commenter that home health agencies have only received one positive inflation update since 2011 as the market basket update has been approximately 2 percent or higher annually. The table 24 shows the home health market basket updates and productivity adjustments from CY 2011 to CY 2018.

TABLE 24: ACTUAL HOME HEALTH MARKET BASKET UPDATES AND PRODUCTIVITY ADJUSTMENTS

	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017	CY 2018
Home Health Market Basket Update	2.1	2.4	2.3	2.3	2.6	2.3	2.8	2.5
Productivity Adjustment	N/A	N/A	N/A	N/A	0.5	0.4	0.3	0.6
Market Basket Update less Productivity Adjustment	N/A	N/A	N/A	N/A	2.1	1.9	2.5	1.9

Over the 2011 to 2018 time period, the home health market basket update and home health payment rates have been reduced to reflect other statutorily required adjustments (such as the MFP adjustment (required by section 1895(b)(3)(B)(vi) of the Social Security Act), and rebasing adjustments to the national, standardized 60-day episode payment rates (required under section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152)). In some years, this has resulted in the 60-day episode payment rates being less than in prior years. The rationale and methodology regarding these other adjustments, along with CMS response to comments, can be found in prior CY HH PPS proposed and final rules.

We would note, however, that since PPS implementation and particularly over the 2011 to 2016 time period, according to MedPAC, freestanding home health agency margins have averaged roughly 14 percent. Furthermore, as shown in the 2016-based home health market basket, approximately 76 percent of home health costs are compensation costs; therefore, we disagree with the commenter's claims that they are unable to attract and retain medically trained personnel due to insufficient payment updates.

Comment: While several commenters commended and supported CMS on recognizing the need for an increase in home health payments per 60-day episode, MedPAC commented that this increase is not warranted based on their analysis of payment adequacy.

Response: We note that we are statutorily required to update the payment rates under the prospective payment system by the home health payment update percentage in accordance with section 1895(b)(3)(B) of the Act.

Final Decision: After considering all comments received on the proposed payment rate update for CY 2019, we are finalizing the application of the wage index budget neutrality factor (which includes making the change in the labor-related share budget neutral), the case-mix adjustment budget neutrality factor and the home health payment update percentage in updating the home health payment rates for CY 2019 as proposed.

D. 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 area (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.

2. 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: (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 (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 ''High utilization'' category (the ''Low population density'' category); and (3) rural counties and equivalent areas not in either the ''High utilization'' or ''Low population density'' categories (the ''All other'' category).

The proposed rule outlined how we categorized rural counties (or equivalent areas) into the three distinct categories outlined in section 50208 of the BBA of 2018 based on CY 2015 claims data and 2015 data from the Medicare Beneficiary Summary File, as well as 2010 Census data. The rural add-on percentages and duration of rural add-on payments outlined in law are shown in Table 25. The HH Pricer module, located within CMS' claims processing system, will increase the base payment rates provided in Tables 16 through 23 by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments.

TABLE 25: 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%	

The proposed rule further described the provisions of section 50208(a)(2) of the Bipartisan Budget Act of 2018, which 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 proposed that HHAs enter the FIPS state and county code, rather than the SSA state and county code, on the claim.

The data used to categorize each county or equivalent area is available in the Downloads section associated with the publication of the 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.

The following is a summary of the public comments received on the proposal for Rural Add-on Payments for CYs 2019 through 2022 and our responses:

Comment: A commenter stated that they do not object to the methodology used by CMS in implementing the rural add-on payments for CYs 2019–CY 2022, but they request that CMS ask Congress to modify and reauthorize the three percent rural safeguard for all rural counties to ensure access to home health services by Medicare beneficiaries in rural areas. Some commenters suggested that the cost reports indicate FFS margins are at 5 percent or below, which they suggested reflects the high cost of travel in rural areas and the cost of staffing of visits into rural areas. The commenters indicated that many margins included

the 3 percent rural add-on, thereby further justifying the continuation of the rural-add on payments. Several commenters expressed concern with the reduction and elimination of the rural add-on payments suggesting that without the payments it would make caring for home health patients in rural areas a challenge. Many urged CMS to continue providing rural add-on payments after 2022 so that beneficiaries in rural communities continue to have access to home health services. Several commenters suggested that CMS establish a workgroup to examine rural costs and how best to address those costs with an add-on payment.

Response: Section 421(a) of the MMA, as amended by section 50208 of the BBA of 2018, provides a 3 percent rural add-on for HH services provided in a rural area for episodes and visits ending before January 1, 2019. Section 421(b)(1) of the MMA, as amended by section 50208 of the BBA of 2018, stipulates the percentage of rural add-on payments by rural county (or equivalent area) classification for episodes and visits ending during CYs 2019 through 2022, as provided in Table 25. As these are statutory requirements, we do not have the authority to provide a 3 percent rural add-on for episodes and visits ending on or after January 1, 2019 across all rural areas, or to extend rural add-on payments beyond the duration of the period for which rural add-on payment are in place under section 421(b)(1) of the MMA. However, we plan to continue to monitor the costs associated with providing home health care in rural versus urban areas.

Comment: MedPAC stated that the rural payment add-on policy for 2019 is an improvement that better targets Medicare's scarce resources. They further stated that average utilization is not significantly different between urban and rural areas, but there is some variation around this average, with high-and-low use areas found in counties. They commented that the proposed policy targets payments to areas with lower population density and limits payments to rural areas with higher utilization.

Response: We thank MedPAC for their comments.

Comment: A commenter recommended that CMS research the impact the rural add-on extension will have on low population density areas particularly with the proposal to move to the cost per minute plus non-routine supplies approach in estimating resource use under the PDGM.

Response: We thank the commenter for this suggestion. We will continue monitoring the impacts due to policy changes, including the changes in rural add-on payments for CYs 2019 through 2022, and will provide the industry with periodic updates on our analysis in rulemaking and/or announcements on the HHA Center web page at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.*

Comment: Several commenters stated that a HHA may have demographic changes within the four-year period and that they should be able to retract and change their category of rural counties or equivalent areas for the HH rural add-on payment.

Response: 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) (the ''High utilization'' category), 421(b)(1)(B) (the ''Low population density'' category), or 421(b)(1)(C) (the ''All other'' category) of the MMA that a rural county or equivalent area is classified into, and that the determination applies for the duration of the period for which rural add-on payments are in place under section 421(b) of the MMA. As these are statutory requirements, we do not have the authority to allow the changes to rural county or equivalent area classifications suggested by the commenters.

Final Decision: We are finalizing the policies for the provision of rural add-on payments for CY 2019 through CY 2022 in accordance with section 50208 of the BBA of 2018, which adds a new subsection to section to 421 of the MMA. This includes finalizing the designations of rural counties (or equivalent areas) into their respective categories as outlined in the excel files published on the HHA center web page in conjunction with the CY 2019 HH PPS proposed rule: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices-Items/CMS-1689-P.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.*

E. 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. 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.

In the CY 2019 proposed rule, we simulated payments using preliminary CY 2017 claims data (as of March 2, 2018) and the CY 2018 HH PPS payment rates (82 FR 51676), and estimated that outlier payments in CY 2018 would comprise 2.30 percent of total payments and approximately 2.32 percent of total HH PPS payments in CY 2019. Our simulations showed 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, in the CY 2019 proposed rule, we proposed 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 noted that we were 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.).

Using updated CY 2017 claims data (as of June 30, 2018) and the final CY 2019 payment rates presented in section III.C of this final rule with comment period, we estimate that outlier payments would continue to constitute approximately 2.47 percent of total HH PPS payments in CY 2019 under the current outlier methodology. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we believe that modifying the FDL ratio from 0.55 to 0.51 with a loss-sharing ratio of 0.80 is appropriate given the percentage of outlier payments projected for CY 2019.

3. Home Health Outlier Payments: Clinical Examples

In the CY 2019 HH PPS proposed rule, we also described clinical examples 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. (83 FR 32340).

The following is a summary of the comments received on outlier payments under the HH PPS and our responses.

Comment: Several commenters recommended that CMS conduct a more detailed analysis to determine whether the total cap of 2.5 percent of total payments as outlier payments is adequate or whether it needs to be increased for future years, particularly given the expected change in Medicare beneficiary demographics anticipated in the coming years.

Response: As established in section 1895(b)(5) of the Act, both the 2.5 percent target of outlier payments to total home health payments and the 10-percent cap on outlier payments at the home health agency level are statutory

requirements. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5-percent target amount. However, we will continue to evaluate for the appropriateness of those elements of the outlier policy that may be modified, including the FDL and the loss-sharing ratio. We note that other Medicare payment systems with outlier payments, such as the IRF PPS and IPPS, annually reassess the fixed-loss cost outlier threshold amount. Adjusting the outlier threshold amount in order to target the statutorily required percentage of total payments as outlier payments is standard practice.

Comment: A commenter recommended that CMS eliminate outlier payments in their entirety.

Response: We believe that section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS. However, we also believe that outlier payments are beneficial in that they help mitigate the incentive for HHAs to avoid patients that may have episodes of care that result in unusual variations in the type or amount of medically necessary care. The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care. We note that we plan to continue evaluating whether or not an outlier policy remains appropriate as well as ways to maintain an outlier policy for episodes that incur unusually high costs due to patient care needs.

Comment: Several commenters suggested that we include the cost of supplies in our outlier calculations as the inclusion of the cost of supplies as opposed to the estimated costs would yield more accurate payment totals to be used for determination of outlier payments.

Response: We appreciate the commenters' suggestion regarding the inclusion of supplies in the outlier calculations. In order to incorporate supply costs into the outlier calculation, significant systems modifications would be required. However, we will consider whether to add supply costs to the outlier calculations and evaluate whether such a policy change is appropriate for future rulemaking.

Comment: A commenter expressed concerns about the per-unit outlier approach established in 2017, stating that the assumptions regarding this policy change were not accurate, thereby leading to difficulties in the HHA community. The commenter further suggested that if the outlier provision is to continue for CY2019, then we should revert to the per-visit approach.

Response: We appreciate the commenter's feedback regarding the revisions to the methodology utilized to calculate outliers in the HH PPS. We maintain that the transition to the per-unit approach advanced our objectives of better aligning payment with the costs of providing care, but we will continue to monitor the impact of this policy change as more recent data become available, and we may propose to modify the outlier policy approaches as needed in the future.

Comment: Several commenters expressed support for the clinical examples provided in the CY 2019 proposed rule and appreciated the descriptions of how an outlier payment may be made for the provision of care for patients living with significant longer-term and debilitating conditions, including ALS.

Response: We appreciate the commenters' support and hope that the examples illustrating how HHAs could be paid by Medicare for providing care to patients with higher resource use in their homes served to highlight that a patient's condition does not need to improve for home health services to be covered by Medicare. We likewise hope that the examples helped to provide a better understanding of Medicare coverage policies and how outlier payments promote access to home health services for such patients under the HH PPS.

Comment: A commenter requested that we identify specific diseases, like ALS, that the commenter asserts are systematically underpaid and exclude outlier payments for such patients from the fixed dollar loss amount and cost sharing percentage up to the full reasonable cost of care at those agencies accepting them for care. Additionally, the commenter suggested that we separately identify those agencies in each area who agree to accept high cost ALS patients under the aforementioned exception. Moreover, the commenter suggested that we undertake a demonstration to test whether an alternative payment mechanism under the home health benefit similar to Disproportionate Share Payments or a Special Needs Plans would provide full access to home health care for ALS and similar patients as well as a demonstration of a bridge program that is a combination of the appropriate features of the Medicare home health and hospice benefits that the commenter asserts would constitute a cost-effective alternative to the use of both benefits and assure access to patients needing ''Advanced Disease Management'' (ADM), blending curative treatment approaches of home health and the palliative care benefits of hospice in a manner that allows a seamless transition for persons whose disease process is highly likely to advance and result in death within a two-year period.

Response: We appreciate the commenter's feedback regarding the suggested modifications to the home health outlier calculation as well as the recommendation for possible demonstrations related to home health cases that may qualify for an outlier payment. We maintain that section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS and we believe that outlier payments are beneficial in that they help mitigate the incentive for HHAs to avoid patients that may have episodes of care that result in unusual variations in the type or amount of medically necessary care. The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care. The outlier calculation is based upon total payments within the HH PPS and we do not believe it would be appropriate to exclude certain cases from the overall calculation or to make additional payments to certain providers that offer services to home health beneficiaries with a certain clinical profile. Regarding the possibility of a demonstration for those beneficiaries with high resource use, we will consider the comments as we develop new models through the Center for Medicare and Medicaid Innovation. We note that we would need to determine whether such a model would meet the statutory requirements to be expected to reduce Medicare expenditures and preserve or enhance the quality of care for beneficiaries.

Final Decision: We are finalizing the change to the FDL ratio or loss sharing ratio for CY 2019. We are establishing an FDL ratio of 0.51 with a loss-sharing ratio of 0.80 for CY 2019. We will continue to monitor outlier payments and continue to explore ways to maintain an outlier policy for episodes that incur unusually high costs.

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

1. Summary of the Proposed PDGM Model, Data, and File Construction

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 proposed case-mix methodology refinements through the

implementation of the Patient-Driven Groupings Model (PDGM). We proposed to implement the PDGM for home health periods of care beginning on or after January 1, 2020. The PDGM: Uses 30-day periods of care rather than 60-day episodes of care as the unit of payment, as required by section 51001(a)(1)(B) of the BBA of 2018; eliminates the use of the number of therapy visits provided to determine payment, as required by section 51001(a)(3)(B) of the BBA of 2018; and 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.

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 proposed 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, we proposed that 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, 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. We proposed to adopt this episode timing classification for 30-day periods with the implementation of the PDGM. 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. 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.''

Under the PDGM, we proposed that each 30-day period would also 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 within the prior 14 days 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.

We proposed further grouping 30-day 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 were receiving home health services under the Medicare home health benefit. The proposed six clinical groups, were as follows:

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

Under the PDGM, we proposed that each 30-day period would be placed into one of three functional impairment levels. The level would indicate if, on average, given the HHA's responses on certain functional OASIS questions, a 30-day period was predicted to have higher costs or lower costs. For each of the six clinical groups, we proposed that total periods would be further classified into one of three functional impairment levels with roughly 33 percent of total 30-day periods for all HHAs in each level. We determined how many periods of care would be in each functional impairment level based on the relative number of periods in a potential impairment level, and on the clustering of summed functional scores. The functional impairment level assignment under the PDGM is very similar to the functional level assignment in the current payment system.

Finally, we proposed that 30-day periods would receive a comorbidity adjustment category based on the presence of secondary diagnoses. We proposed 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 proposed that the LUPA threshold would vary for a 30-day period under the PDGM depending on the PDGM payment group to which it was assigned. For each payment group, we proposed to use the 10th percentile value of visits to create a payment group specific LUPA threshold with a minimum threshold of at least 2 visits for each group.

The proposed rule further outlined the data file construction process for the PDGM-related analyses, including the claims data used, how the data were cleaned, how OASIS data were matched to claims data, how measures of resource use were constructed, and the total number of 30-day periods used for constructing the PDGM case-mix weights in the proposed rule (82 FR 35297 through 35298).

The following is a summary of general comments received on the proposals and our responses.

Comment: Several commenters supported various elements of PDGM. There was broad support for moving from the current payment system to one that uses a broader clinical profile of the patient. There was also support for the budget neutral implementation of the PDGM and the elimination of the service utilization domain (that is, therapy thresholds). Other commenters indicated they supported the PDGM, but stated that implementation of the PDGM should be delayed until after January 1, 2020 to provide assurances that there is sufficient information and guidance to HHAs, physicians, and Medicare Administrative Contractors (''MACs'') to ensure a smooth transition and no unintended consequences. Commenters also suggested that CMS implement the model incrementally or conduct a small scale demonstration of the model.

Response: We thank the commenters for their support. 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 (also referred to as unit of payment), effective January 1, 2020. In addition, section 1895(b)(4)(B)(ii) of the Act, as added by section 51001(a)(3)(B) of the BBA of 2018, requires CMS to remove therapy thresholds from the case-mix adjustment methodology used to adjust payments under the HH PPS for CY 2020 and subsequent years. The PDGM was developed in conjunction with a 30-day period of care and should be implemented simultaneously with the change in the length of the unit of

service. Attempting to implement the PDGM piecemeal could cause more burden and confusion, compared to implementing the entire model at the same time. With regards to conducting a demonstration, we note that a demonstration would likely only occur in selected areas with selected participants and therefore would paint a different picture of the effects of the model compared to what would otherwise occur on a national scale. Furthermore, section 1895 of the Act, as amended by the BBA of 2018, requires a change to the unit of payment and the elimination of therapy thresholds for all payments made under the HH PPS, rather than requiring CMS to conduct a demonstration. While we are finalizing our proposal to implement the PDGM beginning on January 1, 2020, we are sensitive to the concerns expressed by commenters regarding provider outreach, training, billing changes and systems updates needed to implement the PDGM. While we work toward an implementation date of January 1, 2020, we look forward to a continued dialogue with the industry on ways to provide sufficient guidance and training to ensure a smooth transition to the 30-day unit of payment and the PDGM.

Comment: Several commenters asked about what types of training material will be available regarding the PDGM. A commenter asked if and when the claims processing manual will be updated to reflect the PDGM. Additionally, a commenter asked if CMS could develop an email mailbox for patients to offer feedback on the PDGM.

Response: We appreciate comments about the need for guidance and training prior to the implementation of the PDGM. We agree with the commenters that this is an area that deserves attention and we plan to work with HHAs and other stakeholders to ensure a smooth transition between the current payment model and the PDGM. We will update the claims processing manual and we will provide education and support more broadly, which may include MLN articles, program instructions, national provider calls, and open door forums. Once the rule is finalized, we will begin updating the appropriate sections of the Home Health Agency Billing chapter in the Medicare Claims Processing Manual. For questions about the Home Health Prospective Payment System (HH PPS) and the Medicare home health benefit, individuals can email: *HomehealthPolicy@cms.hhs.gov.*

Comment: Several commenters asked how CMS would monitor the PDGM. Specifically, commenters expressed concern that the PDGM may result in inappropriate practice patterns and that the PDGM might introduce claims processing issues that could cause delays in payment. A few commenters also indicated that the technical expert panel (TEP) convened in February, 2018 should continue to stay involved with the implementation and roll-out of the PDGM in order to monitor outcomes.

Response: We will continue to monitor the payment system as we have done since the inception of the benefit. We will closely monitor patterns related to utilization, including changes in the composition of patients receiving the home health benefit and the types and amounts of services they are receiving. CMS will also carefully pay attention to claims processing changes needed to implement the 30-day unit of payment and the PDGM in order to mitigate any issues that could cause delays in payment. We appreciated the help of the TEP and, if needed, we will continue to engage the TEP or another set of key stakeholders as we move forward with the implementation of the PDGM for January 1, 2020.

Comment: Commenters stated there was limited involvement with the industry in the development of the PDGM. Some commenters indicated that CMS needs to perform studies and an evaluation of the work related to the PDGM and alternative payment models suggested, like the ''Risk-Based Grouper Model''.

Response: We thank the commenters' for their willingness to engage in discussion around the PDGM. 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 such 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 were shared with both internal and external 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 to further solicit feedback from stakeholders and the general public. The CY 2018 HH PPS proposed rule further solicited comments on a proposed alternative case-mix adjustment methodology—referred to as the home health groupings model, or HHGM.

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. In addition, 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 has already been completed and is available on the CMS HHA Center web page at: *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html*. CMS addressed the Risk Based Grouper Model in the 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. Lastly, the CY 2019 HH PPS proposed rule solicited comment on the proposed PDGM.

Comment: Several commenters requested that CMS describe how the

proposed PDGM would impact delivery and payment innovations, such as Accountable Care Organizations (ACOs) and Bundled Payments for Care Improvement (BPCI) Models 2 and 3. Other commenters requested that CMS describe how the proposed PDGM fits in with the IMPACT Act-directed post-acute care PPS and other payment system methodology changes in other settings. Other commenters indicated that the PDGM would hurt HHVBP and the star ratings. A commenter asked if the Review Choice Demonstration was still needed if PDGM was implemented and indicated that would cause additional burden.

Response: BPCI Models 2 and 3 ended September 30, 2018; therefore, BPCI Models 2 and 3 would not be affected by PDGM implementation. CMS will determine whether any refinements are needed to the BPCI Advanced Model, a new payment and service delivery model that began on October 1, 2018, and any ACO programs and models, such as the Medicare Shared Savings Program and the Next Generation ACO Model as a result of PDGM implementation. We note that any changes determined to be necessary to the payment methodology used in the Medicare Shared Savings Program due to implementation of the PDGM would require notice and comment rulemaking.

We believe that the proposed PDGM could assist with meeting the IMPACT Act requirement that the Secretary of Health and Human Services develop a technical prototype for a unified post-acute care (PAC) prospective payment system (PAC PPS). We believe many aspects of the PDGM could be used in a unified PAC PPS prototype so that payments under such a prototype would be based according to individual characteristics, as specified by the IMPACT Act. We do not believe that the PDGM will disrupt the HHVBP Model or the Home Health star ratings. The PDGM is a case-mix adjustment model intended to pay for services more accurately and we believe the HHVBP Model and the Home Health star ratings can continue unchanged when HHA periods of care are paid according to the case-mix adjustments of the PDGM. We do not believe the implementation of the PDGM will eliminate the rationale behind the proposed Review Choice Demonstration for Home Health Services. The PDGM is a case-mix adjustment model with the goal of better aligning home health payments with patient care needs and the cost of care, while the proposed Review Choice Demonstration for Home Health Services would be a demonstration aimed at assisting in the development of improved procedures to identify, investigate, and prosecute potential Medicare fraud occurring among HHAs providing services to Medicare beneficiaries.

Comment: A commenter asked CMS to provide greater detail about the appeals process that will be available to help patients address any shortcomings in their care and/or coverage. In addition, the commenter stated that providers also should be able to appeal any inaccurate assignments to payment classifications.

Response: The Advance Beneficiary Notice of Noncoverage (ABN) is issued by providers (including home health agencies and hospices), physicians, practitioners, and other suppliers to Original Medicare (fee-for-service) beneficiaries in situations where Medicare payment is expected to be denied for some or all services. When a home health patient gets an ABN, the ABN gives clear directions for getting an official decision from Medicare about payment for home health services and supplies and for filing an appeal. An HHA must also furnish a ''Home Health Change of Care Notice'' (HHCCN) to beneficiaries when the beneficiary's home health plan of care is changing because the Agency reduces or stops providing home health services or supplies for business-related reasons or because the beneficiary's physician changed orders for such services or supplies. An HHA must also furnish a ''Notice of Medicare Non-Coverage'' (NOMNC) at least 2 days before all covered services end. When home health services are ending, beneficiaries may have the right to an expedited appeal if they believe the services are ending too soon. During an expedited appeal, a Beneficiary and Family Centered Care Quality Improvement Organization (BFCC–QIO) will examine the case and decide whether home health services need to continue. If the beneficiary is dissatisfied with the determination by the QIO, in accordance with § 405.1204, the beneficiary has the right to an expedited reconsideration by a Qualified Independent Contractor (QIC). If the beneficiary is dissatisfied with the determination by the QIC, the beneficiary then has the right to request an Administrative Law Judge hearing or review of a dismissal, Medicare Appeals Council review, and judicial review by a federal district court, so long as jurisdictional requirements are met (as outlined by 42 CFR part 405, subpart I).

With regards to inaccurate assignments to payment classifications under the PDGM, corrections to payment classifications on claims will not require appealing the initial determination. Because the assignment of the payment classification will be performed by the claims system based on data reported by the HHA on the claim or the corresponding patient assessment, the provider could correct this information to change the assignment. The HHA could submit a correction OASIS assessment and subsequently adjust their claim after the corrected assessment is accepted, or simply correct the payment-related items on the claim (occurrence code, diagnosis code, etc.) and submit the adjusted claim.

Comment: Another commenter asked CMS to review the current therapy assessment burden for providers and the time points in which those assessments need to be completed given that the PDGM does not use a service utilization domain.

Response: Prior to January 1, 2015, therapy reassessments were required to be performed on or ''close to'' the 13th and 19th therapy visits and at least once every 30 days (75 FR 70372). As a reminder, in the CY 2015 HH PPS final rule, CMS eliminated the requirement for reassessments to be performed on or ''close to'' the 13th and 19th visits. Instead, the current regulations at § 409.44(c)(2)(B) require a qualified therapist (instead of an assistant) to provide the needed therapy service and functionally reassess the patient at least every 30 days. Where more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must provide the needed therapy service and functionally reassess the patient.

Comment: A commenter indicated that under the PDGM those HHAs with lower margins will be paid less and those HHAs with higher margins will be paid more. Another commenter indicated that there should be a site of service adjustment for patients in assisted living as their needs are greater.

Response: The goal of the PDGM is to more closely align payments with costs based on patient characteristics. The PDGM was not designed to help agencies achieve any particular margin. While a commenter noted that patients in assisted living facilities may have greater needs, we also note that an HHA may have lower costs when treating multiple patients within the same assisted living facility due to economies of scale (lower per visit costs due to transportation and other overhead costs spread over more visits). We will analyze data after implementation of the PDGM to determine whether a site of

service adjustment may be warranted in the future.

Comment: Another commenter asked if CMS would reimburse 30-day periods without a skilled visit when a skilled visit exists for the 60-day episode and certification period.

Response: Current regulation at § 409.45(a) does not permit coverage of dependent services (home health aide services, medical social services, occupational therapy, durable medical equipment, medical supplies, or intern and resident services) furnished after the final qualifying skilled service (skilled nursing; physical therapy; speech-language pathology; or a continuing occupational therapy after the need for skilled nursing, physical therapy and/or speech-language pathology services have ceased), except when the dependent service was not followed by a qualifying skilled service as a result of the unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event. We did not propose to change the regulation regarding coverage of dependent services after qualifying skilled services have ceased in this rule. Therefore, we would not pay 30-day periods without a qualifying skilled service. Furthermore, HHAs should not be billing for dependent services that occur after the last qualifying skilled service, unless such services occurred due to an unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event.

Comment: A commenter asked whether CMS would give guidance to MA plans to implement the PDGM. Another commenter asked how Medicare as a secondary payer would be impacted by the PDGM.

Response: We acknowledge that some Medicare Advantage plans could change their payment models to mirror PDGM, while others may not change their payment models in relation to the changes finalized in this rule. It should be noted that, as private plans, Medicare Advantage plans do not have to use the FFS payment methodology. Medicare Advantage payment models for home health currently take a wide variety of forms and some may already be approximating the structure of PDGM, using patient characteristics rather than service utilization as the basis for payment. We will work generally with stakeholders, including these private plans, to help ensure that adequate education and resources are available for all parties. The implementation of the PDGM will have no impact on the Medicare as a secondary payer process.

Final Decision: We are finalizing the change in the unit of payment from 60 days to 30 days, effective for 30-day periods of care that start on or after January 1, 2020, as proposed and in accordance with the provisions in the BBA of 2018. In addition, we are finalizing the PDGM, with modification, also effective for 30-day periods of care that start on or after January 1, 2020. We are also finalizing the corresponding regulations text changes as described in section III.F.13 of this final rule with comment period. We will provide responses to more detailed comments regarding the PDGM and the calculation of the 30-day budget neutral payment amount for CY 2020 further in this final rule with comment period.

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 proposed 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. Under the proposed PDGM, we group 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 proposed that resource use is the estimated 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. When NRS is factored into the average resource use, NRS costs are reflected in the average resource use that establishes 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. See the proposed rule for more detail on the steps used to generate the measure of resource use under the proposed CPM+NRS approach (83 FR 32385 through 32388).

The following is a summary of the public comments received on the ''Methodology Used to Calculate the Cost of Care'' proposal and our responses.

Comment: Several commenters objected to the use of Medicare cost report data rather than Wage-Weighted Minutes of Care (WWMC) in the methodology used to calculate the cost of care. Commenters indicated that HHAs' inputs, as demonstrated through cost reports, are not accurately reflecting the effects of changes in utilization, provider payments, and provider supply that have occurred over the past decade. They argue that the strength and utility of episode-specific cost depends on the accuracy and consistency of agencies' reported charges, cost-to-charge ratios, and episode minutes and that there are no incentives for ensuring the accuracy of their cost reports; and therefore the data are presumptively inaccurate. Several commenters also indicated that the use of cost report data in lieu of WWMC favors facility-based agencies because they have the ability to allocate indirect overhead costs from their parent facilities to their service cost and argue that the PDGM will reward inefficient HHAs with historically high costs. Finally, a few commenters indicated that they would support the CPM+NRS approach only if HHA cost reports were audited.

Response: We believe that the use of HHA Medicare cost reports better reflects changes in utilization, provider payments, and supply amongst Medicare-certified HHAs that occur over time. Under the WWMC approach, 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. Using 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. We note the correlation coefficient between the two approaches to calculating resource use is equal to 0.8537 (n=8,521,924). Correlation coefficients are used in statistics to measure how strong the relationship is between two variables. The closer to 1 the stronger the relationship (zero means no relationship). Therefore, the relationship between using the CPM+NRS approach compared to the WWMC approach is very similar. In conjunction with this final rule with comment period, we posted an excel file on the HHA Center page that includes the case-mix weights produced using the proposed CPM+NRS approach and those produced using the current

WWMC approach in calculating resource use.[10] The correlation coefficient between the two sets of weights (CPM+NRS versus WWMC using BLS data) is 0.9806, meaning the two methods produce very similar case-mix weights.

In response to comments regarding the accuracy of HHA Medicare cost report data, as we indicated in the proposed rule, we applied the trimming methodology described in detail in the ''Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates'' Report available at: *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf*. 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, 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. In eliminating missing or questionable data with extreme values from the data we obtain 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 relative weight aligns with the use of this data in determining the base payment amount under the HH PPS. Furthermore, we would 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. The HHA Medicare Cost Report (MCR) Form (CMS–1728–94) with this certification statement is available at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1728-94.html*.

As always, we encourage providers to fill out the Medicare cost reports as accurately as possible. We remind the industry again that each home health cost report is required to be certified by the Officer or Director the home health agency. We also welcome suggestions for improving compliance and accuracy on cost reports within the current cost reporting forms. We will explore whether it is feasible to provide some sort of national, mandatory training on completing the Medicare HHA cost report form and whether and to what extent CMS can conduct more desk reviews and audits of Medicare HHA cost reports in the future.

With regards to the case-mix weights rewarding inefficient providers with high costs or facility-based HHAs, each HHA's costs impact only a portion of the calculation of the weights and costs are blended together across all HHAs. To put it simply, the payment regression was estimated using 8,521,924 30-day periods from 10,522 providers. On average, each provider contributed 841 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 impact the results of the payment regression. 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. That is, we may find there are two HHAs with different cost structures (for example, HHA ''A'') has costs that are on average 1.5 times as high as HHA ''B'') but both HHAs can still have similar patterns in resource use across their 30-day periods. Since the PDGM is controlling for the variation in the general costs for HHAs with high and lower costs, including those that have variation in costs due to being facility-based versus freestanding, we do not agree that using the CPM+NRS approach in estimating resource use introduces a bias that favors inefficient or facility-based HHAs.

Comment: Several commenters stated that Non-Routine Supplies (NRS) should not be incorporated into the base rate and then wage-index adjusted. The industry stated that HHAs' supply costs are approximately the same nationally, regardless of rural or urban locations and regardless of the wage-index. Commenters stated that including NRS in the base rate will penalize rural providers and unnecessarily overpay for NRS in high wage-index areas. Another commenter indicated that CMS should lower the labor-related share to account for NRS in the base payment rate.

Response: As we noted in the CY 2008 HH PPS final rule with comment, use of NRS 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. We found 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). We noted in the CY 2008 HH PPS proposed rule that, in particular, commenters were concerned about the adequacy of payment for some patients with pressure ulcers, stasis ulcers, other ulcers, wounds, burns or trauma, cellulitis, and skin cancers (72 FR 25427). At that time (and currently), the clinical levels for the HH PPS did not group patients with similar supply needs together; therefore, for CY 2008 we created a separate case-mix adjustment process for NRS based on a NRS conversion factor and six severity levels. We noted that the NRS case-mix adjustment process did not have a high degree of predictive accuracy, possibly due to the limited data available to model NRS costs and the likelihood that OASIS does not have any measures available for some kinds of NRS. We stated in the CY 2008 HH PPS final rule that we would continue to look for ways to improve our approach to account for NRS by exploring alternative methods for accounting for NRS costs and payments in the future (72 FR 25428). We believe that the PDGM offers an alternative method for accounting for NRS costs and payments by grouping patients more likely to require high NRS utilization into two groups—the Wound group and the Complex Nursing Interventions group. For example, while the Wound group and Complex Nursing Interventions groups comprise about 10 percent and 4 percent of all 30-day periods of care, respectively; roughly 30 percent of episodes where NRS was supplied was for Wound and Complex Nursing Interventions groups and 47 percent of NRS charges fall into the Wound and Complex Nursing Interventions groups. We note that CY 2017 claims data indicates that about 71 percent of 60-day episodes did not provide any NRS.

As noted by the commenters, in the CY 2008 HH PPS proposed rule we stated that because the market for most NRS is national, we proposed not to have a geographic adjustment to the conversion factor (72 FR 25430). More accurately, because the NRS conversion factor reflected supplies and not wage and wage-related costs, we did not subject NRS payments to the geographic wage adjustment process. However, we

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

note that we did not revise the labor-related share to reflect the exclusion of NRS payments from the national, standardized 60-day episode payment amount. The labor-related share (LRS), effective for CY 2013 to CY 2018 home health payments of 78.535 percent is based on the 2010-based HHA market basket where the LRS is equal to the compensation cost weight, including salaries, benefits, and direct patient care contract labor. The non-labor-related share of 21.465 includes the relative costs for the NRS supplies. For comparison purposes, if we had removed NRS supplies from the calculations in the 2010-based Home Health market basket, the LRS would have been 79.7 percent and the non-labor-related share would have been 20.4 percent. Again, the LRS of 78.535 percent did not include NRS costs and therefore, NRS was not subjected to the geographic adjustment as it does not reflect wage and wage related costs. Similarly, the CY 2019 LRS of 76.1 percent, based on the 2016-based HHA market basket, also does not include NRS.

Comment: 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 commenters' human resources/staffing experiences in the markets where they operate. As such, commenters believe the use of cost report data would cause the PDGM model to overpay for nursing services and underpay for therapy services. A commenter indicated that contract staff are more expensive than staff that are hired and indicated this will widen the gap between nursing and therapy costs.

Response: The HHA Medicare cost report data reflects all costs and, most importantly, it reflects all labor costs, including contract labor costs. The BLS data only reflects employed staff. This may at least partially explain why a 40 percent variation between SN and PT costs is not evident in the cost report data. The HHA Medicare cost report data shows about a 20 percent difference between PT and SN compensation costs (wages and salaries, employee benefits and contract labor) per visit, which is consistent with the difference between PT and SN total costs per visit. Moreover, in aggregate, about 15 percent of compensation costs are contract labor costs and this varies among type of visit with contract labor costs accounting for a much higher proportion of therapy visit compensation costs compared to skilled nursing visit compensation cost. 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. It also seems to vary by region. The decision of whether to/or what proportion of contract labor to use is at the provider's discretion. In regards to the comment on expense of contracted services, we note that using cost report data allows those types of relationships to be fully measured. Finally, we note that in order to be eligible for Medicare HH PPS payments, providers must complete the HHA Medicare cost report; therefore, if providers are required to complete the cost report, then we believe such data are appropriate to use for payment purposes.

Comment: Several commenters indicated that WWMC and CPM+NRS results should be blended together to minimize disruptions.

Response: CMS appreciates this suggestion. However, there are difficulties in blending due to the WWMC and CPM+NRS approaches measuring different outcomes. WWMC is focused on cost of labor while CPM+NRS takes a more diverse approach and accounts for labor, overhead, and NRS. As discussed previously, there is very high correlation between the two approaches, meaning they produce very similar weights.

Comment: Another commenter indicated costs related to enrollment should be included in the calculation of resource use.

Response: These costs may be included in staffing and overhead costs and, if so, would be captured by the CPM+NRS approach.

Comment: A commenter cited a report that indicated for ''on-the-job activities undertaken by employees, HHS Guidelines recommend using estimates of pre-tax wages for the particular industry and affected occupation, to the extent possible, and adding estimate of benefits and indirect costs.''

Response: The goal of the CPM+NRS methodology is to not simply measure costs related to on-the-job activities. In order to account for a broader array of costs, which is necessary to assign accurate payment rates, we instead used information from cost reports which is more detailed than information on wages, benefits, and indirect cost.

Final Decision: We are finalizing our proposal to adopt a Cost-per-Minute plus Non-Routine Supplies (CPM+NRS) approach in estimating resource use, which uses information from HHA Medicare cost reports. The following steps would be used to generate the measure of resource use under the 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 do not have a cost report available (or a cost report that was trimmed from the sample), imputed values are used as follows:

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

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. Imputation for missing or trimmed values is done in the same manner as it was done for cost per visit (see [3] as previously indicated).

(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.

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. By examining the resources used within a 60-day episode of care, we 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. 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 apportions payments. In addition, with the removal of therapy thresholds from the case-mix adjustment methodology under the HH PPS, a shorter period of care reduces the variation and improves the accuracy of the case-mix weights generated under the PDGM.

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 final rule with comment period with regards to payment under the HH PPS. Therefore, in accordance with section 1895(b)(2)(B) of the Act, we proposed changing the unit of payment from a 60-day episode of care to 30-day unit of payment, effective January 1, 2020.

Comment: Many commenters understood the requirement for CMS to change from a 60-day episode to a 30-day unit of payment. Several commenters appreciated that CMS was maintaining the existing 60-day timing for comprehensive assessments, certifications and recertifications, and plans of care. Some commenters expressed concern that the 30-day payment period was more confusing because it is on a different a timeline than for other home health requirements such as the certification/recertification, OASIS assessments and updates to the plan of care.

Response: CMS thanks commenters for recognizing that the change from a 60-day unit of payment to a 30-day unit of payment is required by law and we do not have the discretion to implement a different policy. We believe that changing to a 30-day unit of payment will more accurately pay for services in accordance with patient characteristics and is a better approach to focus on patient care needs. We believe maintaining the existing timeframes for updates to the comprehensive assessment, updates to the plan of care, and recertifications will help make the transition to a new case-mix adjustment methodology more seamless for HHAs. Under the PDGM, the initial certification of patient eligibility, plan of care, and comprehensive assessment are valid for two 30-day periods of care (that is, for 60 days of home health care) in accordance with the home health regulations at 42 CFR 409.43 and 424.22, and the home health CoPs at 42 CFR 484.55. Each recertification, care plan update, and comprehensive assessment update will also be valid for two 30-day periods of care, also in accordance with the home health regulations at 42 CFR 409.43(e) and 424.22(b), and the home health CoPs at 484.60(c).

We also note that not all home health requirements have a 60-day timeframe. For example, OASIS reporting regulations require the OASIS to be completed within 5 days and transmitted within 30 days of completing the assessment of the beneficiary. In addition, physical, occupational, and speech therapists must provide the needed therapy service and functionally reassess the patient at least every 30 calendar days. Home health is not the only care setting where billing and certifications are not done in the same timeframe. For example, hospices must certify and recertify patients every 60–90 days and they bill on a monthly basis. Previous to the inception of the HH PPS, HHAs also billed on a monthly basis even though the plan of care and certifications were completed every 60 days.

Comment: Many commenters described the burden that would exist in switching to a 30-day period. Some commenters indicated their overhead costs would increase because they would have to double their billing and CMS should account for those costs. Some commenters believe that switching to 30-days would result in documentation errors and increased administrative burdens to both providers and to CMS due to an increase in claim submissions, resubmissions, and appeals. Some commenters indicated that switching to a 30-day billing cycle would result in a need to change current software and would require additional training for the providers. Commenters remarked they did not have the manpower to implement this change and that it goes against the Secretary's goal of reducing burden. Many commenters expressed concern that switching to a 30-day period would cause undue burden because of the current difficulty in getting physicians to sign the plan of care in a timely manner.

Response: Under section 1895(b)(2)(B) of the Act, we are required to apply a 30-day unit of service for purposes of implementing the HH PPS, effective January 1, 2020. We appreciate the commenters' concern regarding burden surrounding the change in the unit of payment from a 60-day episode to a 30-day period. While the change from a 60-day episode to a 30-day period may increase the billing frequency for final claims, we note that this change should not result in a measurable increase in burden, as many of the data elements that are used to populate an electronic claims submission will remain the same from one 30-day period to the next. HHAs are required to line-item bill each visit performed and whether each visit is recorded on a single 60-day claim or the visits are recorded on two different 30-day claims should not result in a measureable burden increase. Also, current data for CY 2017 suggests that nearly ⅓ of all 60-day periods would not produce a second 30-day period and would not require a second bill to be submitted. The proposed elimination of unnecessary items from the OASIS, especially those items no longer needed on follow-up assessments under the PDGM, would result in a decrease in regulatory burden, as discussed in section V. of this final rule with comment period. We remind commenters that prior to the inception of the HH PPS, HHAs also billed on a monthly basis even though the plan of care and certifications were completed every 60 days. We believe that the 30-day period is appropriate even if some requirements in home health have 60-day timeframes as a 30-day period of care under the PDGM better aligns home health payments with the costs of providing care. While we do not anticipate any increases in the numbers of appeals because of the implementation of the PDGM, we plan to conduct training and education for both HHAs and the MACs on the

operational aspects of the PDGM to mitigate any issues with claims submissions, resubmissions, and appeals.

Just like in the current system, under the PDGM, before a provider submits a final claim, the HHA will need to have a completed OASIS assessment, signed certification, orders, and plan of care. Our expectation is that the HHA will obtain the signed physician certification and plan of care timely. As we have reiterated in previous rulemaking and in sub-regulatory guidance, the certification must be complete prior to when an HHA bills Medicare for payment; however, physicians should complete the certification when the plan of care is established, or as soon as possible thereafter. This is longstanding CMS policy as referenced in Pub 100–01, Medicare General Information, Eligibility, and Entitlement Manual, chapter 4, section 30.1.[11] As stated in sub-regulatory guidance in the Pub. 100–02, Medicare Benefit Policy Manual, chapter 7, section, section 30.5.1, ''it is not acceptable for HHAs to wait until the end of a 60-day episode of care to obtain a completed certification/recertification.'' Per the regulations at § 409.43(c), if the HHA does not have detailed orders for the services to be rendered, the plan of care must either be signed or immediately sent to the physician for signature at the time that the agency submits its request for anticipated payment (submitted at the start of care after the first visit is performed). The Conditions of Participation (CoPs) require the Outcome and Assessment Information Set (OASIS) to be completed within 5 days and submitted within 30 days of completion. Under the PDGM, the initial certification of patient eligibility, plan of care, and comprehensive assessment are valid for two 30-day periods of care. Each recertification, care plan update, and comprehensive assessment update will also be valid for two 30-day periods of care.

Comment: Another commenter indicated that if there was a 30-day period then the face-to-face encounter requirement provision could be eliminated. Another commenter asked if all physicians' orders must be signed and returned before the HHA can bill the first 30-day period. A commenter questioned what would occur with episodes where a portion of the payment started prior to the implementation date of January 1, 2020. Another commenter questioned what would happen if a patient's diagnosis changes for the second 30-day period, as no additional comprehensive assessment is required before the second payment period.

Response: The face-to-face requirement is statutorily required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act as part of the certification for home health services. As a condition of payment for Medicare home health benefits, a face-to-face encounter must meet the requirements as set forth at § 424.22(a)(1)(v). The intent of the face-to-face encounter requirement is to achieve greater physician accountability in certifying a patient's home health eligibility and in establishing a patient's plan of care. As such, this requirement is unrelated to the switch from a 60-day episode to a 30-day period. Likewise, the requirements for submission of home health claims have not changed. The regulations at § 409.43 state that in order to submit a final claim for payment, the plan of care and any physician's orders must be signed and dated by the physician before the HHA bills for the care.

For implementation purposes, 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 periods of care that begin on or after January 1, 2020, the unit of payment 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 periods of care 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.

As we have stated, the requirements for when to update the comprehensive assessment remain unchanged. For example, if the HHA does not need to update the comprehensive assessment prior to recertifying the patient (for which the comprehensive assessment would be completed within the last 5 days of every 60 days beginning with the start of care date), then responses from the start of care OASIS would be used for determining the functional impairment level for both the first and second 30-day periods. The follow-up OASIS completed near the time of recertification would be used for the third and fourth 30-day periods of care. If, for example, the HHA needs to complete a resumption of care OASIS within 48 hours of the patient returning to home health after being transferred and admitted to the hospital for 24 hours or more and this occurs during the first 30-day period of care, then the responses for functional items from the resumption of care assessment would be used to determine the functional impairment level for the second 30-day period of care.

With regards to diagnosis codes, the PDGM uses the diagnoses from the home health claim to group a 30-day home health period of care into a clinical group and to determine if there is a comorbidity adjustment. If a home health patient has any changes in diagnoses (either the principal or secondary), this would be reflected on the home health claim and the case-mix weight could change accordingly. However, we would expect that the HHA clinical documentation would also reflect these changes and any communication/coordination with the certifying physician would also be documented. The home health CoPs at § 484.60(c) require that the HHA must promptly alert the relevant physician(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

b. 30-Day Unit of Payment

Section 1895(b)(3)(A)(iv) of the Act, requires CMS 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. As also required by 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, and take into account behavior changes that could occur as a result of the implementation of the 30-day unit of payment and case-mix adjustment factors 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, before application of the home health applicable percentage increase, the adjustment for case-mix changes, the adjustment if quality data is not reported, and the productivity adjustment.

[11] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ge101c04.pdf.*

To calculate the 30-day budget-neutral payment amount, we proposed 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:

- Clinical Group Coding: This is based on the principal diagnosis code for the patient as reported by the HHA on the home health claim. Our proposed assumption was that HHAs will change their documentation and coding practices and 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.
- Comorbidity Coding: The PDGM further adjusts payments based on patients' secondary diagnoses as reported by the HHA on the home health claim. OASIS only allows HHAs to designate 1 principal diagnosis and 5 secondary diagnoses while the home health claim allows HHAs to designate 1 principal diagnosis and 24 secondary diagnoses. Our proposed assumption was 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
- LUPA Threshold: Under the proposed PDGM, our proposed assumption was 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.

If no behavioral assumptions were made, we estimated 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). Because we proposed to implement the 30-day unit of payment and the 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)(B)(i) of the Act). In the proposed rule, we noted 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 previously outlined, 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.

We solicited comments on the proposed behavior change assumptions previously outlined to be used in determining the 30-day payment amount for CY 2020.

The following is a summary of the public comments received on the ''30-day Unit of Payment'' proposals and our responses.

Comment: Some commenters expressed support for the inclusion of behavioral assumptions in calculating the budget-neutral 30-day payment amount. Some commenters stated that using these behavioral assumptions may help mitigate potential program integrity issues which could cause disruptions in patient care.

Response: We thank commenters for their remarks supporting the behavioral assumptions. The purpose of these behavioral assumptions is not to incorporate a built-in program integrity measure, but rather CMS is required by law to make behavioral assumptions when calculating a 30-day budget-neutral payment amount for CY 2020. Also as required by section 1895(b)(3)(D)(i) of the Act, as added by section 51001 of the BBA of 2018, we will analyze the impact of the assumed versus the actual behavior change after the implementation of the PDGM and the 30-day unit of payment to determine if any payment adjustment, either upward or downward, is warranted. We will monitor utilization trends after implementation of the PDGM in CY 2020 to identify any aberrant behavior or significant changes in practice patterns that may signal potential program integrity concerns and investigate such occurrences accordingly.

Comment: The majority of commenters stated that CMS should not apply behavioral assumptions industry-wide as it punishes all HHAs for the performance of small set of agencies and these commenters expressed concern over what they describe as an adversarial approach to assumed behavior changes. Many of the commenters were concerned with the broad assumption by CMS that HHAs would indulge in ''gaming'' and unethical behavior to compensate for the changes within the PDGM model. It was stated that CMS should instead do more targeted program integrity efforts, such as creating a system of audits and significant monetary or other punishments, or adjust payments only for HHAs whose reimbursement falls outside normal variations. It was also suggested that HHAs that do not actually change their behavior in response to the PDGM should have a different payment rate structure compared to HHAs that do change their behavior.

Response: By including behavior change assumptions in the proposed calculation of the 30-day payment amount, as required by statute, we did not intend to imply that HHAs would engage in unethical behavior; therefore, these assumptions are not meant to be punitive. We acknowledge that in making assumptions about provider behavior, no matter if required by law or well-supported by evidence, there will be those who will disagree with this type of approach to adjusting payment. We have addressed in the CY 2016 HH PPS final rule why we do not believe targeted program integrity efforts would mitigate behavioral changes resulting from a case-mix system (80 FR 68421). As we stated in the CY 2016 HH PPS final rule (80 FR 68421 through 68422), for a variety of reasons, we have not proposed targeted reductions for nominal case-mix growth, meaning the portion of case-mix growth that cannot be explained by changes in patient characteristics. The foremost reason is that we believe changes and improvements in coding have been widespread, so that such targeting would likely not separate agencies clearly into high and low coding-change groups. In that same rule, we referenced an independent review of our case-mix measurement methodology conducted by Dr. David Grabowski, Ph.D., a professor of health care policy at Harvard Medical School, and his team agreed with our reasons for not proposing targeted reductions, stating their concerns about the small sample size of many agencies and their findings of significant nominal case-mix across different classes of agencies (please see the ''Home Health Study Report—Independent Review of the Models to

Assess Nominal Case-Mix Growth'', dated June 21, 2011.) [12]

While certain commenters seem to assume that CMS can precisely identify those agencies practicing abusive coding, we do not agree that agency specific case-mix levels can precisely distinguish the agencies that engage in abusive coding from all others. System wide, case-mix levels have risen over time throughout the country, while patient characteristics data indicate little real change in patient severity over time. That is, the main issue is not the level of case-mix billed by any specific HHA over a period of time, but the amount of change in the billed case-mix weights not attributable to underlying changes in actual patient severity. Therefore, while commenters provided specific suggestions for targeted efforts, we are unable to implement such actions for the reasons described. We note that we have taken various measures to reduce payment vulnerabilities and the federal government has launched actions to directly identify fraudulent and abusive activities. Commenters should be aware of tip lines available that can help support investigative efforts of the federal government. The Office of the Inspector General, Department of Health and Human Services website at: *http://oig.hhs.gov/fraud/report-fraud/index.asp,* provides information about how to report fraud. Another website, *http://www.stopmedicarefraud.gov/index.html,* is oriented to Medicare patients and their families and provides information about recognizing fraud.

Finally, we remind commenters that section 1895(b)(3)(A)(iv) of the Act requires that in calculating a 30-day budget-neutral payment amount, 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 and a change to the case-mix adjustment methodology; therefore, we do not have the discretion to apply different policies. Likewise, we are required to analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and the alternate case-mix adjustment methodology, to annually determine the impact of the differences between assumed behavioral changes and actual behavioral changes on estimated aggregate expenditures and adjust the payment amount either upwards or downwards accordingly.

Comment: Several commenters disagreed with the three behavioral assumptions made and remarked that the assumptions appear to be randomly determined, inappropriate and that there is no evidence to support them. A commenter specifically stated that the assumptions lack any foundation in actual evidence-based data and therefore penalize providers in an arbitrary and capricious fashion in violation of the Administrative Procedures Act (APA). A few remarked that the assumptions are ''mere guesses'' and appear to be used solely to reduce home health payments. Other commenters remarked that the proposed behavioral assumptions appear to be overly complex and unsubstantiated. Some commenters stated the assumptions are illogical because the broad assumptions in the proposed rule basically construct a completely new payment system that is predicated on a presumption that HHAs will attempt to manipulate the system and recommended that the behavioral assumptions be tested before they are implemented. Many commenters asked for additional documentation on how the reductions derived from the three behavioral assumptions were calculated and wanted to know the specific calculations that were made and the rationale behind those calculations.

Response: We disagree that the three behavioral assumptions made are arbitrary, inappropriate, illogical, mere guesses, overly complex, meant to penalize providers, or that there is no evidence to support them. Likewise, we disagree that these assumptions are in violation of the APA given that CMS is required by statute to apply behavioral assumptions in calculating the 30-day budget-neutral payment amount; we described such assumptions in notice and comment rulemaking as required by section 1895(b)(3)(A)(iv) of the Act. Additionally, we examined relevant data and believe we have a satisfactory explanation for these assumptions, including a substantive connection between the data and the behavioral assumptions made. We believe that there is both evidence for and precedent for adjusting the home health prospective payment based on assumed behavioral changes.

With regards to our assumption that HHAs would code the highest-paying diagnosis code as primary for the clinical grouping assignment, this assumption was based on decades of past experience under the case-mix system for the HH PPS and other case-mix systems for other payment systems, such as the implementation of the diagnosis-related groups (DRGs) and the Medicare Severity (MS)-DRGs under the inpatient prospective payment system. In the FY 2008 IPPS final rule (72 FR 47176), we noted that case-mix refinements can lead to substantial unwarranted increase in payments. To address this issue when CMS transitioned from DRGs to MS–DRGs, MedPAC recommended that the Secretary project the likely effect of reporting improvements on total payments and make an offsetting adjustment to the national average base payment amounts (72 FR 47176). In the FY 2008 IPPS final rule (72 FR 47181), we summarized instances where case-mix increases resulted from documentation and coding-induced changes for the first year of the IRF PPS and in Maryland hospitals' transition to APR DRGs (estimated at around 5 percent in both instances). Therefore, we estimated that a total adjustment of 4.8 percent would be necessary to maintain budget neutrality for the transition to the MS–DRGs (72 FR 47178).

In both the FY 2010 and FY 2011 IPPS final rules, subsequent analysis of claims data, using FYs 2008 and 2009 claims, supported the prospective payment adjustments to account for the documentation and coding effects (74 FR 43770 and 75 FR 50356). Specifically, we stated that based on our retrospective evaluation of claims, our actuaries determined that the implementation of the MS–DRG system resulted in a 2.5 percent change and a 5.4 percent change in case-mix not due to actual changes in patient characteristics, but due to documentation and coding changes for discharges occurring during FYs 2008 and 2009, respectively. We stated that the coding assumption is appropriate because, in the absence of such adjustments, the effect of the documentation and coding changes resulting from the adoption of the MS–DRGs results in inappropriately high payments because that portion of the increase in aggregate payments is not due to an increase in patient severity of illness (and costs).

With regards to experience under the HH PPS, we note that effective for CY 2008, CMS finalized changes to the HH PPS case-mix model to reflect different resource costs for early home health episodes versus later home health episodes and expanded the case-mix variables and therapy thresholds included in the payment model (72 FR 49764). These changes resulted in the 153 home health resource groups (HHRGs) currently used to case-mix adjust payment in the HH PPS. Since the CY 2008 proposed rule, we have stated in HH PPS rulemaking that we would continue to monitor case-mix

[12] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HHPPS_HHAcasemixgrowthFinalReport.pdf.*

changes in the HH PPS and to update our analysis to measure change in case-mix, both nominal and real. As discussed in the CY 2010 HH PPS rule (74 FR 40958), the analysis then indicated approximately 9.77 percent of the 15.03 percent increase in the overall observed case-mix between the IPS baseline and 2007 was real, that is, due to actual changes in patient characteristics. Our estimate was that a 13.56 percent nominal increase $(15.03 - (15.03 \times 0.0977))$ in case-mix was due to changes in coding procedures and documentation rather than to treatment of more resource-intensive patients (that is, nominal case mix growth). In the CY 2011 HH PPS proposed rule, we stated from 2000 to 2007, we observed about a 1 percent per year increase in total average case-mix. However, that annual change increased to slightly more than 4 percent [4.37 percent] between 2007 and 2008 (75 FR 43238). Our analyses at that time indicated a 19.40 percent increase in the overall observed case-mix since 2000 with approximately 10.07 percent attributed to actual changes in patient characteristics. Our estimate was that a 17.45 percent nominal increase $(19.40 - (19.40 \times 0.1007))$ in case-mix was due to changes in coding practices and documentation rather than to treatment of more resource-intensive patients. In the CY 2012 HH PPS proposed rule we stated that our analysis indicated another large increase in the average case-mix weight between CY 2008 and CY 2009 of 2.6 percent (76 FR 40990), attributable to the CY 2008 refinements. Therefore, analysis of case-mix growth between the two years immediately after implementation of the CY 2008 refinements demonstrated that average case-mix increased by nearly 7 percent. Our latest analysis continues to support the payment adjustments as outlined in the CY 2018 HH PPS proposed rule (82 FR 35274), which shows that between CY 2000 and 2010, total case-mix change was 23.90 percent, with 20.08 considered nominal case-mix growth, an average of approximately 2 percent nominal case-mix growth per year, including changes due to the CY 2008 case-mix adjustment methodology refinements. Therefore, we believe that there is ample evidence supporting the behavioral assumptions relating to changes, including improvements, in coding.

Our analysis shows that only about a third of 30-day periods move into a different clinical group as a result of the clinical group coding assumption, meaning that the reported secondary diagnosis(es) would place a period of care into a higher case-mix group under the PDGM if reported as the principal diagnosis. Clinically, there are circumstances in which it would be appropriate to report a higher paying code as the principal diagnosis. For example, if medical documentation notes that a patient was recently hospitalized for exacerbation of congestive heart failure (which, if reported as the principal diagnosis, would group a period of care into the clinical group, MMTA) and there is expected teaching by the HHA associated with the recent exacerbation, but the patient also has a stage 2 pressure ulcer (which, if reported as the principal diagnosis, would group a period of care into the clinical group, Wounds) that requires wound care, we believe it would be appropriate to report the pressure ulcer as the principal diagnosis as the pressure ulcer would likely take priority as the primary reason for home health care in terms of increased resource utilization. However, the teaching associated with the exacerbation of heart failure would be a secondary reason, but still an important additional reason for home health care, and congestive heart failure would be reported as an additional diagnosis on the home health claim. In the current HH PPS, the assignment of points as part of the clinical level in the case-mix methodology is dependent upon the reporting of diagnoses. However, the points assigned are not generally dependent on whether the diagnosis is reported as the primary diagnosis or other diagnosis, except for a few exceptions. This means, that for most of the clinical point assignments, the ordering of the diagnosis does not matter as much as whether the diagnosis is present or not. For example, if a cancer diagnosis is reported, there are the same number of associated clinical points regardless of whether the cancer diagnosis is reported as a principal diagnosis or as a secondary diagnosis. However, under the PDGM, the ordering of diagnoses is important in determining the clinical group and the comorbidity adjustment, so we do expect that HHAs will improve the ordering of diagnosis codes to ensure that the home health period of care is representative of patient characteristics and paid accordingly. Furthermore, the implementation of ICD–10–CM has expanded the diagnosis code set significantly, making it possible for HHAs to more accurately and specifically code conditions present in the home health patient population.

With regards to the comorbidity coding assumption, using the home health claim for the comorbidity adjustment as opposed to OASIS provides more opportunity to report all comorbid conditions that may affect the home health plan of care. The OASIS item set only allows HHAs to designate up to 5 secondary diagnoses, while the home health claim (837I institutional claim format-electronic version of the paper UB–04) allows HHAs to report up to 24 secondary diagnoses. Additionally, because ICD–10 coding guidelines require reporting of all secondary diagnoses that affect the plan of care, we would expect that more secondary diagnoses would be reported on the home health claim given the increased number of secondary diagnosis fields on the home health claim compared to the OASIS item set. Therefore, we assume that by taking into account additional ICD–10–CM diagnosis codes listed on the home health claim, more 30-day periods of care will receive a comorbidity adjustment than periods otherwise would have received if we only used the OASIS diagnosis codes for payment. Furthermore, because the comorbidity adjustment in the PDGM can increase payment by up to 20 percent, we assume that HHAs will ensure that secondary diagnoses affecting the home health plan of care would be reported to more accurately identify the conditions affecting resource use.

Regarding the LUPA threshold assumption, as noted in the FY 2001 HH PPS final rule, the episode file showed that approximately 16 percent of episodes would have received a LUPA (65 FR 41162). However, currently, only about 7 percent of all 60-day episodes receive a LUPA. In other words, it appears HHAs changed practice patterns such that more than half of 60-day episodes that would have been LUPAs upon implementation of the HH PPS are now non-LUPAs. Current data for CY 2017 suggest that what would be about one-third of the LUPA episodes with visits near the LUPA threshold would move up to become non-LUPA episodes as we currently see clustering of episodes at and around the current LUPA threshold of 5 visits. Under the current 60-day episode structure, there is a natural breaking point in the distribution of episodes between those with 4 or fewer visits (LUPAs) and those with 5 or more visits (non-LUPAs). The distribution around this breaking point of episodes as a percent of total episodes has remained fairly constant over the last few years. In particular, the episodes with 2, 3, or 4 visits are similar, with each comprising about 2.4 percent of total episodes. Likewise, the

episodes with 5, 6, or 7 visits each represent about 4.6 percent of total episodes. We assume this same phenomenon will be observed in the PDGM, except that, to account for the different threshold structure, it will occur for periods that otherwise would be 1 or 2 visits away from becoming non-LUPA.

We disagree with those commenters who state that the behavioral assumptions basically construct a completely new payment system that is predicated on gaming of the system. The goal of the proposed PDGM is to more accurately pay for home health services based on patient characteristics. As previously noted, section 1895(b)(3)(A)(iv) of the Act requires that behavioral assumptions be made in calculating the payment amount for CY 2020 so that the estimated aggregate amount of expenditures under the HH PPS in CY 2020 is equal to the estimate aggregate amount of expenditures in CY 2020 that otherwise would have been made under the HH PPS if the change to a 30-day unit of payment had not been enacted. Furthermore, we remind commenters that the law requires that CMS analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and the alternate case-mix adjustment methodology, to annually determine the impact of the differences between assumed and actual behavioral changes on estimated aggregate expenditures and adjust the payment amount either upwards or downwards accordingly. As such, we do not believe the law provides the latitude to test behavioral assumptions prior to implementation of the 30-day unit of payment and the PDGM for CY 2020 given these requirements, in law, to make behavioral assumptions in calculating a 30-day budget-neutral payment amount for CY 2020 and to determine the impact on estimated aggregate expenditures of differences between the assumed and actual behavior changes once the data for CYs 2020 through 2026 become available to determine whether temporary and permanent adjustments are needed.

We believe that, as described in the CY 2019 HH PPS proposed rule and throughout this final rule with comment period, we have provided sufficient detail for these behavioral assumptions as well as referenced past rules in which nominal case-mix change has been evaluated. The reconciliation process involving temporary and permanent adjustments required by law should assure HHAs that any over or underestimate of the payment amount will be adjusted accordingly. However, to support HHAs in evaluating the effects of the proposed PDGM, CMS provides, upon request, a Home Health Claims-OASIS Limited Data Set (LDS) to accompany the proposed and final rules. 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.*

Comment: In its public comments to the proposed CY 2019 HH PPS rule, MedPAC stated that the past experience of the home health PPS demonstrates that HHAs have changed coding, utilization, and the mix of services provided in reaction to new payment incentives. MedPAC remarked that CMS continued to find nominal increases in case mix unrelated to patient severity in later years and reduced payment by an average of 1.8 percent a year in 2008 through 2017 to account for this trend. MedPAC remarked that the proposed home health payment reduction of 6.42 percent appears to be consistent with past coding trends but that they do not expect that the reduction would create payment adequacy issues for most HHAs. As MedPAC has noted previously, the average margin of Medicare HHAs is 15.5%.

Response: We thank MedPAC for their comments and we agree that there is sufficient evidence of HHA behavioral responses in reaction to payment incentives. We believe that HHA margins are adequate and that the 30-day budget-neutral payment amount should not cause revenue concerns for the majority of HHAs.

Comment: Some commenters asked CMS to clarify their interpretation of the BBA of 2018 as it relates to budget neutrality. Specifically, Another commenter indicated that CMS should clarify that Congress intended to replace the existing budget neutrality requirement under the HH PPS with a temporary one-year budget neutrality requirement for CY 2020 that would be limited to maintaining equal aggregate expenditures associated with the transition between 60-day to 30-day units of service.

Response: The law does not require CMS to replace the current budget neutrality requirements as set forth in section 1895(b)(3)(A) of the Act. However, 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. 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. However, this does not mean that the 30-day budget-neutral payment amount only pertains to payments made in CY 2020 as we remind commenters that we are required to annually determine the impact of differences between assumed and actual behavior changes on estimated aggregate expenditures for CY 2020 through CY 2026 and adjust the payment amount upwards or downwards accordingly. 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)(B)(ii)(V) of the Act).

Comment: Several commenters asked how CMS will make the reconciliation between assumed and actual behavioral changes upon implementation of the PDGM. A commenter indicated that CMS should fully display the reconciliation process with public notice and an opportunity to comment in advance of its application. Another commenter wanted to know if CMS would update its behavioral assumptions using CY 2020 data to compare actual behavior to assumed behavior. Several commenters were concerned that CMS was placing a cap on the growth in home health services and in the event of growth, future payments would be reduced to match a payment amount from a prior year. A few commenters indicated that the behavioral assumptions are already accounted for in the current PPS and stated that HHAs already are incentivized to report the highest paying clinical diagnosis code on the claim, and also to develop and deliver plans of care that exceed the LUPA threshold.

Response: We provided a detailed explanation as to how we calculated the 30-day budget-neutral payment amount in the CY 2019 HH PPS proposed rule (83 FR 32389) Specifically, we described how we calculated the budget-neutral 30-day payment amounts, both with and without behavioral assumptions and using CY

2019 payment parameters (for example, proposed 2019 payment rates, proposed 2019 case-mix weights, and outlier fixed-dollar loss ratio) to determine the expenditures that would occur under the current case-mix adjustment methodology. As with all elements of the PDGM, we would update the impacts of the proposed behavioral assumptions using CY 2018 claims data in CY 2020 proposed rulemaking. This would be described in the CY 2020 HH PPS proposed rule to ensure HHAs are fully aware of the behavioral assumption impacts on the payment amount for CY 2020 using the most recent data available for CY 2020 implementation.

In accordance with the BBA of 2018, we will annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures for CYs 2020 through 2026. We interpret actual behavior change to encompass both behavior changes that were previously outlined, 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.

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with more current data. Therefore, we refer commenters to previous HH PPS rules (for example, CY 2016 HH PPS final rule, (80 FR 68629)), where we recalibrate case-mix weights to account for nominal case-mix change. We anticipate a similar methodology when making any required permanent and temporary adjustments to payments, as required under sections 1895(b)(3)(D)(ii) and (iii) of the Act, to address the impact of the assumed versus actual behavioral change after implementation of the PDGM and the 30-day budget-neutral payment amount. Section 1895(b)(3)(D)(ii) of the Act requires notice and comment rulemaking for any permanent adjustments. Section 1895(b)(3)(D)(iii) of the Act similarly requires notice and comment rulemaking for any temporary adjustments. As a result, any reconciliation methodology for permanent and/or temporary adjustments would be subject to rulemaking, with the opportunity for the public to provide comments prior to the finalization of any policies. The data from CYs 2020 through 2026 will be available to determine whether temporary adjustments and/or permanent adjustments (increase or decrease) are needed no earlier than in years 2022 through 2028 rulemaking.

We believe that the temporary and prospective adjustments outlined in the statute are not meant to act as a cap on overall home health expenditures. CMS is required by section of 1895(b)(3)(A)(iv) of the Act to calculate a 30-day payment amount for CY 2020 in a budget neutral manner so that estimated aggregate expenditures under the HH PPS during CY 2020 made under the new 30-day unit of payment would be equal to the estimated aggregate expenditures that otherwise would have been made in the absence of the 30-day unit of payment. Likewise, any permanent or temporary adjustments made, as required by the BBA of 2018, would be made to address the impact of differences between assumed and actual behavior changes on estimated aggregate expenditures with respect to years beginning with 2020 and ending with 2026. Any adjustment to the payment amount resulting from differences between assumed versus actual behavior changes would not be related to increases in the number of beneficiaries utilizing Medicare home health services. The purpose of the required behavioral assumptions is to calculate the 30-day budget-neutral payment amount and not to limit payment for home health services or access to needed care.

We disagree with comments that state that the behavioral assumptions made under the PDGM are already accounted for in the current HH PPS case-mix system given the assumptions made under the proposed PDGM are based on a shorter unit of payment, 30 days as opposed to the current 60 days. As described throughout this final rule with comment period and the proposed rule, the variation in resource utilization is most notable in the first versus second and subsequent 30-day periods of care. Consequently, the behavioral assumptions are based on the 30-day unit of payment and the unique case-mix variables that are present under the PDGM, but not under the current HH PPS case-mix system.

Comment: A few commenters remarked that it would be difficult to change their behavior in response to the PDGM. For example, these commenters referenced the LUPA thresholds that vary by case-mix group and stated that these are difficult to understand and that it would be extremely difficult for a front line care provider to know for a specific patient whether they were close to a LUPA threshold.

Response: As we have described in detail in the CY 2019 HH PPS proposed rule and other rules, the evidence supports a pattern of ''practicing to the payment''. Specifically, there is ample evidence that there are notable behavior changes as they relate to payment thresholds. The findings from the Report to Congress on the ''Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations'', note that concerns have been raised about the use of therapy thresholds in the current HH PPS. Under the current payment system, HHAs receive higher payments for providing more therapy visits once certain thresholds are reached. As a result, the average number of therapy visits per 60-day episode of care have increased since the implementation of the HH PPS, while the number of skilled nursing and home health aide visits have decreased over the same time period as shown in Figure 3 of the CY 2018 HH PPS proposed rule (82 FR 35276). The study demonstrates that the percentage of episodes, and the average episode payment by the number of therapy visits for episodes with at least one therapy visit in 2013 increased sharply in therapy provision just over payment thresholds at 6, 7, and 16. Similarly, between 2008 and 2013, MedPAC reported a 26 percent increase in the number of episodes with at least 6 therapy visits, compared with a 1 percent increase in the number of episodes with five or fewer therapy visits.[13] CMS analysis demonstrates that the average share of therapy visits across all 60-day episodes of care increased from 9 percent of all visits in 1997, prior to the implementation of the HH PPS (see 64 FR 58151), to 39 percent of all visits in 2015 (82 FR 35277). Furthermore, as noted in the FY 2001 HH PPS final rule, the episode file showed that approximately 16 percent of episodes would have received a LUPA (65 FR 41162). However, currently, only about 7 percent of all 60-day episodes receive a LUPA. In other words, it appears HHAs changed practice patterns such that more than half of 60-day episodes that would have been LUPAs upon implementation of the HH PPS are now non-LUPAs.

Therefore, past analysis confirms that there are noted changes in provider behavior resulting from the presence of thresholds that affect payment. As such, we believe that the presence of thresholds, regardless of whether they are therapy or LUPA thresholds, provides the incentive for providers to

[13] Medicare Payment Advisory Commission (MedPAC). ''Home Health Care Services.'' *Report to Congress: Medicare Payment Policy.* Washington, DC, March 2015. P. 223. Accessed on September 9, 2018 at *http://www.medpac.gov/docs/default-source/reports/chapter-9-home-health-care-services-march-2015-report-.pdf?sfvrsn=0.*

adopt business practices that encourage the provision of visits to meet and exceed these thresholds to receive higher payment.

Comment: A few commenters noted language in the FY 2019 Skilled Nursing Facility Prospective Payment System (SNF PPS) Final Rule (83FR 39162), which included a payment and case-mix redesign known as the Patient-Driven Payment Model (PDPM) and noted that CMS declined to make any behavioral adjustments in the PDPM. These commenters stated that because the PDPM did not implement behavioral adjustments then the PDGM also should not implement behavioral adjustments.

Response: We remind commenters that section 1895(b)(3)(A)(iv) of the Act requires CMS to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and changes to the case-mix adjustment methodology when calculating the 30-day budget-neutral payment amount for CY 2020. Furthermore, as previously described in detail, we believe we have ample experience and data regarding changes in provider behavior made in response to payment changes that support the proposed behavioral assumptions. Additionally, the law requires us to annually determine the impact of differences between assumed and actual behavior changes on estimated aggregate expenditures for CY 2020 through CY 2026 and adjust the payment amount upwards or downwards accordingly. We will analyze any actual, observed behavioral changes with respect to CYs 2020 through 2026 to make any payment adjustments beginning in CY 2022 at the earliest.

Comment: Some commenters indicated that the behavioral assumptions were too high and out of line with case-mix adjustments made in recent years. Commenters indicated that CMS should phase in reductions over multiple years if they exceeded a certain amount (for example, 2 percent). Commenters indicated that adjustments should be based on actual behavior change and not based on assumed behavioral change. Several commenters recommended delaying implementation of the behavioral assumptions until actual data on provider behavior is available.

Response: As detailed throughout this final rule with comment period, we believe there is sufficient evidence supporting the behavioral assumptions and payment impacts. Therefore, we disagree that the impacts of the assumptions are too high or not in alignment with previous analysis of nominal case-mix growth. Likewise, MedPAC commented that they believe the 6.42 percent reduction to the payment amount from the behavioral assumptions was appropriate and does not expect that this percent reduction would create payment adequacy issues for most HHAs.

We acknowledge that there have been previous phase-ins of other payment adjustments to account for nominal case mix growth. We remind commenters that the statute requires that in calculating the 30-day budget-neutral payment amount, for home health units of service furnished that end during the 12-month period beginning January 1, 2020, the Secretary shall make assumptions about behavior changes that could occur as a result of the implementation of a 30-day unit of payment and the alternate case-mix adjustment methodology. Therefore, we do not have the discretion to implement a different policy. However, because the statute requires that we must 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, and to make payment amount adjustments accordingly, we believe there is already a mechanism in place to assure HHAs that payment amount will be adjusted to accurately account for actual behavior.

We remind commenters that the 30-day unit of payment and the PDGM will not be implemented until CY 2020 and CMS will analyze claims data from CY 2018 to determine any changes to the payment amount for CY 2020 and will propose the amount in the CY 2020 HH PPS proposed rule. Finally, we are required to make the adjustments at a later date when we have actual data. Therefore, we can ensure that the 30-day payment amounts are set at the level they would have been had changes in case mix due to behavior adjustments been known. Therefore, we do not believe it is necessary to phase-in the impacts of the behavioral assumptions. By providing updated analysis and payment rates in the CY 2020 HH PPS proposed rule, this will allow stakeholders additional opportunity to comment on the behavioral assumption impacts. While many commenters wanted CMS to delay implementation of the behavioral assumption impacts until actual data are available, CMS is required under section 1895(b)(3)(A)(iv) of the Act to take into account behavior changes that could occur as a result of the implementation of a 30-day unit of payment and the case-mix adjustment factors that are implemented in CY 2020 when calculating the 30-day budget neutral payment amount for CY 2020. Deferring until actual data are available would delay implementation of the behavioral assumption impacts until CY 2022, which would not meet the requirements of the statute. Data from CY 2020 to 2026 will be available to determine whether temporary or permanent adjustments to the payment amounts are needed.

Comment: Several commenters encouraged CMS to closely monitor utilization patterns, billing trends, and other associated behaviors following implementation of the PDGM, to ensure that beneficiary access is not negatively impacted as a result of the new case-mix system, particularly the switch from a 60-day episode to a 30-day unit of payment. There was also concern that agencies may inappropriately extend 30-day periods that previously would have ended within 30 days in order to receive additional payment. There were other commenters who indicated that 30-day periods would cause beneficiaries to be discharged from home health earlier than they otherwise would be. Some commenters were concerned that certain visits would be frontloaded under a 30-day system as opposed to being spread out over a longer period of time, whereas another commenter indicated that have a 30-day period would discourage frontloading.

Response: The goal of the PDGM is to more accurately align payment with the cost of providing care and is not meant to penalize or harm providers or beneficiaries. We recognize that changes in payment generally have an effect on the provision of services and we believe we have accounted for those assumed behavioral changes in calculating the 30-day budget-neutral payment amount. To address concerns regarding patient access and safety, we remind commenters that the home health CoPs are to help ensure the health and safety of Medicare beneficiaries. The home health CoPs have requirements as they relate to the content of the plan of care. Specifically, the CoPs at § 484.60 state that the individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. Services must be furnished in accordance with accepted standards of practice. Therefore, upon implementation of the PDGM, we expect that HHAs will

continue to provide the services in accordance with the existing requirements. As such, we would not expect HHAs to inappropriately discharge home health patients or extend unnecessary home health services.

CMS does not intend to prescribe how home health agencies provide care to their patients. As reiterated throughout this section, services provided, including the disciplines providing the care and the frequency of those services, are done so in accordance with an individualized plan of care, established and periodically reviewed by the certifying physician. We recognize that some beneficiaries may benefit from the frontloading of visits and there has been research to indicate that the frontloading of skilled visits is beneficial to some patients and may reduce hospitalization.[14] However, there may be other beneficiaries that may benefit from visits that are provided over a longer period of time. In accordance with the plan of care requirements at § 484.60, we expect the provision of services to be made to best meet the patient's care needs. After implementation of the PDGM and a change to the 30-day unit of payment, CMS will closely monitor utilization patterns, beneficiary impact and provider behavior to see if any refinements to the PDGM are warranted, or if any concerns are identified that may signal the need for appropriate program integrity measures.

Comment: MedPAC recommended that CMS include an additional behavioral assumption to account for responses to the shorter unit of payment that would result in increased aggregate payments (that is, HHAs changing visit patterns such that instead of having a single 30-day period of care, they would provide just enough visits to get payment for a second 30-day period of care).

Response: Public comments received in response to both the CY 2018 and CY 2019 HH PPS proposed rules presented conflicting predictions regarding anticipated provider behavior in response to the timing element of the PDGM with regards to 30-day periods of care. 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. We do not believe is it necessary to add any additional behavioral assumptions at this time and we note that CMS is required to make future payment amount adjustments based on the difference between assumed and actual behavioral changes.

Comment: A couple of commenters raised the question of whether CMS removed LUPA payments from the numerator when calculating the budget-neutral 30-day payment amount with and without behavioral assumptions.

Response: CMS did not remove the LUPA payments from the numerator when calculating the budget-neutral 30-day payment amounts. Including LUPA payments provides a broader picture when looking at impacts. In order to calculate the 30-day budget-neutral payment amount, both with and without the behavioral assumptions, we first calculated the total, aggregate amount of expenditures that would occur under the current case-mix adjustment methodology. Because estimated aggregate expenditures under the 30-day unit of payment must be budget neutral to estimated aggregate expenditures made if the 30-day unit of payment was not implemented, we must look at the aggregate payments made under the current HH PPS. This means we must look at all payments made, including LUPA payments.

Comment: Another commenter indicated that according to CMS' 2017 Fee-for-Service Supplemental Improper Payment Data report, the projected amount of improper payments made to HHAs for incorrect coding was $0 and that this zero dollar figure stands in stark contrast to CMS' assumption that all HHAs will use improper codes to bill Medicare for higher payments under PDGM. Conversely, other commenters indicated that the behavioral assumptions will cause a perverse incentive to ''upcode'' when previously agencies wouldn't have engaged in this practice.

Response: CMS uses the Comprehensive Error Rate Testing (CERT) Program to estimate the Medicare Fee-For-Service (FFS) improper payment rate. The purpose of the CERT Program is to identify payments that should not have been made or payments made in an incorrect amount. Specifically, ''improper payments'' include: Both overpayments and underpayments; payments to an ineligible recipient; payments for an ineligible service duplicate payments; payments for services not received; or, payments for an incorrect amount. Conversely, as we have noted throughout this section, the purpose of the behavioral assumptions is to take into account assumed behavioral changes resulting from a change in the unit of payment from 60 to 30 days and the change to the case-mix adjustment methodology in order to calculate a 30-day budget neutral prospective payment amount, and not to determine whether improper payments were or will be made. We have also stated that the purpose of the behavioral assumptions is not to be punitive or to indicate that HHAs are engaging in unethical or inappropriate behavior, but to anticipate those behavioral changes when calculating a prospective payment. We expect coding changes to occur given the expansion of the ICD–10 code set and the PDGM using the diagnoses reported on the claim as opposed to the OASIS. This provides HHAs with an opportunity to report conditions supported in the medical documentation for which home health services are being provided. We remind commenters that ''upcoding'' is a fraudulent billing practice where a healthcare provider assigns an inaccurate billing code to a medical procedure or treatment to increase payment and where the actual service(s) provided are not supported by the codes reported. We do not view reporting diagnoses that are supported in the medical documentation and which reflect the home health care and services provided to be ''upcoding''. We do expect, however, that HHAs will establish the individualized plan of care in accordance with the needs identified in the initial and comprehensive assessments to address all pertinent and supported diagnoses.

Final Decision: We are finalizing the three behavioral assumptions as previously described in calculating a 30-day budget-neutral payment amount. We will update the CY 2020 30-day budget-neutral payment amount in the CY 2020 proposed rule using the most recent data available.

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.

[14] O'Connor M, Bowles KH, Feldman PH, St Pierre M, Jarrín O, Shah S, Murtaugh CM. Frontloading and intensity of skilled home health visits: A state of the science. Home Health Care Services Quarterly. 2014; 33(3):159–75. doi: 10.1080/01621424.2014.931768.

The BBA of 2018 requires a change to the unit of payment from a 60-day episode to a 30-day period of care, effective January 1, 2020. As described in the CY 2018 HH PPS proposed rule (82 FR 35270) and in the CY 2019 HH PPS proposed rule (83 FR 32391), we 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.

In the CY 2019 HH PPS proposed rule, we described in detail, potential program integrity vulnerabilities as they relate to RAP payments (83 FR 32391). We stated that given the program integrity concerns and the reduced timeframe for the unit of payment (30 days rather than 60 days), we proposed 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. We proposed 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 period of care, as well as every 30-days thereafter.

We proposed 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.

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 under our proposal. 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. We also solicited comments on requiring for HHAs to submit a notice of admission within 5 days of the start of care to alert the claims processing system that a beneficiary is under a home health period of care, if in the future the split percentage approach was eliminated. 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 required by law.

The following is a summary of the public comments received on the ''Split Percentage Payment Approach for a 30-day Unit of Payment'' proposal and our responses:

Comment: Many commenters supported all or parts of CMS's changes to the RAP policy. Some commenters indicated that the elimination of the split percentage would align better with a 30-day payment and would simplify claims submission. Other commenters stated they do not want any type of phase-out of RAPs and remarked that RAPs should continue under the PDGM to ensure no disruption in cash flow. There was some commenter support to phase out the split percentage payment over a multi-year period starting at least one year after the implementation of the PDGM in order to allow agencies to adapt to PDGM. Some commenters indicated that RAPs for late periods could be phased out, but that RAPs for early periods should remain in place to ensure an upfront payment for newly admitted home health patients. Some commenters supported the reduction in the split percentage payment but wanted to allow RAPs for newly enrolled HHAs.

Response: We thank commenters for their careful review and suggestions regarding the proposals regarding a potential phase-out of RAPs. We continue to believe that as a result of a reduced timeframe for the unit of payment from a 60-day episode to a 30-day period, that a split percentage approach to payment may not be needed for HHAs to maintain an adequate cash flow. We also believe that by eventually phasing-out the submission of RAPs with each 30-day period, that this will significantly streamline claims processing for HHAs. Likewise, by eliminating RAP payments for newly-enrolled HHAs, we believe this would allow these HHAs to structure their operations without becoming dependent on a partial advanced payment and take advantage of receiving full payments every 30 days. We will continue to monitor the need for RAPs after the implementation of the PDGM. We understand that HHAs may need time to adapt to the PDGM so any phase-out of RAP payments for existing HHAs would be addressed in future rulemaking.

Comment: Many commenters had concerns that CMS was modifying its RAP policy due to abuse by certain agencies. Commenters suggested that CMS should utilize their ability to restrict RAPs for agencies that abuse it instead of modifying the current RAP policy. Some commenters indicated that not all cases where a final claim isn't submitted after a RAP are abusive. Commenters encouraged CMS to identify the agencies that are abusing the system and to impose more oversight through accrediting organizations and the MACs.

Response: While one of the reasons for the elimination of the RAP is to potentially stem program integrity vulnerabilities, it is not the sole reason. We remind commenters that the current median length of days for RAP submission is 12 days from the start of the 60-day episode. With a change to a 30-day unit of payment, if this median length of days for RAP submissions remains constant, there is the possibility that HHAs could be simultaneously submitting a RAP and a final claim for each 30-day period of care. We believe that this defeats the purpose of the RAP to maintain adequate cash flow and only increases complexity for HHAs in their claims processing. With monthly billing, HHAs have the ability to receive an ongoing cash flow which we believe would mitigate concerns over having adequate funds for the provision of care.

We acknowledge and appreciate the concerns commenters have with regards to abuse of the RAP policy by certain HHAs. We plan to continue to closely monitor RAP submissions, service utilization, payment, and quality trends which may change as a result of implementing of the PDGM and a 30-day unit of payment. If changes in practice and/or coding patterns or RAPs submissions arise, we may take further action, which may include administrative action against providers as appropriate and/or proposing changes in policy. We will also continue to work with the HHS Office of Inspector General in case any cases of provider abuse are identified.

We would like to reiterate that in the CY 2019 HH PPS proposed rule, we proposed existing HHAs, that is HHAs that are certified for participation in Medicare with effective dates prior to January 1, 2019, would continue to receive RAP payments upon implementation of the PDGM in CY 2020. Only newly-enrolled HHAs, that is HHAs certified for participation in Medicare effective on or after January 1, 2019, would not receive RAP payments beginning in CY 2020.

Comment: Several commenters believe that newly enrolled HHAs have the same or more cash flow concerns as

existing HHAs and that split-percentage payments should also be made to newly enrolled HHAs. Some commenters expressed concern about HHAs acquired or opened on or after January 1, 2019 under a HHA chain organization and whether these newly enrolled HHAs that are part of a chain would be ''grandfathered'' in and would be allowed to receive RAP payments beginning in CY 2020. These commenters remarked that not allowing these HHAs to be grandfathered in would disrupt operations.

Response: While we appreciate commenter concerns, in the CY 2019 HH PPS proposed rule, when referring to not allowing newly-enrolled HHAs (that is, those certified for Medicare participation effective on or after January 1, 2019) to receive RAP payments beginning in CY 2020, we did not distinguish between solely-owned HHAs and HHAs that are owned by a parent or chain company. For payment purposes, a CMS Certification Number (CCN) is required to be included on the Medicare claim and the RAP. Upon Medicare enrollment, a CCN is issued. This policy is applicable to newly enrolled HHAs and thus this policy would apply to those HHAs with a CCN that is effective on and after January 1, 2019, regardless of whether they are solely-owned or owned by a patent or chain company. We believe that having the opportunity to receive full payment every 30 days may mitigate cash flow concerns for newly enrolled HHAs.

Comment: Some commenters expressed support for the Notice of Admission (NOA) and recognized that the NOA would be necessary to alert the claims processing system of a home health period of care because of the consolidated bulling requirements. Other commenters opposed the use of a NOA and the requirement to submit a NOA within 5 days of the home health start of care. These commenters referenced some of the operational and processing issues with the hospice Notice of Election and expressed concern that there could be delay in needed care. Other questioned the burden associated with a NOA process.

Response: We remind commenters that existing HHAs, meaning those certified for participation in Medicare with effective dates prior to January 1, 2019, would continue with the same RAP submission process as they currently follow under the current HH PPS except that a RAP would have to be submitted at the beginning of each 30-day period of care. Likewise, we proposed that newly-enrolled HHAs (that is, those certified for participation in Medicare effective on and after January 1, 2019) would have to submit a ''no-pay'' RAP at the beginning of care in order to establish the home health period of care, as well as every 30-days thereafter. RAP submissions are significant as the RAP establishes the HHA as the primary HHA for the beneficiary during the timeframe and alerts the claims processing system that the beneficiary is under the care of the HHA. A Notice of Admission (NOA) would only be required if the split-percentage payment approach is eliminated in the future. However, we did not propose to eliminate RAP payments for existing providers and newly-enrolled providers would only have to submit a ''no-pay'' RAP in order to establish a home health period of care within the claims processing system. If we do propose elimination of the split-percentage approach, we would do so in future rulemaking and would solicit comments at that time about the process that would be established in regards to the submission of a Notice of Admission.

Final Decision: We are finalizing the split-percentage proposal as proposed with an effective date of January 1, 2020. This means that newly-enrolled HHAs, that is HHAs certified for participation in Medicare effective on or after January 1, 2019, would not receive RAP payments beginning in CY 2020. 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 period of care, as well as every 30-days thereafter. Existing HHAs, meaning those HHAs that are certified for participation in Medicare effective prior to January 1, 2019, will continue to receive RAP payments upon implementation of the PDGM in CY 2020. For split-percentage payments to be made, existing HHAs would have to submit a RAP at the beginning of each 30-day period of care and a final claim would be submitted at the end of each 30-day period of care. For the first 30-day period of care, the split percentage payment would be 60/40 and all subsequent 30-day periods of care would be a split percentage payment of 50/50. We are also finalizing the corresponding regulations text changes as described in section III.F.13 of this final rule with comment period related to the split percentage payment approach.

4. Timing Categories

In the CY 2019 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 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 PDGM, we proposed 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 proposed that the definition of a ''home health sequence'' (as currently described in § 484.230) would 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 further noted 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-day unit of payment.

We solicited public comments on the timing categories under the proposed PDGM and the associated regulations text changes discussed in section III.F.13 of the proposed rule. The following is a summary of the public comments received and our responses:

Comment: Several commenters supported the inclusion of the timing category in the PDGM, stating that this differentiation reflects that HHA costs are typically highest during the first 30 days of care and supports HHA efforts to follow clinical evidence on the importance of ''frontloading'' resources in the home care setting in order to facilitate improved patient outcomes.

Response: We appreciate the commenters' support regarding the inclusion of the timing element within the PDGM framework, as we believe that the early and late designations will serve to better align payments with the existing resource use pattern observed in home health data. The utilization of increased resources in early periods is demonstrated in the data analyzed during the development of the PDGM, as described in the CY 2019 HH PPS proposed rule (83 FR 32340). We believe that ultimately this component of the PDGM will help to account for the increase in intensity of resources often required at the start of home health care.

Comment: Several commenters expressed concern regarding the change in the definition of ''early'' and ''late'' 30-day periods from the current payment model, stating that many patients need more than 30 days of intense care due to their medically

complex, chronic conditions and their multiple, serious diagnoses requiring skilled assessment and interventions. The commenters asserted that HHAs may ration care to those beneficiaries in ''late'' 30-day periods and that the new timing category would serve to penalize those HHAs that do enroll clinically-complex beneficiaries with ongoing care needs. Several commenters stated that categorizing 30-day home health periods into ''early'' and ''late'' would serve to ''devalue'' later care during a home health period of care. A commenter also stated that categorizing only the first 30 days as ''early'' would potentially put beneficiaries at risk because they state that more costly therapy services become most appropriate as a beneficiary begins to stabilize, which the commenter stated typically occurs around week three of a home health care. Another commenter also stated that caregiver availability also varies in the weeks following an acute event, with support diminishing in the weeks following admission to home health, leading to an increased need for additional support during those 30-day periods that would now be categorized as ''late.'' Several commenters expressed concern that the definition of the ''late'' category would not account for any additional costs that would be associated with a new set of resource-intensive health needs for a patient that may occur after the ''early'' 30-day period.

Response: As described in detail in the CY 2019 HH PPS proposed rule, our proposal regarding the timing element of the PDGM was intended to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the HH PPS (83 FR 32340). 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 beneficiaries, including medically-complex patients with ongoing needs. We have constructed the revised payment 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, and we have not manipulated the resource utilization or weighting to encourage certain patterns of care for the first 30-day period within 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.

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 that providers may not discharge patients when merited. During our analysis in support of subsequent refinements to the HH PPS in 2015, as described in the CY 2015 HH PPS proposed rule (79 FR 38366), 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.[15] 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 use during home health episodes, we believe that restricting the ''early'' definition to the first 30-day is most appropriate for this facet of the PDGM. Our analysis of home health resource use, our review of the literature on ''frontloading,'' as well as comments from the public that confirm that more resources are used in the first 30 days, provide compelling evidence to limit the definition of early to the first 30-day period. As we receive and evaluate new data related to utilization patterns in Medicare home health care, specifically under the PDGM, we will reassess the appropriateness of the payment levels for ''early'' and ''late'' periods in a sequence of periods, and we will evaluate whether changes are needed once the model has been implemented.

Comment: Several commenters described concerns regarding the potential for problematic provider behavior due to financial incentives. Several commenters stated that the timing element of the PDGM has the potential to create an incentive to increase overall patient volume, to discourage providers from accepting community referrals, to extend home health lengths of stay so as to include at least two 30-day periods, and to promote lower quality home health care in order to maximize reimbursements. Several commenters stated that the timing variable in the PDGM payment model would increase the incentive to prematurely discharge patients while other commenters stated that the timing variable may incentivize HHAs to avoid patients who require care over the span of multiple periods of care.

Response: 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 MACs and/or other program integrity contractors. 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 in keeping with eligibility guidelines for the Medicare home health benefit.

Moreover, the public comments we received in response to both the CY 2018 and CY 2019 HH PPS proposed rules presented conflicting predictions regarding anticipated provider behavior in response to the implementation of the PDGM. 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

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

concern that providers may attempt to keep home health beneficiaries on service for as long as possible. We note the PDGM case-mix weights reflect existing patterns of resource use observed in our analyses of home health claims data. Since we proposed 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. Finally, we expect that HHAs will furnish care in accordance with each beneficiary's HH plan of care as required by the HH CoPs at § 484.60.

Comment: Several commenters requested 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 because of the differentiated payment amounts for ''early'' and ''late'' 30-day periods. The commenters also stated that there is concern that the PDGM definitions of ''early'' and ''late'' may hurt agencies due to the decrease in overall payment because of the lower reimbursement for periods categorized as ''late.'' Another commenter stated that the PDGM inaccurately ties payment to time in home health care, with very little regard to actual care needs.

Response: With regard to a potential reduction in overall payment due to the revised designations of ''early'' and ''late'' periods under the PDGM, as we described in the CY 2019 HH PPS proposed rule, our analysis of the related data indicates that there is significant difference in the resource utilization between early and late 30-day periods as demonstrated in Table 34 of the proposed rule (83 FR 32392). One of the driving goals in the development of the PDGM was to better align payments with costs incurred by agencies for patients with differing characteristics and needs under the HH PPS. 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. We believe that the PDGM further promotes the goal of payment accuracy within the HH PPS and Medicare overall. However, we note that we will continue to monitor for any changes in trends as evidenced by home health data reflecting the change to the HH PPS and make modifications to the PDGM as necessary.

Comment: Several commenters suggested that we revise the payment 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. They suggested that we should consider altering the definition of sequences of 30-day periods to include home health re-admissions following acute institutionalization as a condition of determining a new sequence of home health periods of care, in addition to the 60-day gap in home health services, stating that this would be akin to the proposal defining admission source for the purposes of determining institutional payment status.

Response: We appreciate the commenter's suggestion regarding the consideration of a readmission to home health within the 60-day gap be treated as an ''early'' stay. However, we note that the PDGM also includes a category for source of admission, which would account for a readmission to home health within 14 days of an acute care hospital stay. The admission source category is discussed in detail in Section III.E.5 of this final rule with comment period. Under the PDGM we already account for the differentiating features of institutional stays, including inpatient stays that occur within 14 days of the commencement of a home health period. 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 would reflect agencies' average costs for home health patients. We believe that crafting a multi-pronged model, which includes adjustments based both on timing within a home health sequence as well as the source of the beneficiary's admission, will serve to more accurately account for resources required for Medicare beneficiaries and similarly provide a differentiated payment amount for care.

Comment: A commenter stated that the timing categories create disincentives for home health care providers to prevent hospital readmissions because a resumption of care would then generate higher revenues. Another commenter stated that HHAs often front load visits post hospitalization or admission to a SNF, including the ''resumption of care period.'' The commenter expressed concern that the proposed timing categories for the PDGM do not capture the resources required for a resumption of care and asks that we expand the definition of sequencing of ''early'' periods to include home health readmissions following acute hospital or SNF stays.

Response: For the purposes of the timing category of the PDGM, an intervening hospital stay would not trigger re-categorization to an ''early'' 30-day period of care unless there was more than 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. Additionally, we note that the admission source category within the PDGM serves to capture the increased resource needs in the home health population referred from an inpatient hospital stay, occurring within 14 days of home health admission, creating differentiated case-mix weights that align payment with the resource use for that subpopulation of home health beneficiaries.

Comment: Several commenters expressed concern regarding the operational aspects of the timing element of the PDGM. Another commenter asked how patient transfers would be addressed, asserting that the second agency should not receive lower payment if they were unaware that the patient was being served by another home health agency. A commenter expressed concern regarding the identification of the timing of the 30-day period, stating that the OASIS in particular does not provide enough information to determine timing for a 30-day period.

Response: As we described in the CY 2019 HH PPS proposed rule, we will use Medicare claims data and not the OASIS assessment in order to determine if a 30-day period is considered ''early'' or ''late'' (83 FR 32393). Regarding transfers, we note that 30-day periods are considered to be adjacent if they are contiguous, meaning they are separated by no more than a 60-day period between 30-day periods of care. This would mean that if a patient transfers from one HHA to another HHA after the first 30-day period of care, all adjacent 30-day periods of care would be considered ''late''. In order for any 30-day period of care to be considered ''early'', there would have to be a gap in home health services of more than 60

days. We have developed claims processing procedures to reduce the amount of administrative burden associated with the implementation of the PDGM. Providers will 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 will be used during claims processing to automatically assign the appropriate timing category. Details regarding these processes are outlined in the CY 2019 HH PPS proposed rule (83 FR 32394). We reiterate that we plan to develop materials regarding the 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 the 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 from the current payment system to the PDGM, including the unique aspects of the timing categories.

Final Decision: We are finalizing our proposal to classify 30-day periods of care under the PDGM as ''early'' or ''late'' depending on when they occur within a sequence of 30-day periods. The first 30-day period would be classified as early and all subsequent 30-day periods in the sequence (second or later) would be classified as late and 30-day periods of care cannot be considered early unless there is a gap of more than 60 days between the end of one period and the start of another.

5. Admission Source Categories

In the CY 2019 HH PPS proposed rule, we described analysis showing the impact of the source of admission on home health resource use and proposed 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 (83 FR 32340). We proposed 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 also proposed 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 also proposed 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. We proposed that this admission source designation process would be applicable to institutional stays both paid by Medicare or another payer. All other 30-day periods would be designated as community admissions. For the purposes of a RAP, we proposed that we would only adjust the final home health claim submitted for source of admission. Additionally, we also proposed that HHAs would only indicate the proposed admission source occurrence codes on the final claim and not on any RAPs submitted. The proposed admission source category was discussed in detail in the proposed rule.

We solicited public comments on the admission source component of the proposed PDGM. The following is a summary of the public comments and our responses:

Comment: Several commenters expressed their support for the admission categories within the framework of the PDGM, as they believe patient needs significantly differ between these groups and payment differences are warranted in order to better reflect the cost of Medicare home health care, thus improving the accuracy of payments in the revised system.

Response: We appreciate the commenters' support with regard to the admission source element of the PDGM. The intention of the PDGM proposal, including the admission source component, is to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the prospective payment system, and we believe that the differing weights for source of admission will facilitate more appropriate alignment within the HH PPS.

Comment: Several commenters stated that the source of a home health admission may not always correspond with home health beneficiary needs and corresponding provider costs, as some community entrants sometimes require more intensive resources than their institutional counterparts, presenting with complex conditions such as psychiatric and neurological conditions, pressure and stasis ulcers, and a history of falls. Several commenters also stated that we are ''devaluing'' community entrants by providing lower reimbursement for those beneficiaries when compared with institutional entrants.

Response: As described in detail in the CY 2019 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 PDGM (83 FR 32340). We do not seek to ''devalue'' or show preference to any particular patient profile, but rather aim to better align home health payment with the costs observed in providing care. Additionally, as discussed in our CY 2019 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 (83 FR 32396). As further described in the CY 2019 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 (83 FR 32397). We continue to believe that accounting for the material differences in the care needs of the home health beneficiary population admitted from institutional settings and their resulting, differentiated resource use, will serve to better align payments

with actual costs incurred by HHAs when providing care. We will carefully monitor the outcomes of this change, including any impacts to community entrants, and make further refinements as necessary. We also note that a component of the PDGM is the classification of periods of care into clinical groups according to the principal diagnosis reported. This component of the PDGM serves to capture the different resource needs of different conditions in the home health population, including complex conditions such as neurological conditions.

Comment: Several commenters noted that the admission source component of the PDGM has strong explanatory power in the model, outweighing clinical and functional factors. Several commenters believe the inclusion of admission source in the PDGM is akin to the use of therapy thresholds in HHRGs, as the commenters assert that it has the potential to create inappropriate incentives. Some commenters suggested that admission source not be utilized used in the model; instead, only patient clinical and functional status should be considered. Other commenters believe that the payment differences by admission source is too great. A commenter recommended that additional analysis be conducted regarding the payment adjustment for admission source and that we determine if other elements of the case-mix system would more adequately account for differences in payments when compared to the admission source variable. Another commenter stated that the admission source component of the PDGM is inaccurate and will likely push patients into the institutional setting and suggested that we instead utilize a ''risk of readmission'' measure, which could serve to gauge patient severity and promote value-based care.

Response: We appreciate the commenters' feedback regarding the admission source component of the PDGM. However, we reiterate that the analytic findings presented in the CY 2019 HH PPS proposed rule point to clear differences in resources utilized by beneficiaries with differing sources of admission. In developing the various elements of the PDGM, we sought to focus on variables that predicted care needed by the patient (83 FR 32340). We disagree that using an admission source variable is equivalent to therapy thresholds. The data supports that resource utilization is higher among those with beneficiaries who have had a previous institutional stay prior to admission to home health, which accounts for the explanatory power of this particular variable. Conversely, increased payment associated with the therapy thresholds is directly correlated with the number of therapy visits provided. Regarding the suggestion that we instead utilize a ''risk of readmission'' measure, we remind commenters that the PDGM does include an OASIS item for ''Risk for Hospitalization'' in its construction at the functional level to further account for patient characteristics that could translate into resource use. We note that we will continue to analyze the inclusion of other variables in the PDGM case-mix adjustment and will consider such additional components for future refinement.

Comment: Commenters stated that inpatient settings would become the primary patient referral target for HHAs and that community referral beneficiaries may find HHAs less willing to admit them to home health care if CMS were to finalize the admission source categories in the PDGM as proposed.

Response: We appreciate the commenters' concern regarding possible behavioral changes by providers given the perceived incentives created by the admission source categories within the PDGM. 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 recognize that providers may shift practices based upon strategies meant to maximize payment; therefore, we plan to closely monitor for any concerning trends in provider behavior, including such metrics as proportion of cases in a provider's caseload referred from both the community and institutional settings. We also note that in previous analysis related to the solicitation of home health referrals, research has shown that many agencies seek referrals from any setting, institutional or otherwise. In the FY 2001 HH PPS proposed rule, evaluators assessing the HH PPS demonstration came to the conclusion that agencies did not alter their behavior in response to payment changes in the home health demonstration in such a way that impacted beneficiary access or quality of care, nor did they employ practices in order to avoid costly patients or recruit lower-care cases (64 FR 58140). Many agencies wanted to maintain a steady stream of referrals and were therefore not in a position to avoid a specific referral source, and, as a result, did not do so. We expect that HH providers will continue to seek referrals from all sources under the PDGM system, resulting in continued access to home health care for Medicare beneficiaries.

Comment: Several commenters suggested the inclusion of inpatient psychiatric facility (IPF) stays in the institutional category for the purposes of the PDGM.

Response: We appreciate the commenters' feedback and agree that inpatient psychiatric facility (IPF) stays should be included in the institutional category for the payment system under the PDGM. We agree that admission to an inpatient psychiatric facility would merit inclusion as an institutional source under the PDGM and therefore, we will include this site of service as part of the institutional category case-mix variable.

Comment: Several commenters recommended that CMS consider incorporating other clinical settings into the definition of the institutional category, including hospices and outpatient facilities, including emergency rooms. The commenters asserted that the criteria for inpatient hospital admission versus outpatient and other non-acute/PAC services are not always clear and that the differences between patients admitted as inpatient versus as outpatient are minimal. The commenters also stated that observation stays, which are not considered institutional stays by CMS, should be considered as such for the purposes of the PDGM, in part because beneficiaries and their families will have the ''perception'' of an inpatient stay and inform the HHA of what they perceive to have been an institutional stay. Another commenter stated that patients who utilize emergency room services either need a higher level of home health services once they transition to home health care or they require a lot of education to encourage them to utilize options other than the ER when issues arise. The commenter moreover asserted that hospitals have become adept at using observation stays for purposes of avoiding re-hospitalization penalties but maintains that these patients have just as high acuity as those referred to home health from a typical inpatient hospital stay. A commenter stated that joint replacement surgery continues to evolve, and patients are having surgery and are being treated as an ''observation stay'' rather than a hospital admission despite requiring a high level of service once they return home. A commenter noted concern that categorization could limit access to home care for joint replacements that may occur in ambulatory surgery centers and other outpatient facilities,

settings not currently considered institutional for the purposes of the PDGM. Another commenter stated that the exclusion of observation stays and ED visits from the institutional category would create an incentive for HHAs to potentially encourage hospitalizations for potentially higher reimbursement.

Response: We appreciate the commenters' concerns regarding potential impacts to those patients who may have experienced an event in a setting that is not defined as acute or post-acute, including visits to emergency departments. However, for the purposes of the PDGM, we will only include those stays in the institutional category that are considered institutional stays in other Medicare settings. As described in detail in the CY 2019 HH PPS proposed rule, we analyzed the resource use of admission source categories, including ED visits and observational stays, as well as corresponding payment weights based upon the resource use demonstrated in existing home health data (83 FR 32340). Our findings indicate that the volume of patients utilizing such settings prior to a home health episode is very low. Given that the proportion of home health periods with admissions from ED visits and observational stays is low relative to community and institutional counterparts, we believe that creating a third community admission source category for observational stays and ED visits could potentially introduce added complexity into the payment system in order to address a small portion of home health stays, which could in turn 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. Moreover, we remain concerned that a third admission source category for observational stays and ED visits could potentially create an incentive for HHAs 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 increasing costs to the Medicare program overall. 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.

While we recognize that there is more recent use of Ambulatory Surgery Centers (ASCs) for certain joint replacement surgeries, we do not have sufficient data at this time to determine the impact on home health resource use for beneficiaries coming from an ASC facility after these types of surgeries. As mentioned previously, we will only include those stays that are considered institutional stays in other Medicare settings and where ''institutional'' refers to discharges from acute-care hospitals, IRFs, LTCHs, IPFs, and SNFs. Therefore, a discharge from an ASC does not meet the definition of ''institutional''. Likewise, discharge from hospice care would not be considered an institutional discharge, nor would we expect large enough numbers of beneficiaries discharging from hospice to home health to warrant such an inclusion.

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 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.

Comment: Several commenters stated that the addition of the admission source category and potential payment differential could negatively affect agencies' ability to provide the care for beneficiaries in the community and that the admission source categories placed a higher value on care provided to a beneficiary referred to home health care from an acute setting. Several commenters stated that home health community entrants are provided education and oversight as well as preventative and maintenance therapy and care, citing the Jimmo Settlement Agreement.[16] Commenters assert that such maintenance care ultimately prevents beneficiaries from requiring an admission to a more expensive hospital setting. Several commenters stated that the admission source element of the PDGM would lead to reduced access to home-based care, which may, in turn, result in an increase in emergency department visits, an increase in hospital admissions, and increased use of high cost institutional care for patients. The commenters further suggested that the maintenance interventions provided produce value for the Medicare system and that these savings should be reflected through higher payment to HHAs for the care of community entrants.

Response: HHAs should 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 in accordance with the home health CoP requirements at § 484.60. As we noted in the CY 2019 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 (83 FR 32375). The primary goal of the HH PPS is to align payment with the costs of providing home health care. As described in the CY 2019 HH PPS proposed rule, we have developed the PDGM categories and corresponding payment weights based upon the resource use demonstrated in existing home health data, which shows that differentiated amounts are merited between the two admission sources (83 FR 32375). 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). Commenters further noted that home health beneficiaries referred from institutional settings typically required more visits and more intensive teaching. Given our analyses as well as clinical observations regarding the resource needs of the institutional entrants to home health, we believe that differentiated admission source categories are merited. We will continue to monitor home health data for impacts of this payment policy change, potentially evaluating for increases in hospital admissions during home health stays, poorer quality outcomes, and increases in costs for the overall Medicare program, and we will make refinements to the payment system as appropriate.

Comment: Several commenters 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 (for example, for both non-Medicare and Medicare institutional stays). Several commenters expressed concern that the usage of occurrence codes for institutional admissions will increase burden on providers, cause difficulties for HHAs when having to rely on institutional providers to submit timely claims to Medicare, and create

[16] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Jimmo-Settlement-Agreement.pdf.*

challenges when modifications to home health payments are made retroactively due to the re-categorization of a community stay when an institutional claim was not submitted correctly. Several commenters requested that CMS clarify the length of time that a HHA would have to resubmit a home health claim when it learns of a non-Medicare institutional stay occurring within 14 days of the home health admission. A commenter expressed concern regarding the usage of the OASIS for identification of institutional admission sources.

Response: As described in the CY 2019 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 PDGM (83 FR 32375). 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 post-acute claim. The OASIS assessment will not be utilized in evaluating for admission source information.

Moreover, we proposed 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/post-acute Medicare claim, if any, by Medicare systems in order to receive the higher payment associated with the institutional admission source sooner (83 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/post-acute claims were paid by Medicare. HHAs would also use the occurrence codes for beneficiaries with acute/post-acute care stays paid by other payers, such as the Veterans Administration (VA).

If a HHA does not include the occurrence code on the HH claim 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/post-acute 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.

Again, however, we note that the Medicare claims processing system will check for the presence of an acute/post-acute 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 the 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.

Comment: Another commenter requested details regarding the process by which HHAs should verify a non-Medicare institutional stay.

Response: As we noted in in the CY 2019 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) (83 FR 32340). 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 the Medicare CoPs.

Comment: Several commenters expressed concern that the use of occurrence codes will lead to claims

denials by MACs and stated that MAC staff will require training in order to ensure appropriate application of the admission source policy as well as avoid any unintended consequences.

Response: We intend to provide education and training regarding the usage of the admission source occurrence codes to providers through such tools are Medicare Learning Network articles. We are also working closely with the MACs to ensure proper processing of home health claims under the new PDGM. Additionally, as we noted in in the CY 2019 HH PPS proposed rule, while a home health claim with a non-Medicare institutional admission source can be categorized by the HHA as an institutional admission and paid accordingly, we may conduct medical review if deemed appropriate (83 FR 35312).

Comment: Several commenters expressed concern regarding our proposal to potentially conduct post-payment medical review of home health claims in order to assess whether a home health admission was preceded by an institutional stay, asserting that HHAs should not be held responsible for other providers' claim activity. The commenters stated that post-payment medical review for instances in which HHAs manually indicate on the claim an institutional admission source, and the institution's claim for an acute/post-acute stay is subsequently denied or not filed in a timely manner could be problematic. The commenters stated that a denial for the acute/post-acute stay could be due to a number of reasons of which the HHA has no knowledge or involvement and noted that any denial of an institutional claim or non-timely filing of a claim, would be outside of the control of the HHAs.

Response: Our evaluation process within the Medicare claims processing system will check for the presence of an acute/post-acute 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/post-acute 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/post-acute admissions. Moreover, 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.'' If in the case of a Medicare institutional stay, upon review after finding no Medicare acute or post-acute care claims in the National Claims History, and there is documentation of a Medicare acute or post-acute care 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 non-Medicare institutional stay, if documentation of a non-Medicare acute or post-acute care 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 post-acute care Medicare claims in the National Claims History, and there is no documentation of an acute or post-acute care stay, either a Medicare or non-Medicare stay, within 14 days of the home health admission, we would correct the overpayment and re-categorize the stay as community. If upon medical review after finding no Medicare acute or post-acute care 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, including any potential administrative action.

Comment: A commenter suggested that we only conduct post-payment review for HHAs that have claims that are consistently associated with acute/post-acute claim denials, or whose utilization pattern of acute/post-acute occurrence codes is aberrant when compared with their peers, which the commenter asserts would ensure a more equitable approach toward conducting post-payment medical review of home health claims.

Response: We appreciate the commenter's suggestions regarding targeted approaches for medical review after the implementation of the admission source element of the PDGM, and we will consider such metrics in the development of any targeted reviews.

Comment: Another commenter expressed concerns regarding operational aspects of the admission source portion of the PDGM, stating that if the institutional stay were billed very late in the timely filing period, the HHA might not receive an appropriate admission source adjustment within the PDGM. The commenter also expressed concern regarding the timely filing window for HHAs, asking if we will increase the timely filing period for home health agencies. The commenter also wanted to understand how home health agencies will know if institutional providers are submitting their claim correctly and meeting the necessary criteria. Additionally, the commenter asked why we were not allowing payment to the home health agency if the agency's billing is submitted appropriately based on the information currently at hand and later recalculate and adjust payment if necessary. The commenter also asked if discharge summaries received by home health from external institutions will serve as ''proof'' in the event of medical review. The commenter also asked what would transpire if an institutional provider decided post-discharge that the inpatient admission did not meet inpatient criteria when discharge summary documents still indicate the patient was being discharged to home health following a qualifying inpatient stay.

Response: We appreciate the commenter's questions regarding the operational aspects of the admission source category within the PDGM. With respect to any issues around a Medicare institutional claim submitted near the end of the timely filing period, if the institutional stay is billed very late in the timely filing period, that institutional stay claim would trigger an automatic adjustment to the HH claim whenever it is received by CMS's claims processing system and the HHA would be paid appropriately. 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 to indicate an institutional admission source, subject to the timely filing deadline, and payment adjustments would be made accordingly. Regarding timely filing timeframes, we do not have the authority to extend timely filing timeframes as they are mandated by statute. However, the HHA may utilize the newly-established occurrence codes to indicate an institutional admission source without dependency on the claims submission by the institutional provider.

Additionally, we reiterate that the HHA is not dependent on the institutional provider's ''correct'' submission of the institutional claim for appropriate admission source categorization, as HHAs will have the

option of including the relevant occurrence codes to indicate an HH admission from an institutional provider separate and apart from any claims submission by the institutional provider. In the case of a Medicare institutional stay, if the institutional setting did not submit its claim in a timely fashion, or at all, but there is documentation of a Medicare acute or PAC stay within the 14 days prior to the home health admission, we would permit the institutional categorization for the payment of the home health claim through appropriate administrative action. Similarly, in the case of a non-Medicare institutional stay, if documentation of a non-Medicare acute or post-acute care 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''. Regarding the usage of discharge summaries as evidence of a prior institutional stay, such summaries may be considered in the assessment of the appropriateness of the usage of an occurrence code indicating admission to HH from an institutional setting and determinations will be made based upon the evidence gathered. Regarding a scenario where an institutional provider determines post-discharge that an admission did not meet inpatient criteria but the discharge summary utilized by an HHA indicated that the patient was being discharged to home health following a qualifying inpatient stay, the home health agency would not be left with a non-covered claim. However, the home health claim may be paid as non-institutional rather than institutional, given the source of the admission. Furthermore, we note that details regarding the claims processing instructions for Medicare home health claims will be updated in our Medicare Claims Processing Manual. We plan to provide education and training regarding all aspects of the admission source process and to develop materials for guidance on claims adjustments, and for appropriate usage of occurrence codes.

Final Decision: We are finalizing our proposal 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. Thirty-day periods for beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility (IPF) stays, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long term care hospital (LTCH) stays within the 14 days prior to a home health admission will be designated as institutional admissions. The institutional admission source category will also include patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care 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 will not categorize post-acute care stays (SNF, IRF, or LTCH) or IPF stays that occur during a previous 30-day period and within 14 days of a subsequent, contiguous 30-day period of care (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 post-acute care in a different setting or inpatient psychiatric care and then readmit 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 post-acute care 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 another 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. As noted previously, we plan to provide future training and guidance of operational aspects of claims processing under the PDGM especially regarding the admission source case-mix variable.

6. Clinical Groupings

In the CY 2019 HH PPS proposed rule (83 FR 32340), we proposed 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, and Medication Management, Teaching, and Assessment (MMTA). We stated that by placing periods of care into clinical groups reflecting the primary reason the patient is receiving home health, as determined by the principal diagnosis on the claim, we would capture the most common types of care provided and more accurately align payments with the cost of providing care (that is, resource use).

In response to comments on the CY 2018 HH PPS proposed rule (82 FR 35317) and a Technical Expert Panel (TEP) held in February 2018, we conducted further analysis on the division of the MMTA clinical group into subgroups. We conducted a thorough review of all the diagnosis codes grouped into the MMTA group and we grouped codes into MMTA subgroups based on feedback from public comments, which mainly focused on cardiac, oncology, infectious, and respiratory diagnoses. We created the additional subgroups (Surgical Aftercare, Cardiac/Circulatory, Endocrine, GI/GU, Infectious Diseases/Neoplasms/Blood Forming Diseases, 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.

Similar to the initial Home Health Groupings Model (HHGM) analysis conducted in 2016 that was discussed in the CY 2018 HH PPS proposed rule, results showed that the change in case-mix weights, as well as impacts to the other case-mix variables (admission source/timing, comorbidity adjustment) was minimal for the 30-day periods assigned to these subgroups compared to the case-mix weights without the subgroups. We showed that overall, using the MMTA subgroup model would result in more payment groups but no significant differences in case-mix weights across those groups. For that reason, in the CY 2019 HH PPS proposed rule, we proposed to retain the six clinical groups as shown in Table 26, and not divide the MMTA clinical group into subgroups. 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 2019 HH PPS proposed rule as well as the Summary of the Home Health Technical Expert Panel Meeting.[17] However, we solicited comments from the public on whether there may be other compelling reasons why the MMTA clinical group should be broken out into subgroups, despite analysis indicating that additional subgroups do not result in significant differences in case-mix weights. We noted that we also planned to 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 26: 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 disorder
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 previously listed groups.

The following is a summary of the public comments received on the proposed clinical groups under the PDGM and our responses:

Comment: Many commenters supported the patient-centered approach to grouping patients by clinical characteristics, and appreciated that additional codes were added to the PDGM in comparison to the HHGM.

Response: We appreciate these comments and thank the commenters for their support of the clinical groupings as defined in the CY 2019 HH PPS proposed rule.

Comment: Many commenters reiterated concern that the MMTA group was too large (that is, too many 30-day periods group into the MMTA clinical group under the PDGM) and stated preference for more specificity within this group despite analysis showing a lack of variation in resource use across subgroups. A commenter specifically noted that the groupings exclude heart failure and pulmonary clinical groups, which are two medically complex categories that result in significant time and resource use in order to prevent hospital readmissions.

Response: As discussed in the CY 2019 HH PPS proposed rule, health teaching; guidance and counseling; case management, treatments and procedures; and surveillance are integral in the care of the majority of home health patients. Additionally, these important interventions are often the primary reason for home health services. However, because these interventions cross the spectrum of diagnoses, the MMTA clinical group included the largest number of 30-day periods among the proposed clinical groups in the PDGM. Despite additional analysis showing very little variation in resource use after sub-dividing MMTA into smaller subgroups, we understand stakeholder preference to capture the distinctions in care provided to patients within this group. The majority of commenters still expressed concern with the high number of diagnoses that grouped into the MMTA and preferred greater specificity over having fewer HHRGs.

Therefore, we will create 7 additional clinical groups to replace the comprehensive MMTA group. These subgroups were selected based on public comments in response to the CY 2018 HH PPS proposed rule and these comments mainly focused on cardiac, oncology, infectious disease, and respiratory diagnoses.[18] We created the additional subgroups based on data that showed above-average resource use for codes in those groups, and then combined certain groups that had a minimal number of codes. These subgroups were presented to the TEP convened in February, 2018 and were detailed in the CY 2019 HH PPS proposed rule; commenters were generally supportive of these seven subgroup designations. As such, these MMTA subgroups will be called:

- MMTA—Surgical Aftercare

[17] *https://www.cms.gov/center/provider-type/home-health-agency-HHA-center.html.*

[18] Public comments can be viewed at: *Regulations.gov*, ID: CMS–2017–0100–0002: Medicare and Medicaid Programs: Home Health Prospective Payment System Rate Update, etc.

- MMTA—Cardiac/Circulatory
- MMTA—Endocrine
- MMTA—GI/GU
- MMTA—Infectious Disease/Neoplasms/Blood-forming Diseases
- MMTA—Respiratory
- MMTA—Other

The addition of these 7 new groups generated a new table of case-mix weights for the model. The PDGM will now contain 432 case-mix groups. We agree with commenters that greater specificity in the MMTA clinical group will help distinguish differences in care and allow for greater transparency in resource use. We also believe that with the elimination of therapy thresholds, having more discrete subgroups within this clinical group may result in more variation in resource use over time.

Comment: Several commenters submitted specific diagnosis codes that they believe should be reassigned to different clinical groups or added to the grouper tool. Another commenter stated that any existing ICD–10–CM diagnosis code should be considered when assigning a clinical group. Several commenters submitted new codes effective for October 1, 2018 that were not in the grouper tool released with the proposed rule on July 2, 2018.

Response: We thank commenters for thoroughly reviewing the PDGM Grouper tool and providing questions and detailed examples regarding the grouping of specific codes. As discussed in the CY 2019 HH PPS proposed rule, one of the main goals of the PDGM is to clearly account for resource use by highlighting the main reason for home health services. The ICD–10–CM code list is an exhaustive list that contains many codes that do not support the need for home health services and so are not appropriate as principal diagnosis codes for grouping home health periods into clinical groups. Dental codes, for example, are included in the ICD–10–CM code list, but are not Medicare covered services. Others are Medicare covered codes, but are not relevant to home health, for example, codes that indicate death as the outcome. Another reason a code is not appropriate for grouping home health periods into clinical groups is because of coding guidelines. For example, this would include codes listed out of sequence when ICD–10 coding conventions indicate certain codes in which the underlying condition must be listed first (that is, Parkinson's disease must be listed prior to Dementia if both codes were listed on a claim).

In addition to coding guidelines, we also looked at clinical practice guidelines and the interventions and skilled care involved in managing the diagnosis at home. We believe these guidelines provide valuable information for establishing a plan of care and support home health resource use. For instance, an infection of an amputation stump may only require treatment with antibiotics, whereas management of necrotic tissue always involves debridement and subsequent wound care in order to allow wound healing to take place. Thus, necrosis of an amputation stump clearly denotes wound care. For a period to be grouped into the wound category, the diagnosis on the claim must reflect a break in skin integrity for which clinical practice guidelines involve wound care necessitating skilled nursing services. A diagnosis simply indicating infection may or may not necessitate wound care.

We also expect that whenever possible, the most specific code that describes a medical disease, condition, or injury should be documented. For instance many codes contain the word ''unspecified.'' Generally, ''unspecified'' codes are used when there is lack of information about location or severity of medical conditions in the medical record. However, we would expect a provider to use a precise code whenever more specific codes are available. Furthermore, if additional information regarding the diagnosis is needed, we would expect the HHA to follow-up with the referring provider in order to ensure the care plan is sufficient in meeting the needs of the patient. We believe that a vague principal diagnosis does not clearly identify the primary reason for home health, and subsequently leads to ambiguous resource use. For example, T14.90 ''Injury, unspecified'', lacks clarity regarding the type and extent of injury and therefore, fails to indicate and support the needed resources. Additionally, the ICD–10–CM code set includes laterality. We believe a home health clinician should not report an ''unspecified'' code if that clinician can identify the side or site of a condition. For example, a home health clinician should be able to state whether a fracture of the arm is the right or left arm.

Similarly, many of the codes that indicate pain or contractures as the primary diagnosis, for example M54.5, Low back pain or M62.422, Contracture of muscle, right hand, although site specific, do not indicate the cause of the pain or contracture. We would expect a more definitive diagnosis indicating the cause of the pain or contracture, as the reason for the skilled care, in order to appropriately group the home health period.

We also believe that the majority of the R codes (codes that describe signs and symptoms, as opposed to diagnoses) are not appropriate as principal diagnosis codes for grouping home health periods into clinical groups. While we recognize that the coding guidelines allow for the reporting of signs, symptoms, and less well-defined conditions, HHAs are required to establish an individualized plan of care in accordance with the home health CoPs at § 484.60. The plan of care must specify the services necessary to meet the patient-specific needs as identified during the comprehensive assessment. This includes identification of the responsible discipline(s), and anticipated measurable outcomes as a result of implementing and coordinating the plan of care. We believe that the use of symptoms, signs, and abnormal clinical and laboratory findings would make it difficult to meet the requirements of an individualized plan of care. Likewise, we believe that clinically it is important for home health clinicians to have a clearer understanding of the patients' diagnoses in order to safely and effectively furnish home health services. Interventions and treatment aimed at mitigating signs and symptoms of a condition may vary depending on the cause. For example, if a patient has been referred to home health with a diagnosis of ''other abnormalities of gait and mobility'' (R26.89), we believe it is important for the home health clinician to know what is precipitating the abnormality. For instance, a plan of care for a gait abnormality related to a neurological diagnosis is likely to be different from a plan of care for a gait abnormality due to a fracture or injury. Anecdotally, we have heard that the home health referral may be non-specific or that the physician may be in the process of determining a more definitive diagnosis. However, with respect to patient safety and quality of care, we believe it is important for a clinician to investigate the cause of the signs and/or symptoms for which the referral was made. This may involve calling the referring physician to gather more information regarding the gait abnormality. We note that HHAs are required under the home health CoPs at § 484.60 to participate in care coordination to assure the identification of patient needs and factors that could affect patient safety and treatment efficacy. Coding guidelines are clear that R codes are to be used when no more specific diagnosis can be made even after all the facts bearing on the case have been investigated. Therefore, these codes

should not be used as a primary diagnosis for the provision of home health services while a physician may still be in the diagnostic process. By the time the patient is referred to home health and meets the qualifications of eligibility, we would expect that a more definitive code exists to substantiate the need for services. Furthermore, commenters have indicated a preference for greater specificity in the clinical groups, therefore, we believe this should extend to the codes within the clinical groups as well.

Another commonly reported diagnosis, M62.81, ''Muscle weakness, generalized'' is extremely vague. Generalized muscle weakness, while obviously a common condition among recently hospitalized patients does not clearly support a rationale for skilled services and does not lend itself to a comprehensive plan of care. In § 409.44(c)(1)(ii) we state that ''the patient's clinical record must include documentation describing how the course of therapy treatment for the patient's illness or injury is in accordance with accepted professional standards of clinical practice.'' If there is not an identified cause of muscle weakness, then it would be questionable as to whether the course of therapy treatment would be in accordance with accepted professional standards of clinical practice. Additionally, in the 2008 HH PPS final rule, we identified ''muscle weakness (generalized)'' as a nonspecific condition that represents general symptomatic complaints in the elderly population. We stated that inclusion of this code ''would threaten to move the case-mix model away from a foundation of reliable and meaningful diagnosis codes that are appropriate for home care'' (72 FR 49774). Specifically, the 2008 HH PPS final rule stipulated that the case-mix system avoid, to the fullest extent possible, non-specific or ambiguous ICD–9–CM codes, codes that represent general symptomatic complaints in the elderly population, and codes that lack consensus for clear diagnostic criteria within the medical community. We believe that diagnostic approaches to determining the cause of muscle weakness, polyneuropathy, and other vague conditions, combined with the expanded ICD–10 list, ensure that codes exist that more clearly describe a patient's need for home health. With respect to commenter rationale for coding ''Muscle weakness, generalized'' in response to severe deconditioning and weakness due to extended hospitalization, we believe a more appropriate code would be one of the muscle wasting and atrophy codes as grouped into the musculoskeletal group. Muscle wasting and atrophy would indicate the reason for the generalized muscle weakness and provide more clarity for the necessity of skilled services.

Using these guidelines, we worked with certified coders to review all of the codes submitted with commenter feedback. We included the new codes added with respect to Fiscal Year 2018 (for use beginning October 1, 2017) and with respect to Fiscal Year 2019 (for use beginning October 1, 2018) and grouped the MMTA diagnosis codes into the appropriate sub-groups. We remind commenters that the ICD 10–CM code list is updated each fiscal year with an effective date of October 1st. Because of an annual October effective date for updated ICD 10–CM codes, the HH PPS is subject to two Grouper releases, one in October and one in January, to ensure that claims are submitted with the most current code set available. Additionally, we re-grouped many of the codes submitted by commenters based on feedback we received and changed the clinical grouping of many additional codes based on commenter rationale. For example, we agree with commenters regarding many of the S and T codes where the fracture and/or injury is unspecified, but the site is specified. We maintain that the site of injury and/or fracture should be identified; however, we believe that, as the treatment or intervention would likely not change based on the exact type of injury or fracture, many of these codes are appropriate to group the period into a clinical group. These codes were changed to either the musculoskeletal group or the wounds group. We also agreed with commenters regarding some of the combination diagnosis/symptom codes. For example, we re-grouped I13.2, Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease into MMTA-Cardiac/Circulatory, as despite the likelihood that the patient is covered under the End Stage Renal Disease (ESRD) benefit, the patient may also be receiving home health services for hypertension. We also agree that Z46.6, Encounter for fitting and adjustment of urinary device should be grouped into the Complex Nursing Interventions group.

Regarding A41.0, Sepsis due to Staphylococcus aureus and A40.0, Sepsis due to streptococcus, group A, as guidelines state that a sepsis diagnosis should be assigned the appropriate code for the underlying systemic infection, these codes will be classified under MMTA—Infectious Disease/Neoplasms/Blood-forming Diseases. With regards to Z45.2, Encounter for adjustment and management of VAD, per coding guidelines, Z45.2 can be reported as the principal diagnosis and will remain in the Complex Nursing Interventions group. However, we recognize that coding guidelines indicate that if treatment is directed at current, acute disease, then the disease diagnosis code should be reported first, followed by the Z aftercare codes. Therefore, in a case where the patient is receiving an IV antibiotic for sepsis, as the HHA is required to code sepsis as the primary diagnosis, the Z code must be listed as the first secondary diagnosis code listed on the claim in order to group the period into the Complex Nursing Interventions group.

Ultimately we believe that precise coding allows for more meaningful analysis of home health resource use and ensures that patients are receiving appropriate home health services as identified on an individualized plan of care. We thank the commenters for their in-depth review and suggested changes to the ICD–10–CM code assignments for the clinical groups under the PDGM. We note that we did regroup additional codes to the ones identified in this section, based on the reasons previously discussed, and we encourage HHAs to continue to review the list of diagnosis codes in the PDGM Grouper Tool posted with the final rule on the HHA Center web page (*https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html*). Commenters are encouraged to continue to submit comments to the home health policy mailbox (*HomehealthPolicy@cms.hhs.gov*) regarding diagnosis coding under the PDGM. We will continue to review ICD–10–CM code assignments for the clinical groups under the PDGM and make future refinements as necessary, including refinements to reflect new codes added to the ICD 10–CM code list.

Comment: Another commenter expressed concern about patients grouped into the MMTA group who experience a change of condition that warrants additional resources during a period of care that is not properly accounted for under the PDGM. The commenter gave the example of an MMTA patient who experiences a fall and thereafter requires therapy services which are not accounted for in the case-mix weight based on the HHRG. The commenter suggested that ''it may be necessary for CMS to reinstate a payment adjustment similar to the Significant Change in Condition (''SCIC'') adjustment when HHGM is

implemented to address these patients' needs.''

Response: If the primary diagnosis changes between the first and the second 30-day periods, then the claim for the second 30-day period would reflect the new diagnosis, and providers would not change the claim for the first 30-day period. We note that if a patient experienced a significant change in condition before the start of a subsequent, contiguous 30-day period, for example due to a fall, in accordance with § 484.55(d)(1)(ii), the HHA is required to update the comprehensive assessment. Furthermore, in accordance with § 484.18(b) the total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode. A follow-up assessment would be submitted at the start of the second 30-day period to reflect the change in the functional level and the second 30-day claim would be grouped into its appropriate case-mix group accordingly. In this respect, two 30-day periods can have two different case-mix groups to reflect any changes in patient condition. This is different from the current payment system where the case-mix group does not change in the middle of a 60-day episode. However, similar to the current system, the case mix group cannot be adjusted within each 30-day period. HHAs must be sure to update the assessment completion date on the second 30-day claim if a follow-up assessment changes the case-mix group to ensure the claim can be matched to the follow-up assessment. HHAs can submit a claims adjustment if the assessment is received after the claim has been submitted, if the assessment items would change the payment grouping.

Comment: A few commenters questioned what will happen when a provider who has a claim returned for a principal diagnosis code that does not group into one of the six clinical groups and the provider corrects the claim by changing the principal diagnosis to one that corresponds to a clinical category. The commenter expressed concern that this may be regarded as ''up-coding'' and wanted to know how CMS would prevent this.

Response: As we are posting a complete list of ICD–10–CM codes that are available at the time of this final rule with comment period and their assigned clinical groupings on the CMS HHA Center web page, HHAs should have ample time to become familiar with codes that would be used to group 30-day periods of care into the 12 clinical groupings, therefore we believe the number of returned claims should be minimal as HHAs will avoid listing codes as the principal diagnosis code on the home health claim knowing in advance that such claims will be returned to the provider for more appropriate or specific coding. Returning a claim for more appropriate or specific coding would not be considered as ''up-coding'' assuming the documentation clearly supports the need for services. Furthermore, it is required per § 409.43(c)(4) that any changes in the plan of care must be signed and dated by a physician. If a claim is returned for more specific coding, then it is expected that the diagnosis on the plan of care will be corrected as well.

Under the PDGM, case-mix assignment is based, in part, on certain items in patient assessments completed by home health agencies and the diagnoses reported on the home health claim. Thus, if the average case-mix weight of Medicare home health patients increases over time, the extent to which case-mix increases reflect real changes in patient characteristics versus nominal case-mix changes attributable to changes in coding practices (more commonly referred to as ''up-coding'') has been examined. CMS examines the proportion of total case-mix change that is nominal versus real across all HHAs on an annual basis as this has important implications for determining home health payment rates that are accurate and reasonable. We do not determine nominal case-mix changes on a case-by-case basis.

Comment: A commenter indicated that SNFs and HHAs should use the same diagnosis classification system. Another commenter noted that providers do not generally determine their treatment based on a patient's clinical diagnosis, but rather ''treat the body structure and impairments derived from the diagnosis within each patient's unique environment.'' This commenter also suggested building a ''Diagnosis-Driven Groupings Model.''

Response: We stated in the CY 2019 HH PPS proposed rule that we agree that diagnosis alone does not provide the entire clinical picture of the home health patient. However, we maintain that a diagnosis is important to the overall care of a patient, as it crosses disciplines when identifying signs and symptoms of a disease or condition that may impact care planning. We stated that we believe that different healthcare disciplines use the signs and symptoms associated with a diagnosis to apply their own approach and skill set to treat the patient. We also reiterated that the clinical group is only one aspect of the PDGM, and that the combination of the clinical group with the other aspects of the PDGM, such as functional level and comorbidity adjustment, provide a more complete picture of the patient, allowing a thorough understanding of the resources needed for treatment. Payment would, in turn, be aligned with the more clearly defined resource use. It is unclear why the commenter suggested a ''Diagnosis-Driven Groupings Model,'' as the preceding comment indicates a rejection of the concept of grouping patients by diagnosis, but rather favors grouping patients by impairment. We would argue that, as the clinical group is determined by the patient's primary diagnosis, this aspect of the PDGM is diagnosis-driven. While CMS is making strides in aligning the patient assessment instruments, and in some cases aligning the case-mix adjustment methodology by virtue of removing therapy visit/minute thresholds, across the four post-acute care settings; we note that the SNF and HH benefits do not include the same set of services. For example, while not covered under the Medicare home health benefit, SNF covered services include room and board, medications, and ambulance transportation. Based on differences in setting of care and coverage between the SNF and Home Health benefits, we believe that there are appropriate reasons for the case-mix adjustment methodology to differ between the two settings.

Comment: Some commenters stated that patients who are not categorized into either the musculoskeletal or neuro rehabilitation groups, but who require physical therapy, occupational therapy, or speech-language pathology services may be at risk for receiving an inordinately low level of rehabilitation due to the allocation of resources to address those patients' other conditions. Another commenter indicated this undermined Jimmo Settlement Agreement and the provision of maintenance therapy. A commenter suggested removing therapy thresholds in stages. Another commenter also requested that CMS institute a mechanism within the PDGM to hold providers accountable for the delivery of appropriate, medically necessary care and provide safeguards to ensure how the delivery of therapy services aligns with individual patient characteristics and clinical needs.

Response: With respect to the provision of therapy services as they

relate to the home health period's clinical group, we should emphasize that 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 care plan. We stated in the CY 2019 HH PPS proposed rule that it is the responsibility of the patient's treating physician to determine if and what type of therapy (that is, maintenance or otherwise) the patient needs regardless of clinical grouping. As such, 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 when therapy is deemed reasonable and necessary. Therefore, a home health period's clinical group should not solely determine the type and extent of therapy needed for a particular patient.

Ultimately, case-mix adjustment takes into account the resource use of different groups of home health patients, and although not the sole determinant, diagnosis has always been a factor. Highlighting the principal diagnosis in the case-mix model helps to define the primary reason for home health, but does not in any way dictate what services should be included in the plan of care. Therefore, if the primary reason for home health care is for maintenance purposes with the primary need being therapy, this would be indicated on the plan of care and the patient would likely be grouped into one of the therapy groups.

The home health benefit is a bundled payment. It allows home health agencies the discretion to allocate resources based on their knowledge of the patient and the services needed to meet the goals of the individualized home health plan of care. This would mean that the HHA would consider the most appropriate and efficient use of home health services based on patient needs. Therefore, therapy may be an important service in any of the clinical groups; however, it may not necessarily be the primary reason for home health care, which is what the clinical group is intended to capture. Similarly, we expect that skilled nursing, home health aide, and medical social services would likely be included in the care plan for patients in the rehabilitation clinical groups.

While implementing the use of safeguards to ensure comprehensive evaluation of therapy needs is out of scope for this rule, we note that the home health CoPs establish the health and safety standards for care given to Medicare home health beneficiaries. As such, the CoPs would include such safeguards such as the type and frequency of patient assessments. Finally, section 1895(b)(4)(B)(ii) of the Act, as added by section 51001 of the BBA of 2018 requires elimination of therapy thresholds as part of the case-mix adjustment methodology, effective for January 1, 2020.

Comment: Another commenter expressed concern with the lower reimbursement assigned to the musculoskeletal rehabilitation clinical group, stating that home health providers may not have the same incentives to admit and treat these patients under PDGM. Another commenter suggested the addition of a complex therapy clinical group.

Response: We believe that it is important to look at the entire structure of the model, not only the clinical grouping, in order to understand how a patient with different skilled therapy or nursing needs are placed into a payment group. The clinical grouping is only one step in establishing a home health payment for a period of care. Again, this group is based on the principal diagnosis listed on the claim as well as specific OASIS items that indicate the need for more complex interventions that correlate with higher resource use. The clinical group is intended to capture the main reason the patient is receiving home health, but as we state in the CY 2019 HH PPS proposed rule, we understand that not all care needs can be identified by a diagnosis alone. Therefore, after the primary reason for the 30-day period is captured by the clinical grouping, the PDGM then takes into account the functional impairment level of the patient. Decreasing functional status, as indicated by a specific set of OASIS items, is associated with increased resource use. We believe that the functional impairment level of patients, when combined with the clinical grouping, would capture additional resource use from any multi-disciplinary therapy patients, or patients with ''complex-therapy'' needs. For instance, a patient grouped into the Neuro-Rehabilitation clinical grouping with a high Functional Impairment Level 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 services and medical management, is captured by the combination of the different levels of the model. Furthermore, we note that the current payment model does not differentiate between utilization of therapy disciplines and whether or not all three therapy disciplines are utilized for the same patient. We believe that the PDGM's functional impairment level when combined with the clinical grouping provides a much clearer picture of the patient's needs, particularly in relation to therapy services.

Final Decision: We are finalizing, with modification, our approach to grouping 30-day periods of care into clinical groups that represent the primary reason for home health care. We are finalizing twelve clinical groups, as shown in Table 27, which capture the most common primary reasons for home health care. The additional groups are a result of dividing the MMTA clinical group into 7 sub-groups. We note that although we are categorizing patients into twelve groups according to the principal diagnosis, these groups do not reflect all the care being provided to the home health patient during a 30-day period of care. Home health care remains a multidisciplinary benefit. Additionally, as stated in the CY 2019 HH PPS proposed rule, we will 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 in CY 2020.

TABLE 27: FINAL 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
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)	
MMTA –Surgical Aftercare	Assessment, evaluation, teaching, and medication management for surgical aftercare
MMTA – Cardiac/Circulatory	Assessment, evaluation, teaching, and medication management for cardiac or other circulatory related conditions
MMTA – Endocrine	Assessment, evaluation, teaching, and medication management for endocrine related conditions
MMTA – GI/GU	Assessment, evaluation, teaching, and medication management for gastrointestinal or genitourinary related conditions
MMTA – Infectious Disease/Neoplasms/Blood-forming Diseases	Assessment, evaluation, teaching, and medication management for conditions related to infectious diseases, neoplasms, and blood-forming diseases
MMTA –Respiratory	Assessment, evaluation, teaching, and medication management for respiratory related conditions
MMTA – Other	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the previously listed groups

7. Functional Impairment Levels and Corresponding OASIS Items

As part of the overall case-mix adjustment under the PDGM, we proposed in the CY 2019 HH PPS proposed rule to include a functional impairment 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.[19] 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.[20] 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).

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 PDGM would also adjust payments based on responses to selected functional OASIS items that have demonstrated higher resource use. 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.

Each proposed OASIS item included in the PDGM has a positive relationship with resource use, meaning as functional status declines (as measured by a higher response category), home health periods have more resource use, on average. In the CY 2019 HH PPS proposed rule, we proposed that the following OASIS items would be included as part of the functional impairment level adjustment under the PDGM:

- 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).[21]

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 the OASIS items previously discussed are found at Exhibit 7–2 in the technical report, ''Overview of the Home Health Groupings Model,'' on the HHA Center web page.[22]

Under the PDGM, a home health period of care receives points based on each of the responses associated with

[19] 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.

[20] 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.

[21] 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.

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

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. In the CY 2019 HH PPS proposed rule, we also discussed the potential, future inclusion of the IMPACT Act section GG functional items, which will be collected on the OASIS starting January 1, 2019. A detailed analysis of the development of the functional points and the functional impairment level thresholds by clinical group can be found in the technical report on the HHA Center web page.

As noted in section III.F.6 of this final rule with comment period, we are subdividing the MMTA clinical group into seven sub-groups (MMTA-aftercare; cardiac/circulatory; endocrine; gastrointestinal/genitourinary; infectious disease/neoplasms/blood-forming diseases; respiratory; and other) to more accurately capture unique patient characteristics associated with patients receiving home health services for medication management, teaching, and assessment. As such, we recalculated the functional points and the thresholds for the functional impairment levels by clinical group. This also resulted in a few minor changes to the functional thresholds compared to the thresholds in the CY 2019 HH PPS proposed rule (Table 42, 83 FR 32406). The updated OASIS points table for the functional items and the table of functional impairment level thresholds for by clinical group are found in Tables 28 and 29.

TABLE 28: 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	23.7%
M1840: Toilet Transferring	1	4	32.1%
M1850: Transferring	1	4	37.7%
	2	8	59.3%
M1860: Ambulation/Locomotion	1	10	25.1%
	2	12	52.9%
	3	24	14.8%
M1032: Risk of Hospitalization	4 or more items checked	11	17.8%

TABLE 29: THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, CY 2017

Clinical Group	Level of Impairment	Points (2017 Data)
Behavioral Health	Low	0-36
	Medium	37-52
	High	53+
Complex Nursing Interventions	Low	0-38
	Medium	39-58
	High	59+
Musculoskeletal Rehabilitation	Low	0-38
	Medium	39-52
	High	53+
Neuro Rehabilitation	Low	0-44
	Medium	45-60
	High	61+
Wound	Low	0-42
	Medium	43-61
	High	62+
MMTA - Surgical Aftercare	Low	0-24
	Medium	25-37
	High	38+
MMTA - Cardiac and Circulatory	Low	0-36
	Medium	37-52
	High	53+
MMTA - Endocrine	Low	0-51
	Medium	52-67
	High	68+
MMTA - Gastrointestinal tract and Genitourinary system	Low	0-27
	Medium	28-44
	High	45+
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	0-32
	Medium	33-49
	High	50+
MMTA - Respiratory	Low	0-29
	Medium	30-43
	High	44+
MMTA - Other	Low	0-32
	Medium	33-48
	High	49+

In the CY 2019 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 PDGM, as previously outlined. The majority of comments received were very similar to those received on the alternate case-mix adjustment methodology (HHGM), in the CY 2018 HH PPS proposed rule. The comments received are summarized in this section.

Comment: 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. Commenters stated that including a robust functional level variable in the home health payment system will eliminate 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 PPS.

Response: We thank commenters for their careful review of all variables contributing to the overall case-mix adjustment in the PDGM. We agree that functional status is an important component in understanding patient characteristics to help facilitate the development of an individualized home health plan of care based on identified needs and to help ensure that payment

is in alignment with the costs of providing care.

Comment: Several commenters supported the examination and possible inclusion of the IMPACT Act's section GG, Functional Abilities and Goals, as part of the functional level case-mix adjustment in the PDGM. A commenter remarked that by adding the section GG functional items to the HH VBP model and the HH QRP, CMS would be able to better monitor provider behavior to detect inappropriate responses to implementation of the PDGM, including withholding therapy services that could result in poor outcomes; selecting patients who are likely to be relatively more profitable; generating unnecessary periods of care; or prematurely discharging patients. However, a few commenters recommended that CMS study and validate the predictive capability of such items prior to pursuing any refinements to the PDGM's functional level category. This commenter remarked that it is critical that CMS is confident in the capability of Section GG functional items to sufficiently predict functional impairment level and associated resource use.

Response: We appreciate the commenter feedback on the potential use of the GG functional items as part of the functional impairment level case-mix adjustment in the PDGM. We remind commenters that because these GG functional items are not required to be collected on the OASIS until January 1, 2019, we do not have the data at this time to determine the effect, if any, of these newly added items on resource costs during a home health period of care. Therefore, the GG functional items would not be used immediately upon implementation of the PDGM in CY 2020. We will continue to analyze all OASIS items, including the newly added GG functional items, after the implementation of the PDGM, to determine if the data supports any refinements to the case-mix adjustments. The goal is to keep only those items that are reliable, validated, have an impact on resource utilization, and address quality outcomes in order to ultimately decrease the number of OASIS items and reduce burden. Likewise, while the GG functional items may be able to play an important role in the HHVBP Model and HH QRP in monitoring for quality outcomes, their consideration for use in the PDGM would be to identify their relationship to resource utilization to more accurately align payment with home health costs.

Comment: Commenters stated that the functional impairment level thresholds do not fully capture the functional impairments that translate to the actual resources needed on the home health plan of care. Many commenters believe that the functional impairment level adjustment is relatively small and inadequate to reimburse for patients with chronic care needs potentially creating access issues for people who are chronically ill and may require a prolonged period of home health care. Many commenters remarked that HHAs would not admit these types of patients or would cut back on the number of therapy visits provided, especially now that therapy thresholds will be removed in CY 2020. Several commenters stated that the PDGM favors only patients who are expected to improve and not those who require ongoing, maintenance therapy but do not group into one of the predominantly therapy groups and therefore is counter to the provisions in the Jimmo Settlement Agreement.

Response: We believe that the functional impairment level adjustment would adequately capture the level of functional impairment based on patient characteristics reported on the OASIS. The PDGM not only uses the same five OASIS items used in the current HH PPS to determine the functional case-mix adjustment (M1810, M1820, M1830, M1830, M1850, and M1860), but adds two additional OASIS items (M1800 and M1033) to determine the level of functional impairment. 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 home health episodes using functional scores 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' home health periods of care using functional impairment scores based on functional OASIS items with similar resource use and has three levels of functional severity: low, medium and high. However, the PDGM differs from the current HH PPS functional variable in that the three functional impairment level thresholds in the PDGM vary between the clinical groups. The PDGM functional impairment level structure accounts 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 characteristics and 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 therapists to tailor a more patient-centered home health plan of care to meet the individualized needs of their patients.

We disagree that the functional impairment level case-mix payment adjustment is inadequate and that the PDGM would inhibit access to care for those with patients with complex and/or chronic care needs and high functional impairments. The absence of discipline-related therapy thresholds allows for a more equitable distribution of services based on patient needs, including needs for chronically ill patients. We note that the PDGM is structured to capture patient characteristics, including functional impairment status, similar to the functional case-mix adjustment in the current HH PPS. As HHA-reported OASIS information determines the payment amounts for each of the functional levels, accurate reporting on the OASIS by HHAs will help to ensure that the case-mix adjustment is in alignment with the actual level of functional impairment.

We also disagree with the comment that the PDGM favors only those home health patients who are expected to improve, does not take into account patients with longer term maintenance therapy needs, and is counter to the provisions of the Jimmo Settlement Agreement. We remind commenters that the structure of the home health benefit requires a multidisciplinary approach, and the PDGM promotes the provision of not only therapy services, but skilled nursing, home health aide, and medical social services as well. The clinical groups, as well as the functional impairment level case-mix adjustment, account for the full range of services available under the Medicare home health benefit. We believe that the functional impairment level adjustment compensates for the resource needs of those with functional impairment and ongoing therapy needs, and therefore does not endorse one type of patient over another. There has never been an expectation that only patients who demonstrate the ability to improve are eligible for the Medicare home health benefit. We have educated the MACs extensively to ensure that any medical review of claims for cognitively or functionally impaired patients who are receiving maintenance therapy to prevent further deterioration, are doing

so according to the parameters within the *Jimmo* Settlement Agreement.

We believe adding a more robust and granular functional impairment level adjustment should preserve, and potentially increase access to therapy services for vulnerable patients who may not otherwise have received needed therapy services, including those with complex and/or chronic care needs. As such, we would expect continued admissions of these patient populations with therapy visits provided in accordance with physician orders as documented on the plan of care, including the frequency and duration of these orders. We remind HHAs that the PDGM case-mix adjusters work in tandem to reflect a patient's resource needs. The overall payment for a home health period of care under the PDGM is determined by the cumulative effect of all of the variables used in the case-mix adjustments. Ultimately, the goal of the PDGM is to provide more accurate payment based on the identified resource use of different patient groups.

The PDGM is not limiting or prohibiting the provision of therapy services or the number of home health periods of care, nor is there a reduction to the overall base rate of home health payment. The commenters imply that HHAs would ''cherry pick'' the type of patients to admit primarily based on Medicare payment under the PDGM and that care decisions, including the number of therapy visits, are determined solely on profitability of patients. As such, any potential access issues would be the result of a change in HHA behavior in response to the removal of therapy thresholds to maximize margins of a bundled payment rather than the result of a case-mix adjustment model that seeks to more accurately pay for home health services. Manipulating visit patterns, including the type and number of visits provided, and/or admitting only certain patient populations to maximize payment is counter to the purpose of a prospective payment system and the intent of a patient-driven Medicare home health benefit. Furthermore, this could result in a violation of the home health CoPs and may signal program integrity issues. We will continue to monitor the impact of all of the case-mix adjustments in the PDGM to determine if any changes to utilization are occurring, especially as they relate to the provision of therapy. This may involve, but is not limited to, comparative analysis of utilization patterns prior to and after the implementation of the PDGM and could result in additional enforcement actions as a result of any program integrity concerns. Likewise, the BBA of 2018 requires that we calculate the 30-day budget-neutral payment amount based on assumed behavior changes resulting from the implementation of a 30-day unit of payment and the PDGM. The law also requires that we annually analyze the impact of differences between the assumed and actual behavioral changes on estimated aggregate expenditures for CYs 2020 through 2026 and to make any payment amount adjustments, either upwards or downwards, accordingly.

Comment: Some commenters remarked that the PDGM diminishes and devalues the role physical, occupational, and speech language pathology therapists play in quality outcomes by alleviating risks of increased falls, emergency room visits, re-hospitalizations, improving or maintaining functional level, and keeping patients in their homes. Other commenters stated that minimization of the importance of the home health therapy disciplines would cause therapists to lose their jobs in home health. Commenters said that access to home therapy will be significantly curtailed as a result and functional outcomes would be negatively impacted. These commenters remarked that the PDGM appears to be counter to the Triple Aim: improving the patient experience of care (including quality and satisfaction); improving the health of populations; and reducing the per capita cost of health care.

Response: We disagree that the PDGM diminishes or devalues the clinical importance of therapy. The musculoskeletal and neurological rehabilitation groups under the PDGM recognize the unique needs of patients with musculoskeletal or neurological conditions who require therapy as the primary reason for home health services. For the other clinical groups, we note that the 30-day base payment amount includes therapy services, even if the primary reason for home health is not for the provision of therapy. The functional impairment level adjustment in conjunction with the other case-mix adjusters under the PDGM, aligns payment with the costs of providing services, including therapy.

We agree with commenters that the role of the physical, occupational, and speech language pathology therapists is important in quality outcomes and the prevention of adverse events, such as falls and emergency room visits, and that these disciplines are important in helping patients remain in their own homes. However, we note that the goal of the PDGM is to provide appropriate payment based on the identified resource use of different patient groups; not to encourage, discourage, value, devalue, or promote one type of skilled care over another.

We do not expect HHAs to make personnel decisions solely based on a change to the HH PPS case-mix methodology as the requirements for providing home health services have not been changed. Under the Medicare home health benefit, skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in § 409.44, and dependent services include home health aide services and medical social work services, as specified in § 409.45. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care. Additionally, we note that the home health CoPs at § 484.60 require that each patient receive an individualized written plan of care that must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s).

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 adjustment is reflective of the resource costs associated with the 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.

Finally, we believe that the PDGM is in alignment with the tenants of the CMS Triple Aim to provide better care for individuals; promote better health outcomes for populations; and lower health care costs. The PDGM does so by taking a patient-driven approach over a volume-based approach by using patient characteristics, rather than arbitrary thresholds of visits that do not necessarily equate to better outcomes or

lower costs. The PDGM seeks to better define the services needed by home health beneficiaries. We believe that developing a case-mix system that provides a clearer picture as to the services provided under the Medicare home health benefit can help promote efficiencies in achieving desired patient outcomes.

Comment: Several commenters expressed concern over how CMS would ensure that necessary therapy visits are provided to home heath beneficiaries. These commenters remarked that it is unclear how CMS intends to capture an accurate assessment of the services delivered during the home health period of care, particularly physical therapy, occupational therapy, and/or speech-language pathology services. Other comments stated that they fail to see how medical review is a sufficient option to remedy the consequences associated with delivering inadequate care, as they said that medical review does nothing that would allow care delivery to be modified during the period of care. A few commenters urged CMS to use ''accountability mechanisms,'' such as medical review, and recommended that the agency analyze the medical review findings and publically report any observed patient care trends via Home Health Compare.

Response: The purpose of the changes to the case-mix adjustment methodology is to more accurately align home health payments with the costs of providing care. Other accountability mechanisms, such as survey and certification of HHAs, are the most appropriate ways to ensure quality and safety for Medicare home health recipients. Quality is also determined through other mechanisms, such as the HH QRP and the HHVBP Model.

The new home health CoPs are more detailed in the expectations of the provision of needed home health services. Specifically, the CoPs at § 484.60 require that patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Services are required to be identified in an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care.

It is difficult to proactively determine that care is ''inadequate'' or ''of poor quality'' given that we do not know the type, frequency or quality of services until after those services are provided. The volume of services provided does not necessarily equate with higher quality of care.

We believe that the home health CoPs provide the requirements to promote and ensure quality home health care. However, as we indicated in the CY 2019 HH PPS proposed rule, we will continue to analyze utilization trends, including therapy visits as reported on home health claims, to identify any issues that may warrant any quality or program integrity intervention.

Comment: Some commenters expressed concerns that Medicare beneficiaries' functional outcomes may significantly decline following PDGM implementation because the provision of therapy services would be reduced without the extra payment for increased therapy services. These commenters stated that research has shown a significant correlation between volume of therapy and improvement in outcomes. Some commenters stated adoption of the PDGM could reverse the progress in patient outcomes that was seemingly ignited by a ''financial incentive'' to increase therapy visits versus skilled nursing visits.

Response: We disagree that patients' functional outcomes would significantly decline following PDGM implementation. We reference a study conducted by RAND contrasting the effects of two payment reforms for home health agencies, specifically comparing the Interim Prospective Payment System (IPS) and the Prospective Payment System (PPS). This study did not show worsening patient outcomes (that is, increased hospitalizations or mortality) when there was a transition from one payment system to another (that is, from the IPS to the PPS). In this particular study, the analysis also showed both payment reforms had limited effects on costs in other post-acute settings, and limited effects on patient outcomes as the study noted that there was not any substantial increase in hospital readmissions or patient mortality after the implementation of the PPS.[23] Furthermore, in its March, 2010 report, MedPAC stated that higher home health spending is not yielding better outcomes. In this report, MedPAC stated that undesirable outcomes (for example, unnecessary complications) may result in additional payments, and sectors with more than adequate payments may have little incentive to improve quality.[24]

We believe that the structure of the PDGM is more patient-driven than the current case-mix system and more accurately represents the patient characteristics that will correspond to an appropriate individualized care plan to provide those needed services. We believe that the PDGM will allow for more tailored, appropriate quality of care and removes the financial incentive to focus on the volume of care and not patient needs. By keeping patient characteristics at the center of the case-mix adjustment methodology, we believe that patient needs will be more accurately addressed and that this has the potential to result in care plan goal achievement and desired patient outcomes.

Comment: Another commenter remarked that using the term ''Functional Level'' with a score of low-medium-high is confusing. This commenter stated that this will confuse providers into believing the reference is to low, medium, or high functional level. It would be clearer to refer to this measure as a ''Functional *Impairment* Level'' in which case a low, medium, or high functional impairment would be properly indicated.

Response: As explained in the CY 2019 HH PPS proposed rule, 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. As such, we agree that adding the term ''impairment'' when referring to the functional level adjustment is appropriate.

Comment: A few commenters stated that the PDGM case-mix variables, including the functional impairment level adjustment would make it more difficult to manage costs and revenues for patients with high functional impairments. Some commenters disagreed with the removal of therapy thresholds as they asserted that the increased payments with the thresholds allowed for the provision of adequate therapy services. These commenters indicated that the reductions in payment for therapy visits would result

[23] Huckfeldt, P., Sooda, N., Escarcea, J., Grabowski, D., Newhouse, J. *Effects of Medicare payment reform: Evidence from the home health interim and prospective payment systems.* Journal of Health Economics (34) 1–18. March, 2014. *https://doi.org/10.1016/j.jhealeco.2013.11.005.*

[24] *http://www.medpac.gov/docs/default-source/reports/Mar10_EntireReport.pdf.*

in a decrease in HHA viability and would force many HHAs to go out of business.

Response: We remind commenters that the removal of therapy thresholds for CY 2020 and subsequent years is required by section 1895(b)(4)(B)(ii) of the Act, as added by section 51001 of the BBA of 2018, and therefore we are statutorily mandated to exclude therapy thresholds in the development of an alternate case-mix adjustment methodology effective January 1, 2020. We note that since 2000, under the Medicare home health benefit, HHAs receive a bundled payment for the provision of care to include skilled nursing; physical, occupational, and speech-language pathology therapy; medical social work; home health aides; and medical supplies. Under the PDGM, home health payments remain prospective payments similar to the current payment system, meaning an overall national, standardized base rate with case-mix adjustments. The structure of a prospective payment system is such that payment is based on a predetermined base rate regardless of the volume, frequency, or intensity of the actual service(s) provided. The case-mix adjustments provide additional payment to account for patient characteristics. As such, the overall payment amount is known to the HHA at the beginning of each home health episode and this fixed home health rate necessitates better management and estimation of costs and payments, and helps to motivate providers to be more efficient in the provision of quality care. Therefore, a home health bundled payment allows HHAs the discretion to allocate resources based on their knowledge of the patient and the services needed to meet the goals of the individualized home health plan of care. This would mean that the HHA would consider the most appropriate and efficient use of home health services based on patient needs. A bundled payment reduces the uncertainty in payment, affording the HHA more information to help manage revenues and costs in order to allocate resources accordingly.

Additionally, the Medicare home health benefit requires a multidisciplinary approach to care and the expectation is that HHAs provide the full range of services under the benefit to all eligible beneficiaries, and not solely therapy services. As such, developing a business model designed to target only those patients requiring therapy in order to maximize Medicare payment is counter to the requirements under the benefit. It also places the HHA at financial risk if payment is reliant only on a specific patient population. For those HHAs who do provide the full range of services and do not target only those patients for whom they can maximize payment based on therapy thresholds, we believe that the functional impairment level adjustment provides sufficient additional payment across all clinical groups. This would include those patients who are receiving home health services primarily for other skilled needs but who may also require therapy services as part of their home health plan of care. The PDGM is clinically-based, meaning it relies more heavily on patient characteristics to place home health periods of care into clinically meaningful payment categories. These patient characteristics also help home health clinicians differentiate between the services needed by home health patients. We believe that a patient-driven approach to case-mix adjusting payment better clarifies the services provided under the Medicare home health benefit. Therefore, we believe this patient-driven approach better promotes efficiencies in the provision of care based on actual patient needs and will make it easier for HHAs to manage revenues and costs.

Finally, to support HHAs in evaluating the effects of the proposed PDGM, CMS is providing, upon request, a Home Health Claims-OASIS Limited Data Set (LDS).[25] Additionally, CMS has posted an interactive PDGM Grouper Tool on the HHA Center web page that will allow HHAs to determine case-mix weights for their patient populations.[26]

Comment: Several commenters stated that inclusion of caregiver availability and support should be part of the functional level payment adjustment in the PDGM because they report that a lack of caregiver support plays a significant role in a patient's overall functional level and resource needs especially as they relate to ADLs and IADLs. Another commenter remarked that research has shown non-compliance and readmission risk is higher when other psychosocial factors are present. Several commenters recommended that the functional level include OASIS items related to social determinants of health, such as those associated with caregiver support.

Response: We understand the value of caregiver support for home health patients and its potential to affect resource utilization and the inclusion of caregiver variables has been examined several times since the development of the current HH PPS. As explained in the FY 2001 HH PPS final rule (65 FR 41145), we examined the usefulness of caregiver factors but found them to be only minimally helpful in explaining or predicting resource use. We found that variables on the availability of a caregiver had no impact on average resource cost and only a modest impact after controlling for other patient characteristics. We stated that we recognized that adjusting payment in response to the presence or absence of a caregiver may be seen as inequitable by patients and their families. To the extent the availability of caregiver services, particularly privately paid services, reflects socioeconomic status differences, reducing payment for patients who have caregiver assistance may be particularly sensitive. Furthermore, adjusting payment for caregiver factors may introduce new and negative incentives into family and patient behavior. It is questionable whether Medicare should adopt a payment policy that could weaken informal familial supports currently benefiting patients at times when they are most vulnerable (65 FR 41145). Similarly, when we re-examined caregiver assistance as a potential case-mix variable in the CY 2008 HH PPS proposed rule to analyze the payment adequacy of the current four-equation model, we found that for patients without a caregiver, on average, episodes would be ''underpaid'' (72 FR 25361). However, the score to be gained by adding the variable was not large and the overall ability of the four-equation model to explain resource costs was improved only minimally by adding this variable. As such, we did not propose that a caregiver variable be added to the case-mix model at that time.

When we re-examined the OASIS caregiver items for possible inclusion in the functional impairment level case-mix adjustment in the PDGM, we found inverse patterns in resource use (82 FR 35319). We examined OASIS items associated with types and sources of caregiver assistance and frequency of ADL/IADL assistance. These items assess the ability and willingness of non-agency caregivers (such as family members, friends, or privately paid caregivers) to provide categories of assistance needed by the patient, including ADL/IADL assistance, medication administration, and management of equipment. As responses to these items generally are not based on direct observation by the clinician conducting the assessment,

[25] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html.*

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

this presents a limitation for use in a case-mix adjustment as the accuracy of the responses cannot be easily validated. Patients or caregivers may overestimate or underestimate their ability or willingness to assist in the patient's care. Likewise, analysis of these items generally showed that an increased need for assistance had a negative impact on resource costs, meaning that as need for assistance increased, costs decreased. We believe this is clinically counterintuitive and, as outlined in both the Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements Overview of the Home Health Groupings Model technical report [27] and the CY 2018 and CY 2019 HH PPS proposed rules (82 FR 35270 and 83 FR 32340), we excluded any OASIS items that had a negative relationship with resource costs. Including these items would only serve to reduce the home health period of care payment. As such, the current data analysis findings we conducted on caregiver variables weaken the assertion that failure to adjust for caregiver factors could render payments inadequate.

Finally, we continue to believe that including this kind of variable in the case-mix system raises significant policy concerns. We maintain that a case-mix adjustment should not discourage assistance from family members of home care patients, nor should it make patients believe there is some financial stake in how they report their familial supports during their convalescence. We have concerns that adjusting payment in response to the absence of a caregiver would introduce negative incentives with adverse effects on home health Medicare beneficiaries.

Comment: Several commenters recommended that cognition, pain and dyspnea should be included as functional level determinants as they affect functional performance and trajectory for improvement. Many commenters supported the inclusion of cognitive items as part of the functional case-mix adjustment, and noted that there is a correlation between cognitive status and functional impairment. A few commenters suggested that OASIS item M1242, Frequency of Pain interfering with Activity, should be included as part of the functional level items in the PDGM. These commenters stated that pain directly impacts functional performance. These same commenters remarked that PT and OT can directly reduce pain thus improving the patient's quality of life.

Response: The current HH PPS does not use OASIS items associated with IADLs or cognition. We agree with commenters that the relationship between cognition and functional status is important and well-documented in health care literature. We discussed our analysis and rationale for evaluating all of the OASIS items related to function, including the relationship between cognitive functioning and resource use, extensively in both the technical report [28] and the CYs 2018 and 2019 HH PPS proposed rules (82 FR 35319, 83 FR 32404). Empirically, it appears that cognition does impact functionality, and initially these items were included in the PDGM. Counterintuitively, however, resource use declined as cognitive status worsened. This negative relationship with resource use was consistent throughout all levels of cognitive functioning as assessed on the OASIS, including mild impairment. While we cannot explain this phenomenon from OASIS or home health claims alone, anecdotally we have heard that while cognitive impairment may intuitively signal increased resource use, the cognitive items are not currently payment items and therefore do not receive the same attention as the payment items when completing the OASIS. Likewise, we have received reports that as cognition declines, individuals often become more dependent on caregivers for functional tasks and thus the home health clinician is not performing those tasks during a visit. We frequently hear from clinicians that as it becomes increasingly difficult to teach the cognitively impaired patient how to perform ADLs/IADLs, teaching the caregiver to perform the functional tasks is more efficient or beneficial. Additionally, we have been told it that generally takes more time to teach and train the cognitively impaired patient to perform a functional task so the clinician may simply perform the functional task him or herself as the patient's ability to independently perform these tasks progressively declines. All of these anecdotes potentially could explain the inverse relationship between cognitive impairment and resource use.

As discussed previously, the OASIS cognitive items are not used for a payment adjustment under the current HH PPS, but most of the proposed functional items are. As commenters have stated, there is potentially more HHA focus on the OASIS payment items, which could explain why the functional items show a positive relationship to resource use while the cognitive items do not. As many commenters have stated and as supported in the research, there is a relationship between cognition and functional status. As such, we believe that the functional items included in the functional impairment level case-mix adjustment provide a reasonable proxy for cognitive status given their interrelatedness. Because of the negative relationship between the OASIS cognitive items and resource use, we decided not to include the items as part of the functional adjustment in the PDGM but will continue to analyze their inclusion once the PDGM is implemented.

Similarly, we also examined pain and dyspnea OASIS items for inclusion in the case-mix adjustment methodology including OASIS items M1242, Pain and M1400, Shortness of Breath. While M1242, Pain, is used in the current HH PPS, this was shown to have only a minimal relationship with resource use in the current payment model. Additionally, we believe that this one item alone may not be robust enough to fully capture the pain presentation of the patient and its impact on resource utilization and therefore it was dropped from consideration. While M1400, Shortness of Breath, is also used in the current HH PPS, it too shows minimal impact on resource use. We did not include M1400 in the PDGM case-mix adjustment methodology because we believe the more granular ICD–10 codes that describe respiratory conditions, more accurately capture this patient characteristic. Again, we refer commenters to the more detailed discussion on why certain OASIS items were included or excluded from the model, the ''Overview of the Home Health Groupings Model Technical Report'' [29] and the CY 2018 HH PPS proposed rule (82 FR 35307).

Comment: The majority of commenters agreed that the elimination of therapy thresholds is appropriate because of the current financial incentive to overprovide therapy services. However, these commenters believe that the functional impairment level adjustment is not an adequate proxy to ensure the provision of therapy services needed for patients requiring multiple disciplines of therapy or the frail elderly with multiple chronic conditions and associated functional impairment. A few commenters questioned whether CMS has evidence

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

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

[29] ''Overview of the Home Health Groupings Model'' technical report, Appendix Exhibit A7–1 on the HHA Center web page (*https://ww.com.gov/center/provider-type/home-health-agency-hha-center.html*).

that Medicare beneficiaries have received ''too much'' therapy, or that the functional outcomes of Medicare beneficiaries receiving home health services have suffered, under the current payment system. These commenters stated that given the ever-increasing effort to promote the delivery of care in the home and community settings, it is imperative that the Medicare program continue to incentivize providers to deliver care in non-facility-based settings while also ensuring that patients may continue to receive the highest quality of care that aligns with their preferences, desires, and needs.

Response: We agree that the therapy thresholds have created an incentive to overprovide therapy services that are not in alignment with patient characteristics and care needs. Section 1895(b)(4)(B)(ii), as added by section 51001 of the BBA of 2018, requires that CMS eliminate the use of therapy thresholds as part of the case-mix adjustment methodology beginning in CY 2020. We note that the purpose of the functional impairment level case-mix adjustment is not meant to act as a direct proxy to replace the current therapy thresholds. As noted, the presence of the therapy thresholds provided an incentive to overprovide services and their removal deflates that financial incentive to help ensure that therapy services are based on actual patient needs. However, we recognized that in order to account for levels of functional impairment and to help ensure that necessary therapy services are provided, the development of a functional impairment level case-mix adjustment with more granularity was necessary. We believe that the three PDGM functional impairment levels in each of the 12 clinical groups are designed to encourage therapists to determine the appropriate services for their patients in accordance with identified needs rather than an arbitrary threshold of visits.

The PDGM has other case-mix adjustments in addition to the functional impairment level to adjust payment for those patients requiring multiple therapy disciplines or those chronically ill patients with significant functional impairment. We believe that also accounting for timing, source of admission, clinical group (meaning the primary reason the patient requires home health services), and the presence of comorbidities will provide the necessary adjustments to payment to ensure that care needs are met based on actual patient characteristics.

To address comments about evidence regarding ''too much'' therapy, we remind commenters that analysis has repeatedly shown that the current HH PPS therapy thresholds promote the provision of care based on increased payment associated with each of these thresholds as opposed to actual patient needs. In the CY 2018 HH PPS proposed rule, analysis of home health claims shows that the average episode payment by the number of therapy visits for episodes with at least one therapy visit increases sharply just over payment thresholds at 6, 7, and 16 (82 FR 35276).

Furthermore, CMS analysis demonstrates that the average share of therapy visits across all 60-day episodes of care increased from 9 percent of all visits in 1997, prior to the implementation of the HH PPS (see 64 FR 58151), to 39 percent of all visits in 2015 (82 FR 35276). We note that the therapy thresholds have been widely criticized by MedPAC who has recommended the removal of therapy thresholds for the past 5 years, as their analysis has repeatedly shown that Medicare payments for home health services have substantially exceeded costs. Additionally, the Senate Committee on Finance conducted an investigation and issued a report on therapy practices of four of the largest publically-traded home health agencies where three out of the four companies investigated encouraged therapists to target the most profitable number of therapy visits, even when patient need alone may not have justified such patterns. The Senate investigation also highlighted the abrupt and dramatic responses the home health industry has taken to maximize payment under the therapy threshold models (both the original 10-visit threshold model and under the revised thresholds implemented in the CY 2008 HH PPS final rule (72 FR 49762)). The report noted that, under the current HH PPS, HHAs have broad discretion over the number of therapy visits provided, and therefore have control of the single-largest variable in determining reimbursement and overall margins. The report recommended that CMS closely examine a future payment approach that focuses on patient wellbeing and health characteristics, rather than the numerical utilization measures.

We agree that most patients would prefer to receive services in their own home whenever feasible and the Medicare home health benefit affords a comprehensive range of services for eligible beneficiaries. However, we are cognizant that payment may affect practice patterns and our analysis has shown that visits vary in response to financial incentives. While the goal of the PDGM case-mix adjustments is to align payment with actual patient characteristics, we are aware that practice patterns may shift upon implementation of a new case-mix methodology. Our goal is to protect patient choice and preferences as well as promote the provision of high quality, appropriate home care. As we have reiterated throughout this final rule with comment period, upon implementation of the PDGM, we will continue to examine the impact of all OASIS items on resource costs. Likewise, we will also examine any changes in the number of therapy visits provided that could indicate HHAs stinting on needed therapy services to determine whether any impacts warrant additional refinements to the case-mix adjustments under the PDGM.

Comment: Some commenters expressed concern that eliminating the therapy thresholds, which dominate the current HH PPS, would cause the unintended consequence of shifting patients to other home health disciplines, specifically nursing and home health aides, which would steer patients away from restorative therapies and ultimately increase Medicare costs. Some expressed concern about other disciplines providing therapy services outside of the scope of their practice. Some expressed reservations about possible misuse of aides to provide what should be skilled therapy, such as providing exercise programs or evaluating self-care needs and safety as a substitute for skilled therapy. These commenters state that both substitutions are inappropriate and may violate state licensure law, for example, the provision of therapy services by unqualified personnel.

Response: Regarding the comment that the removal of therapy thresholds would shift patients to other home health disciplines, we note that in the CY 2001 HH PPS final rule, we expressed concern over using a therapy utilization measure to determine home health payment because it could be susceptible to manipulation and may cause a shift away from home health nursing and other services. In this same rule, commenters expressed concern that implementing a therapy threshold would divert utilization of the home health benefit away from the frail elderly and in favor of the short-term patient (65 FR 41149). These concerns about the impact of the introduction of the therapy thresholds are the same concerns now expressed by commenters regarding the impact of the elimination of the therapy thresholds. In the CY 2001 rule, we stated that we would continue to review the use of a utilization variable in the payment

system over the long-term. As discussed previously in this section, there was a noted shift to increased therapy services after the implementation of the HH PPS with the therapy thresholds. We believe that the elimination of the therapy thresholds will remove the financial incentive to provide therapy solely for increased payment. As we are not adding any service utilization measure for nursing or home health aides, this would mitigate the financial incentive to provide more of those services solely for increased payment as well. Essentially, this would mean that no one home health discipline is favored or paid differently than any other discipline within the home health bundled payment and the plan of care would be patient-centered as opposed to payment-centered. We believe that elimination of the therapy thresholds is more in alignment with the intent of the home health benefit to be patient-centered and based on patient characteristics, such as functional status, and actual patient needs. Likewise, we expect that any services provided would be in accordance with all Federal and State laws, including all licensure requirements. The provision of skilled therapy services as part of a home health plan of care must also adhere to the home health CoPs, and substituting a home health aide to provide those skilled therapy services would be a violation of the CoPs (42 CFR 484.32).

We note that the goal of the PDGM is to provide appropriate payment based on the identified resource use of different patient groups; not to encourage, discourage, value, devalue, or promote one type of skilled care over another. Because there are no service utilization thresholds in the PDGM, we expect that HHAs will respond by adapting a business model based on more patient-centered care as opposed to payment-driven care.

Comment: Several commenters stated that the PDGM would reward inefficiency but not high quality outcomes by redistributing payments away from services such as physical, occupational and speech therapy. They remarked that this shift would make it harder for patients with high functional impairment to achieve quality outcomes.

Response: The intent of the PDGM is to more accurately apportion payment with the costs of providing care. We disagree that the redistribution of payments would reward inefficiency as the home health agency is already tasked with developing efficiencies within the current home health bundled payment. Additionally, the home health quality reporting program (HH QRP), and the HH VBP Model contain outcome measures which are used, respectively, for the Home Health star ratings and a total performance score used to tie payments to quality performance for HHAs in certain states. As such, we believe that both the HH QRP and the HH VBP Model help to promote and ensure quality outcomes, whereas the PDGM is the mechanism for payment for services provided. Furthermore, regardless of level of functional impairment, we expect that HHAs always strive for efficiency and high quality outcomes for their patients. This is achieved through the appropriate provision of services in accordance with patient characteristics and physician orders as documented on the home health plan of care.

Final Decision: After review of public comments, we are finalizing the use of OASIS items: M1800, M1810, M1820, M1830, M1840, M1850, M1860 and M1033 for the functional impairment level case-mix adjustment under the PDGM. We are finalizing that a home health period of care receives points based on each of the responses associated with the functional OASIS items which are then converted into a table of points corresponding to increased resource use (see Table 28). 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 finalizing 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 29). For the implementation of the PDGM in CY 2020, we will update the functional points and functional thresholds as previously described based on analysis of CY 2018 home health claims, and using the most current version of the OASIS data set, to reflect any changes in resource use associated with these variables. Likewise, as articulated in the proposed rule and throughout this final rule with comment period, once the PDGM is implemented in CY 2020, we will continue to analyze the impact of all of the PDGM case mix variables to determine if any additional refinements need to made to ensure that all variables used as part of the overall case-mix adjustment appropriately align home health payment with the actual cost of providing home health care services.

8. Comorbidity Adjustment

The proposed PDGM 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, we proposed to use the presence of home health specific comorbidities as part of the overall case-mix adjustment under the PDGM. The home health-specific comorbidity list is 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. These broad, body system-based categories we proposed to use to group comorbidities within the PDGM 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 broader categories were further refined into comorbidity subcategories to more accurately capture differences in resource use. All of the comorbidity diagnoses grouped into these comorbidity categories and subcategories are posted on the Home Health Agency web page and listed in the HHGM technical report, ''Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements Overview of the Home Health Groupings Model'', at the following link: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.*

We originally proposed in the CY 2018 HH PPS proposed rule that if a period had at least one secondary diagnosis reported on the home health claim that fell into one of the proposed body-system based subcategories listed in that rule, the period would receive a comorbidity adjustment to account for higher costs associated with the comorbidity (82 FR 35309). A period 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. We received comments supporting the inclusion of a comorbidity adjustment, but the

majority of commenters also stated that the presence of multiple comorbidities has more of an effect on home health resource use than a single comorbidity. We agreed with commenters that the relationship between comorbidities and resource use can be complex and that a single adjustment, regardless of type or number of comorbidities, may be insufficient to fully capture the resource use of a varied population of home health beneficiaries. A TEP was convened and we conducted additional analyses on methodologies for incorporating multiple comorbidity adjustments into the PDGM. 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 (83 FR 32375).

Taking these comments into consideration, CMS conducted additional analysis on the effect of comorbidities on resource utilization during a home health period of care. 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. In the CY 2019 HH PPS proposed rule, we described the methodology used to identify, group, and appropriately weight comorbidity subgroups and interactions between subgroups (83 FR 32375). 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. This meant that patients with certain comorbidities and interactions of certain comorbid conditions have home health periods of care with higher resource use than home health periods of care without those comorbidities or interactions. Specifically, we identified individual comorbidity subgroups that were statistically and clinically significant for case-mix adjustment and these are identified in Table 30. From the individual comorbidity subgroups, we then identified a subset of statistically and clinically significant comorbidity interactions for case-mix adjustment and these are identified in Table 31.

In the CY 2019 HH PPS proposed rule, we proposed three mutually exclusive levels of comorbidity case-mix adjustment that depend on the presence of certain secondary diagnoses codes: No Comorbidity Adjustment, Low Comorbidity Adjustment, and High Comorbidity adjustment. We proposed that home health 30-day periods of care can receive a comorbidity payment adjustment under the following circumstances:

- *Low comorbidity adjustment:* A 30-day period of care would receive a low comorbidity adjustment if there is a reported secondary diagnosis that falls within one of the home-health specific individual comorbidity subgroups, as listed in Table 30, for example, Heart 11, Cerebral 4, etc., associated with higher resource use, or;
- *High comorbidity adjustment:* A 30-day period of care would receive a high comorbidity adjustment if a 30-day period has two or more secondary diagnoses reported that fall within one or more of the comorbidity subgroup interactions, as listed in Table 31, for example, Heart 11 plus Neuro 5, that are associated with higher resource use.

A 30-day period would receive no comorbidity adjustment if no secondary diagnoses exist or none meet the criteria. A 30-day period of care can receive only one comorbidity adjustment—low or high—regardless of the number of subgroups or subgroup interactions. We proposed that the low comorbidity adjustment amount would be the same across the individual subgroups and the high comorbidity adjustment would be the same across the subgroup interactions. Table 46 in the CY 2019 HH PPS proposed rule showed the average resource use by comorbidity adjustment (83 FR 32411).

With dividing the MMTA clinical group into subgroups as finalized in section III.E.6 of this final rule with comment period, we note that the number of comorbidity subgroups in both the low and high comorbidity adjustment is higher than as described in the CY 2019 HH PPS proposed rule. This more recent analysis of CY 2017 home health claims results in 13 comorbidity subgroups which would receive the low comorbidity adjustment and 34 comorbidity subgroup interactions which would receive the high comorbidity adjustment (see Tables 30 and 31).

TABLE 30: LOW COMORBIDITY ADJUSTMENT SUBGROUPS

Comorbidity Subgroup	Description
Cerebral 4	Includes sequelae of cerebral vascular diseases
Circulatory 10	Includes varicose veins with ulceration
Circulatory 9	Includes acute and chronic embolisms and thrombosis
Heart 10	Includes cardiac dysrhythmias
Heart 11	Includes heart failure
Neoplasms 1	Includes oral cancers
Neuro 10	Includes peripheral and polyneuropathies
Neuro 11	Includes diabetic retinopathy and other blindness
Neuro 5	Includes Parkinson's disease
Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia
Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018).

TABLE 31: HIGH COMORBIDITY ADJUSTMENT INTERACTION SUBGROUPS

Comorbidity Subgroup Interaction	Comorbidity Subgroup	Description	Comorbidity Subgroup	Description
1	Behavioral 2	Includes depression and bipolar disorder	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
2	Cerebral 4	Includes sequelae of cerebral vascular diseases	Circulatory 4	Includes hypertensive chronic kidney disease
3	Cerebral 4	Includes sequelae of cerebral vascular diseases	Heart 10	Includes cardiac dysrhythmias
4	Cerebral 4	Includes sequelae of cerebral vascular diseases	Heart 11	Includes heart failure
5	Cerebral 4	Includes sequelae of cerebral vascular diseases	Neuro 10	Includes peripheral and polyneuropathies
6	Circulatory 10	Includes varicose veins with ulceration	Endocrine 3	Includes diabetes with complications
7	Circulatory 10	Includes varicose veins with ulceration	Heart 11	Includes heart failure
8	Circulatory 4	Includes hypertensive chronic kidney disease	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
9	Circulatory 4	Include hypertensive chronic kidney disease	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
10	Circulatory 4	Include hypertensive chronic kidney disease	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
11	Circulatory 7	Includes atherosclerosis	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
12	Endocrine 3	Includes diabetes with complications	Neuro 5	Includes Parkinson's disease
13	Endocrine 3	Includes diabetes with complications	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia
14	Endocrine 3	Includes diabetes with complications	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
15	Endocrine 3	Diabetes with complications	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
16	Heart 10	Includes cardiac dysrhythmias	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
17	Heart 11	Includes heart failure	Neuro 10	Includes peripheral and polyneuropathies
18	Heart 11	Includes heart failure	Neuro 5	Includes Parkinson's disease
19	Heart 11	Includes heart failure	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
20	Heart 11	Includes heart failure	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
21	Heart 12	Includes other heart diseases	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
22	Heart 12	Includes other heart diseases	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
23	Neuro 10	Includes peripheral and polyneuropathies	Neuro 5	Includes Parkinson's disease
24	Neuro 3	Includes dementias	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
25	Neuro 3	Includes dementias	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
26	Neuro 5	Includes Parkinson's disease	Renal 3	Includes nephrogenic diabetes insipidus
27	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia	Renal 3	Includes nephrogenic diabetes insipidus

28	Renal 1	Includes Chronic kidney disease and ESRD	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
29	Renal 1	Includes Chronic kidney disease and ESRD	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
30	Renal 3	Includes nephrogenic diabetes insipidus	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
31	Resp 5	Includes COPD and asthma	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
32	Resp 5	Includes COPD and asthma	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
33	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
34	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018).

We solicited comments on the comorbidity case-mix adjustment in the PDGM, which includes three comorbidity levels: No Comorbidity, Low Comorbidity, and High Comorbidity Adjustment. We also invited comment on the payments associated with the Low and High Comorbidity Adjustment to account for increased resource utilization resulting from the presence of certain comorbidities and comorbidity interactions. These comments are summarized in this section along with our responses.

Comment: The majority of commenters were generally supportive of the change in the comorbidity adjustment in the PDGM to include both a low and high comorbidity adjustment and believe that adding the Low and High Comorbidity adjustment will yield a more accurate and robust payment that accounts for the additional resource intensity needed to care for patients with multiple comorbidities. Commenters stated that it is appropriate to examine the relationship of reported comorbidities on resource utilization to ensure that payment is in alignment with the actual costs of providing care. Several commenters encourage ongoing monitoring to ensure that subcategories of diagnoses and associated comorbidity payment adjustments remain appropriate and adequate. Several commenters believe the comorbidity adjustment should be expanded since as proposed it would only apply to only a small proportion of patients compared to the number of home health patients with multiple chronic conditions. This would result in providers facing financial difficulty in caring for medically complex patients. A commenter urged us to expand the Low Comorbidity Adjustment criteria. Another commenter believe the comorbidity adjustment was overly simplistic and that it should incorporate social determinants of health. The commenter also suggested inclusion additional comorbidity adjustments levels, including moderate and very high.

Response: We thank the commenters for their support regarding a comorbidity case-mix adjustment that accounts for the interaction between multiple comorbid conditions. We believe that this change for the PDGM (compared to the comorbidity adjustment proposed under the HHGM) addresses stakeholder comments regarding the impact of the presence of multiple comorbidities and their interactions on resource utilization. This change also helps to ensure that payment is more in alignment with the actual costs of providing care.

We agree that continued monitoring is needed to understand how the PDGM, including the comorbidity adjustment, affects home health patients and providers and inform future refinements. While we are aware of the prevalence of comorbidities in the Medicare home health population, we note that the average number of comorbidities in the aggregate becomes the standard within that population for the purpose of payment. For example, if the Medicare home health patient population has an average of three comorbidities then this is already factored into the base rate given that this rate represents the average home health payment for the average patient. The case-mix adjustment process recognizes increased resource use beyond the average. If the ''average'' patient under home health is multi-morbid, then additional resource use is not evident as the data reflects this average.

As noted in the CY 2019 HH PPS proposed rule, the comorbidity subgroups were selected through a stepwise process that identified clinically and statistically meaningful diagnosis-based comorbidity groups that were associated with higher resource use than the average or that would be indicated by examining clinical and functional groups, admission source, and timing characteristics. As such, the comorbidity subgroups were meant to identify only those cases when resource use was higher than the median when accounting for other attributions of the patient. A similar process was used to identify the comorbidity subgroup interactions that would result in a high comorbidity adjustment. We agree that social determinants of health is an important consideration in providing effective patient-centered health care, and we thank the commenter for raising this point. However, the comorbidity adjustment in the PDGM is meant to capture clinical conditions that are present that affect resource utilization under a home health plan of care.

We anticipate that we would annually recalibrate the PDGM case-mix weights, which would include the comorbidity adjustment. This would be similar to the annual recalibration of case mix weights under the current HH PPS. Therefore, this could mean additions or subtractions of comorbidity subgroups and/or comorbidity subgroup interactions in the low and/or high comorbidity adjustment groups in the future. We will continue to analyze and monitor reported secondary diagnoses to inform the need for any future refinements to the comorbidity adjustment under the PDGM.

Comment: Some commenters remarked that the comorbidity adjustment would provide insufficient payment for providers and that not enough periods of care would receive a comorbidity adjustment even though the treatment of home health patients with comorbidities is commonplace. Another commenter stated that the average amount of $35 for low comorbidity adjustment and $350 for high comorbidity adjustment is out of sync

with the costs of serving these complex beneficiaries. Another commenter stated that the comorbidity adjustment is not adequate to cover ancillary services. These same commenters wrote that this would expose a high proportion of HHAs to additional risk and recommended that CMS return to its' comorbidity payment adjustment as proposed under the HHGM in the CY 2018 HH PPS proposed rule or to expand both the application and the value of the PDGM's low comorbidity adjustment so that it would more fully cover the frequent instances in which more complex care is provided to those beneficiaries with comorbid conditions.

Response: The payments associated with the low and high comorbidity adjustment are the result of actual resource utilization as reported on home health claims. As detailed in both the CY 2018 HH PPS proposed rule (82 FR 35322) and the CY 2019 HH PPS proposed rule (83 FR 32407), we analyzed home health claims to determine the actual resource utilization associated with the presence of certain comorbid conditions. We remind commenters that the additional diagnoses used for analysis are reported by the HHAs themselves and therefore we could only analyze those comorbidities reported, whether or not beneficiaries receiving home health care had other, unreported conditions that potentially could have affected resource utilization. Regardless, the payment amount proposed for the low and high comorbidity adjustment is driven by the actual resource utilization as identified on home health claims and therefore we believe to be sufficient to align the comorbidity adjustment to the costs of providing care. Likewise, the difference in payment between the low and the high comorbidity adjustment is reflective of the resource use between those patients with individual comorbid conditions and those with multiple comorbid conditions. This is also in alignment with what commenters and the TEP that was convened in February 2018 stated in regards to the more complex needs of patients who have multiple comorbidities.

We disagree with commenters who stated that not enough periods of care would receive the comorbidity adjustment. To better ensure that reported conditions represented an actual impact on resource use, the proposed comorbidities include those conditions that represent more than 0.1 percent of periods and have at least as high as the median resource use as they indicate a direct relationship between the comorbidity and resource utilization. Under the PDGM, this approach increases the 30-day periods of care that would receive a comorbidity adjustment compared to the approach proposed in the CY 2018 HH PPS proposed rule. Under the proposed PDGM, almost 40 percent of home health periods of care would receive a low or high comorbidity adjustment compared to approximately 15 percent of home health periods under the HHGM. We believe a more granular approach to the comorbidity adjustment more accurately represents patient characteristics and more accurately aligns payments with the cost of providing care. Again, we remind commenters that the comorbidity adjustment is just one of the case-mix variables in the PDGM made in addition to the base payment and adjustments made for clinical and functional status, admission source, and timing. These variables work in tandem to account for the complexity of patient care needs and to make payment for home health services accordingly. Similarly, the HH PPS is a bundled payment to cover all home health services, including ancillary services such as home health aides. HHAs are expected to provide the services, including the disciplines responsible for providing those services, in accordance with the home health plan of care.

We disagree that this approach to a comorbidity adjustment exposes HHAs to additional risk. In the CY 2001 HH PPS final rule, commenters stated that patients with multiple diagnoses should be credited with additional points in their clinical dimension measurement given the impact of comorbidities on resource use (65 FR 41153). We stated that time constraints and the data available during the development of the HH PPS was not robust enough for the inclusion of a comorbidity variable as part of the HH PPS case-mix adjustment (65 FR 41153). We also reiterated that we would consider comorbidities for future case-mix analyses and that such an effort would be significantly aided by complete four-digit and 5-digit diagnosis coding on the OASIS record. 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 that time 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. For CY 2018, there was a 0.97 percent reduction to the national, standardized 60-day payment rate to account for nominal case-mix growth between CY 2012 and CY 2014. Therefore, during the development of the PDGM, we sought to mitigate nominal case-mix growth and looked at different ways to account for comorbidities in the overall case-mix adjustment. The description of the initial comorbidity analysis for an alternate case-mix methodology is included in the technical report, ''Overview of the Home Health Groupings Model'' found on the HHA Center web page.[30]

Comment: A commenter expressed concern that underlying mood disorders, cognitive impairments and other behavioral issues may be underreported and therefore not prevalent enough to be represented in a comorbidity subgroup. The commenter further noted that current guidelines state that clinicians should list diagnoses that support the disciplines and services provided, which appears contrary to current guidance to report any and all diagnoses the patient has whether or not they are related to treatment indicated in the plan of care.

Response: Behavioral Health Care is one of the PDGM clinical groupings, and as such, principal diagnoses related to these conditions are already incorporated into the case-mix weight. HHAs already should be reporting any and all secondary diagnoses on the plan of care that affect resource use, including diagnoses related to cognitive and behavioral issues. We agree that coding guidelines are clear that additional (secondary) diagnoses are only to be reported if they are conditions that affect patient care in terms of requiring clinical evaluation; or therapeutic treatment; or diagnostic procedures; or extended length of hospital stay; or increased nursing care and/or monitoring. We do not expect that HHAs would report comorbid conditions that are not being addressed in the individualized plan of care. The home health CoPs at § 484.60 state that the plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, which would include all pertinent diagnoses.

Comment: A commenter stated patients with comorbidities frequently require multiple episodes of home health care and instead of the comorbidity adjustment, the PDGM should have more payment groups to

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

more accurately predict resource use among patients.

Response: We remind commenters that the subdivision of the MMTA clinical group into subgroups, as finalized in section III.F.6 of this final rule with comment period, results in 432 payment groups in the PDGM. Therefore, we believe that the presence of more clinical groups better describes patient characteristics and care needs which will translate to more accurate payment. Likewise, adjusting a home health period of care payment to account for the presence of comorbidities will help to more accurately pay for those patients with chronic, comorbid conditions who require multiple periods of home health care.

Comment: We received a specific comment on the comorbidity subgroups where a commenter recommended that instead of having Skin 3 and Skin 4 should be in their own separate clinical group instead of including them as part of the comorbidity adjustment.

Response: The diagnoses that are in the Skin 3 and Skin 4 comorbidity subgroups are already included in the Wounds clinical group and therefore are already accounted for in a separate clinical group. We believe it is important, clinically, to retain these two subgroups in the comorbidity adjustment as these can be conditions found in patients who are primarily receiving home health services for other reasons. For example, a patient who has recently suffered from a stroke with significant functional deficits and developed a pressure ulcer would likely be appropriately grouped into the Neuro Rehab group. Having these comorbidity subgroups which represent the presence of chronic wounds and/or pressure ulcers would provide additional payment to account for the complex care needs of a patient receiving Neuro Rehab services and who also has a wound. However, we will continue to reexamine reported secondary diagnoses upon implementation of the PDGM to see which conditions are associated with increased resource use and will make any refinements, as necessary, to more accurately align payment with patient characteristics and costs.

Comment: Another commenter stated that with the adoption of ICD 10–CM, HHAs have been instructed through coding guidance to code all diagnoses that impact the patient's care and that it is not uncommon to fill all 25 code fields on the claim. This commenter remarked that Direct Data Entry (DDE) only considers the first 9 codes on the patient's claim and therefore would limit payment for those periods of care if there are any comorbidities listed beyond the first 9 diagnosis fields on the claim.

Response: We remind commenters that the DDE supports 25 diagnoses just like the electronic 837I claim format. The difference between the DDE and the electronic formats is that for the DDE format, the reporting of diagnosis codes is split between two screens, meaning the first 9 diagnosis codes are entered on the first screen, and diagnosis codes 10–25 are entered on the second screen. To reach the second screen to enter these codes, the person entering the claim information would hit the F6 key to move from the first screen to the second screen.

Final Decision: After considering the public comments, we are finalizing the comorbidity adjustment as part of the overall case mix in the PDGM. To summarize, this includes the home health specific list of comorbidity subgroups and comorbidity subgroup interactions. One of the three mutually exclusive categories of comorbidity adjustment will be applied to each period: No Comorbidity Adjustment, Low Comorbidity Adjustment, and High Comorbidity Adjustment. 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 the subgroups and the high comorbidity adjustment would be the same across the subgroup interactions. Upon implementation of the PDGM in CY 2020, we will analyze the most recently available claims to update the comorbidity list to include those comorbid conditions and interaction subgroups that represent more than 0.1 percent of periods and have at least as high as the median resource use. Likewise, we will continue to evaluate reported secondary diagnoses and interactions between comorbidities to identify their impact on resource costs to determine if any additional refinements to this case-mix adjustment variable are warranted.

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 proposed PDGM system in the CY 2019 HH PPS proposed rule would still include LUPA payments, 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. We note that in the current payment system, approximately 8 percent of episodes are LUPAs. Under the PDGM, the 30-day periods of care have substantially more periods with four or fewer visits than 60-day episodes. Therefore, to create LUPA thresholds under the PDGM, in the CY 2019 proposed rule (82 FR 32411), we proposed to set the LUPA threshold at the 10th percentile value of visits or 2 visits, whichever is higher, for each payment group in order to target approximately the same percentage of LUPAs. This resulted in approximately 7.1 percent of 30-day periods that would be LUPAs (assuming no behavior change) under the PDGM. We also proposed that the LUPA thresholds for each PDGM payment group would be re-evaluated every year based on the most current utilization data available.

We received several comments on the LUPA threshold methodology proposed for the PDGM and these are summarized in this section with our responses:

Comment: Several commenters agreed in concept with the proposed changes to the LUPA threshold, but stated that additional time is necessary to fully evaluate the model's impact, especially in conjunction with the transition from a 60-day to a 30-day payment period. Several commenters requested a more cautious approach of delayed implementation, to allow providers and software vendors an opportunity to prepare for implementation of the new thresholds.

Response: We appreciate commenters agreeing that LUPA thresholds should vary by clinical group. LUPA thresholds that vary by case-mix group level take into account different resource use patterns based on clinical characteristics and is a more patient-driven approach. We note that we will implement the PDGM for home health periods of care starting on or after January 1, 2020, giving HHAs and vendors sufficient time to evaluate the impact of the PDGM and make necessary changes to their software systems to accommodate a 30-day unit of payment and the varying LUPA threshold approach.

Comment: Many commenters expressed concern that creating

different LUPA thresholds, in which the thresholds vary from 2–6 minimum visits, depending on the home health grouping, will greatly increase the complexity of the payment system, administrative burden, and costs to agencies. Several commenters suggested maintaining the use of a single LUPA threshold. Other commenters suggested a system of varying LUPA thresholds (that is, more than one), but more simplified to include a narrower range of thresholds than the proposed 2–6 thresholds. Commenters recommended that any LUPA threshold options should be fully evaluated for potential impacts, including behavioral changes that could affect patient access to care.

Response: The concept of case-mix adjusted LUPA thresholds is not new. In the FY 2001 HH PPS final rule (42 FR 41143), when the LUPA threshold of four or fewer visits was introduced, commenters suggested that CMS instead use specific LUPA thresholds for each HHRG. We are unsure why case-mix-specific LUPA thresholds would result in additional administrative burden and costs. We note that under the current HH PPS, LUPA episodes are billed the same as a non-LUPA episodes and this will not change under the PDGM where LUPA periods of care will be billed the same way as non-LUPA 30-day periods of care. We are unsure why case-mix group specific LUPA thresholds would impact patient access and commenters did not provide any additional information to inform such assertions. While some commenters suggested a system of varying LUPA thresholds (that is, more than one), but more simplified to include a narrower range of thresholds than the proposed 2–6 thresholds, they did not provide specifics on their recommendation nor any rationale for this suggestion. However, we remind commenters that we set the LUPA threshold at the 10th percentile value of visits or 2 visits, whichever is higher, for each payment group in order to target approximately the same percentage of LUPAs as under the current system. Therefore, we believe this approach to be the most reasonable. However, we will analyze this methodology once the PDGM is implemented in CY 2020 to determine whether any changes to the LUPA thresholds are warranted.

Comment: Several commenters expressed concern that this policy change could increase the number of LUPAs, which present a financial loss for agencies. A commenter remarked that a 60-day episode under the current system with 14 visits would potentially become two 30-day LUPAs under the proposed PDGM.

Response: As explained in the CY 2019 HH PPS proposed rule (83 FR 32412), our methodology for determining LUPA assignment was calibrated to target approximately the same rate of LUPA occurrences as under the current HH PPS case-mix system. Based on our analysis of CY 2017 home health utilization data, under the PDGM, a slightly lower rate of 30-periods would be assigned as LUPAs (approximately 7%) than 60-day episodes under the current payment system (approximately 8%). We believe that targeting approximately the same percentage of LUPA periods under the PDGM as the current HH PPS should mitigate HHA concerns of an increased number of LUPA periods of care and we do not believe this approach would create a financial hardship for HHAs.

Comment: A commenter questioned the methodology of the LUPA threshold calculation. They suggested that low counts of visits due to the patient's death or transfer to another agency are not comparable with counts of low visits due to patient needs and thereby these two situations at least should be excluded when determining the thresholds.

Response: While we appreciate the commenter's suggestion, when we examined the data, we found the combined occurrences of patient deaths or transfers to another agency did not impact the threshold numbers.

Comment: Another commenter expressed concern about how the change to the LUPA thresholds under the PDGM would affect the provision and payment of Non-Routine Supplies (NRS). The commenter cited an example of periods of care classified under the Wound clinical group for which the commenter noted use disproportionately greater amounts of NRS, and questioned whether the per-visit rates alone would be sufficient to recoup costs. Another commenter noticed that, with some groupings and all else equal, the threshold amounts can be seen to rise and then fall with functional level and thereby the thresholds were not consistent with patient needs.

Response: We remind commenters that payment for NRS has been included in the per-visit LUPA rates since the implementation of the HH PPS (65 FR 41128). At that time, commenters expressed concern that the per-visit LUPA rates would not adequately compensate for NRS and the per visit payment rates were updated to reflect those concerns (65 FR 41138). In the CY 2014 HH PPS final rule (72 FR 72280), we rebased the national, per-visit payment amounts the highest amounts allowed by law. Under the PDGM, the LUPA thresholds are data-driven and determined based on the visit patterns reflected in each of the case-mix groups. Any noted patterns of LUPA thresholds varying with functional level is the result of provider reported information on the OASIS. Accurate reporting on the OASIS is imperative to fully account for the level of impairment at the time of the assessment and to be reflective of the services provided. We reiterate, that in order to maintain approximately the same proportion of LUPA periods under the PDGM with a 30-day unit of payment compared to the current HH PPS with a 60-day episode of payment, the LUPA thresholds were set at the 10th percentile of visits or 2 visits, whichever is higher.

Final Decision: We are finalizing our proposal to vary the LUPA threshold for each 30-day period of care depending on the PDGM payment group to which it is assigned. Likewise, we are finalizing that the LUPA thresholds for each PDGM payment group will be re-evaluated every year based on the most current utilization data available. The LUPA thresholds for the PDGM payment groups with the corresponding HIPPS codes based on CY 2017 home health data are listed in Table 32. Since we propose to implement the PDGM on January 1, 2020, LUPA thresholds for the PDGM payment groups with the corresponding HIPPS codes for CY 2020 will be updated in the CY 2020 HH PPS proposed rule using CY 2018 home health data.

TABLE 32–LUPA THRESHOLDS FOR THE 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)
1FC11	Behavioral Health - High	Early - Community	0	4
1FC21	Behavioral Health - High	Early - Community	1	4
1FC31	Behavioral Health - High	Early - Community	2	4
2FC11	Behavioral Health - High	Early - Institutional	0	4
2FC21	Behavioral Health - High	Early - Institutional	1	4
2FC31	Behavioral Health - High	Early - Institutional	2	4
3FC11	Behavioral Health - High	Late - Community	0	2
3FC21	Behavioral Health - High	Late - Community	1	2
3FC31	Behavioral Health - High	Late - Community	2	3
4FC11	Behavioral Health - High	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4FC21	Behavioral Health - High	Late - Institutional	1	3
4FC31	Behavioral Health - High	Late - Institutional	2	2
1FA11	Behavioral Health - Low	Early - Community	0	3
1FA21	Behavioral Health - Low	Early - Community	1	3
1FA31	Behavioral Health - Low	Early - Community	2	4
2FA11	Behavioral Health - Low	Early - Institutional	0	3
2FA21	Behavioral Health - Low	Early - Institutional	1	3
2FA31	Behavioral Health - Low	Early - Institutional	2	4
3FA11	Behavioral Health - Low	Late - Community	0	2
3FA21	Behavioral Health - Low	Late - Community	1	2
3FA31	Behavioral Health - Low	Late - Community	2	2
4FA11	Behavioral Health - Low	Late - Institutional	0	2
4FA21	Behavioral Health - Low	Late - Institutional	1	2
4FA31	Behavioral Health - Low	Late - Institutional	2	2
1FB11	Behavioral Health - Medium	Early - Community	0	4
1FB21	Behavioral Health - Medium	Early - Community	1	4
1FB31	Behavioral Health - Medium	Early - Community	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	4
3FB11	Behavioral Health - Medium	Late - Community	0	2
3FB21	Behavioral Health - Medium	Late - Community	1	2
3FB31	Behavioral Health - Medium	Late - Community	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	4
1DC11	Complex - High	Early - Community	0	2
1DC21	Complex - High	Early - Community	1	2
1DC31	Complex - High	Early - Community	2	2
2DC11	Complex - High	Early - Institutional	0	4
2DC21	Complex - High	Early - Institutional	1	4
2DC31	Complex - High	Early - Institutional	2	4
3DC11	Complex - High	Late - Community	0	2
3DC21	Complex - High	Late - Community	1	2
3DC31	Complex - High	Late - Community	2	2
4DC11	Complex - High	Late - Institutional	0	3
4DC21	Complex - High	Late - Institutional	1	3
4DC31	Complex - High	Late - Institutional	2	3
1DA11	Complex - Low	Early - Community	0	2
1DA21	Complex - Low	Early - Community	1	2
1DA31	Complex - Low	Early - Community	2	2
2DA11	Complex - Low	Early - Institutional	0	3
2DA21	Complex - Low	Early - Institutional	1	3
2DA31	Complex - Low	Early - Institutional	2	4
3DA11	Complex - Low	Late - Community	0	2
3DA21	Complex - Low	Late - Community	1	2
3DA31	Complex - Low	Late - Community	2	2
4DA11	Complex - Low	Late - Institutional	0	2

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4DA21	Complex - Low	Late - Institutional	1	3
4DA31	Complex - Low	Late - Institutional	2	3
1DB11	Complex - Medium	Early - Community	0	3
1DB21	Complex - Medium	Early - Community	1	3
1DB31	Complex - Medium	Early - Community	2	3
2DB11	Complex - Medium	Early - Institutional	0	4
2DB21	Complex - Medium	Early - Institutional	1	4
2DB31	Complex - Medium	Early - Institutional	2	5
3DB11	Complex - Medium	Late - Community	0	2
3DB21	Complex - Medium	Late - Community	1	2
3DB31	Complex - Medium	Late - Community	2	2
4DB11	Complex - Medium	Late - Institutional	0	3
4DB21	Complex - Medium	Late - Institutional	1	3
4DB31	Complex - Medium	Late - Institutional	2	3
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	4
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	4
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	4
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	4
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	5
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	5
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	2
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	2
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	3
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	4
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	4
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	3
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	3
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	3
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	3
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	4
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	4
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	2
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	2
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	2
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	3
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	3
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	3
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	4
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	4
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	5
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	4
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	5
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	5
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	2
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	3
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	4
1HC11	MMTA - Cardiac - High	Early - Community	0	5
1HC21	MMTA - Cardiac - High	Early - Community	1	4
1HC31	MMTA - Cardiac - High	Early - Community	2	4
2HC11	MMTA - Cardiac - High	Early - Institutional	0	4
2HC21	MMTA - Cardiac - High	Early - Institutional	1	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	4
3HC11	MMTA - Cardiac - High	Late - Community	0	2
3HC21	MMTA - Cardiac - High	Late - Community	1	2
3HC31	MMTA - Cardiac - High	Late - Community	2	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	3
4HC21	MMTA - Cardiac - High	Late - Institutional	1	4
4HC31	MMTA - Cardiac - High	Late - Institutional	2	4
1HA11	MMTA - Cardiac - Low	Early - Community	0	4
1HA21	MMTA - Cardiac - Low	Early - Community	1	4
1HA31	MMTA - Cardiac - Low	Early - Community	2	4
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	4
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	4
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	2
3HA21	MMTA - Cardiac - Low	Late - Community	1	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	3
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	5
1HB21	MMTA - Cardiac - Medium	Early - Community	1	4
1HB31	MMTA - Cardiac - Medium	Early - Community	2	5
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	4
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	5
3HB11	MMTA - Cardiac - Medium	Late - Community	0	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	3
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	3
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	4
1IC11	MMTA - Endocrine - High	Early - Community	0	5
1IC21	MMTA - Endocrine - High	Early - Community	1	5
1IC31	MMTA - Endocrine - High	Early - Community	2	4
2IC11	MMTA - Endocrine - High	Early - Institutional	0	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	4
3IC11	MMTA - Endocrine - High	Late - Community	0	3
3IC21	MMTA - Endocrine - High	Late - Community	1	3
3IC31	MMTA - Endocrine - High	Late - Community	2	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4IC21	MMTA - Endocrine - High	Late - Institutional	1	3
4IC31	MMTA - Endocrine - High	Late - Institutional	2	4
1IA11	MMTA - Endocrine - Low	Early - Community	0	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	4
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	2
3IA21	MMTA - Endocrine - Low	Late - Community	1	2
3IA31	MMTA - Endocrine - Low	Late - Community	2	2
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	3
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	3
1IB11	MMTA - Endocrine - Medium	Early - Community	0	5
1IB21	MMTA - Endocrine - Medium	Early - Community	1	5
1IB31	MMTA - Endocrine - Medium	Early - Community	2	5
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	4
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	4
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	4
3IB11	MMTA - Endocrine - Medium	Late - Community	0	2
3IB21	MMTA - Endocrine - Medium	Late - Community	1	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	3
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	3
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	3
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	3
1JC11	MMTA - GI/GU - High	Early - Community	0	4
1JC21	MMTA - GI/GU - High	Early - Community	1	4
1JC31	MMTA - GI/GU - High	Early - Community	2	3
2JC11	MMTA - GI/GU - High	Early - Institutional	0	4
2JC21	MMTA - GI/GU - High	Early - Institutional	1	4
2JC31	MMTA - GI/GU - High	Early - Institutional	2	4
3JC11	MMTA - GI/GU - High	Late - Community	0	2
3JC21	MMTA - GI/GU - High	Late - Community	1	2
3JC31	MMTA - GI/GU - High	Late - Community	2	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	3
4JC21	MMTA - GI/GU - High	Late - Institutional	1	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	3
1JA11	MMTA - GI/GU - Low	Early - Community	0	3
1JA21	MMTA - GI/GU - Low	Early - Community	1	3
1JA31	MMTA - GI/GU - Low	Early - Community	2	4
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	4
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	4
3JA11	MMTA - GI/GU - Low	Late - Community	0	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	4
1JB21	MMTA - GI/GU - Medium	Early - Community	1	4
1JB31	MMTA - GI/GU - Medium	Early - Community	2	5
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	4
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	4
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	5
3JB11	MMTA - GI/GU - Medium	Late - Community	0	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	3
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	4
1KC11	MMTA - Infectious - High	Early - Community	0	3
1KC21	MMTA - Infectious - High	Early - Community	1	3
1KC31	MMTA - Infectious - High	Early - Community	2	3
2KC11	MMTA - Infectious - High	Early - Institutional	0	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	4
3KC11	MMTA - Infectious - High	Late - Community	0	2
3KC21	MMTA - Infectious - High	Late - Community	1	2
3KC31	MMTA - Infectious - High	Late - Community	2	2
4KC11	MMTA - Infectious - High	Late - Institutional	0	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	3
4KC31	MMTA - Infectious - High	Late - Institutional	2	3
1KA11	MMTA - Infectious - Low	Early - Community	0	3
1KA21	MMTA - Infectious - Low	Early - Community	1	3
1KA31	MMTA - Infectious - Low	Early - Community	2	3
2KA11	MMTA - Infectious - Low	Early - Institutional	0	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	4
3KA11	MMTA - Infectious - Low	Late - Community	0	2
3KA21	MMTA - Infectious - Low	Late - Community	1	2
3KA31	MMTA - Infectious - Low	Late - Community	2	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	2
4KA21	MMTA - Infectious - Low	Late - Institutional	1	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	3
1KB21	MMTA - Infectious - Medium	Early - Community	1	3
1KB31	MMTA - Infectious - Medium	Early - Community	2	4
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	4
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	4
3KB11	MMTA - Infectious - Medium	Late - Community	0	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	3
1AC11	MMTA - Other - High	Early - Community	0	5
1AC21	MMTA - Other - High	Early - Community	1	5
1AC31	MMTA - Other - High	Early - Community	2	5
2AC11	MMTA - Other - High	Early - Institutional	0	4
2AC21	MMTA - Other - High	Early - Institutional	1	5
2AC31	MMTA - Other - High	Early - Institutional	2	5
3AC11	MMTA - Other - High	Late - Community	0	2
3AC21	MMTA - Other - High	Late - Community	1	3
3AC31	MMTA - Other - High	Late - Community	2	3
4AC11	MMTA - Other - High	Late - Institutional	0	3
4AC21	MMTA - Other - High	Late - Institutional	1	3
4AC31	MMTA - Other - High	Late - Institutional	2	4
1AA11	MMTA - Other - Low	Early - Community	0	4
1AA21	MMTA - Other - Low	Early - Community	1	4
1AA31	MMTA - Other - Low	Early - Community	2	4
2AA11	MMTA - Other - Low	Early - Institutional	0	3
2AA21	MMTA - Other - Low	Early - Institutional	1	4
2AA31	MMTA - Other - Low	Early - Institutional	2	4
3AA11	MMTA - Other - Low	Late - Community	0	2
3AA21	MMTA - Other - Low	Late - Community	1	2
3AA31	MMTA - Other - Low	Late - Community	2	3
4AA11	MMTA - Other - Low	Late - Institutional	0	3
4AA21	MMTA - Other - Low	Late - Institutional	1	3
4AA31	MMTA - Other - Low	Late - Institutional	2	3
1AB11	MMTA - Other - Medium	Early - Community	0	5
1AB21	MMTA - Other - Medium	Early - Community	1	5
1AB31	MMTA - Other - Medium	Early - Community	2	5
2AB11	MMTA - Other - Medium	Early - Institutional	0	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	5
2AB31	MMTA - Other - Medium	Early - Institutional	2	5
3AB11	MMTA - Other - Medium	Late - Community	0	2
3AB21	MMTA - Other - Medium	Late - Community	1	2
3AB31	MMTA - Other - Medium	Late - Community	2	3
4AB11	MMTA - Other - Medium	Late - Institutional	0	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	4
4AB31	MMTA - Other - Medium	Late - Institutional	2	4
1LC11	MMTA - Respiratory - High	Early - Community	0	4
1LC21	MMTA - Respiratory - High	Early - Community	1	4
1LC31	MMTA - Respiratory - High	Early - Community	2	5
2LC11	MMTA - Respiratory - High	Early - Institutional	0	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	4
2LC31	MMTA - Respiratory - High	Early - Institutional	2	4
3LC11	MMTA - Respiratory - High	Late - Community	0	2
3LC21	MMTA - Respiratory - High	Late - Community	1	2
3LC31	MMTA - Respiratory - High	Late - Community	2	2
4LC11	MMTA - Respiratory - High	Late - Institutional	0	3

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10th percentile or 2 - whichever is higher)
4LC21	MMTA - Respiratory - High	Late - Institutional	1	3
4LC31	MMTA - Respiratory - High	Late - Institutional	2	4
1LA11	MMTA - Respiratory - Low	Early - Community	0	4
1LA21	MMTA - Respiratory - Low	Early - Community	1	4
1LA31	MMTA - Respiratory - Low	Early - Community	2	4
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	3
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	4
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	4
3LA11	MMTA - Respiratory - Low	Late - Community	0	2
3LA21	MMTA - Respiratory - Low	Late - Community	1	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	4
1LB21	MMTA - Respiratory - Medium	Early - Community	1	4
1LB31	MMTA - Respiratory - Medium	Early - Community	2	5
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	5
3LB11	MMTA - Respiratory - Medium	Late - Community	0	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	4
1EC11	MS Rehab - High	Early - Community	0	5
1EC21	MS Rehab - High	Early - Community	1	5
1EC31	MS Rehab - High	Early - Community	2	5
2EC11	MS Rehab - High	Early - Institutional	0	6
2EC21	MS Rehab - High	Early - Institutional	1	6
2EC31	MS Rehab - High	Early - Institutional	2	6
3EC11	MS Rehab - High	Late - Community	0	2
3EC21	MS Rehab - High	Late - Community	1	2
3EC31	MS Rehab - High	Late - Community	2	3
4EC11	MS Rehab - High	Late - Institutional	0	4
4EC21	MS Rehab - High	Late - Institutional	1	4
4EC31	MS Rehab - High	Late - Institutional	2	4
1EA11	MS Rehab - Low	Early - Community	0	5
1EA21	MS Rehab - Low	Early - Community	1	5
1EA31	MS Rehab - Low	Early - Community	2	5
2EA11	MS Rehab - Low	Early - Institutional	0	5
2EA21	MS Rehab - Low	Early - Institutional	1	5
2EA31	MS Rehab - Low	Early - Institutional	2	5
3EA11	MS Rehab - Low	Late - Community	0	2
3EA21	MS Rehab - Low	Late - Community	1	2
3EA31	MS Rehab - Low	Late - Community	2	2
4EA11	MS Rehab - Low	Late - Institutional	0	4

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)
4EA21	MS Rehab - Low	Late - Institutional	1	4
4EA31	MS Rehab - Low	Late - Institutional	2	3
1EB11	MS Rehab - Medium	Early - Community	0	5
1EB21	MS Rehab - Medium	Early - Community	1	5
1EB31	MS Rehab - Medium	Early - Community	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
3EB11	MS Rehab - Medium	Late - Community	0	2
3EB21	MS Rehab - Medium	Late - Community	1	2
3EB31	MS Rehab - Medium	Late - Community	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
1BC11	Neuro - High	Early - Community	0	4
1BC21	Neuro - High	Early - Community	1	5
1BC31	Neuro - High	Early - Community	2	5
2BC11	Neuro - High	Early - Institutional	0	5
2BC21	Neuro - High	Early - Institutional	1	5
2BC31	Neuro - High	Early - Institutional	2	5
3BC11	Neuro - High	Late - Community	0	2
3BC21	Neuro - High	Late - Community	1	3
3BC31	Neuro - High	Late - Community	2	3
4BC11	Neuro - High	Late - Institutional	0	4
4BC21	Neuro - High	Late - Institutional	1	4
4BC31	Neuro - High	Late - Institutional	2	4
1BA11	Neuro - Low	Early - Community	0	4
1BA21	Neuro - Low	Early - Community	1	5
1BA31	Neuro - Low	Early - Community	2	4
2BA11	Neuro - Low	Early - Institutional	0	5
2BA21	Neuro - Low	Early - Institutional	1	5
2BA31	Neuro - Low	Early - Institutional	2	5
3BA11	Neuro - Low	Late - Community	0	2
3BA21	Neuro - Low	Late - Community	1	2
3BA31	Neuro - Low	Late - Community	2	2
4BA11	Neuro - Low	Late - Institutional	0	3
4BA21	Neuro - Low	Late - Institutional	1	4
4BA31	Neuro - Low	Late - Institutional	2	3
1BB11	Neuro - Medium	Early - Community	0	5
1BB21	Neuro - Medium	Early - Community	1	5
1BB31	Neuro - Medium	Early - Community	2	6
2BB11	Neuro - Medium	Early - Institutional	0	6
2BB21	Neuro - Medium	Early - Institutional	1	6
2BB31	Neuro - Medium	Early - Institutional	2	6
3BB11	Neuro - Medium	Late - Community	0	2
3BB21	Neuro - Medium	Late - Community	1	2
3BB31	Neuro - Medium	Late - Community	2	3
4BB11	Neuro - Medium	Late - Institutional	0	4

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)
4BB21	Neuro - Medium	Late - Institutional	1	4
4BB31	Neuro - Medium	Late - Institutional	2	5
1CC11	Wound - High	Early - Community	0	4
1CC21	Wound - High	Early - Community	1	5
1CC31	Wound - High	Early - Community	2	4
2CC11	Wound - High	Early - Institutional	0	4
2CC21	Wound - High	Early - Institutional	1	5
2CC31	Wound - High	Early - Institutional	2	4
3CC11	Wound - High	Late - Community	0	3
3CC21	Wound - High	Late - Community	1	3
3CC31	Wound - High	Late - Community	2	3
4CC11	Wound - High	Late - Institutional	0	3
4CC21	Wound - High	Late - Institutional	1	3
4CC31	Wound - High	Late - Institutional	2	4
1CA11	Wound - Low	Early - Community	0	5
1CA21	Wound - Low	Early - Community	1	4
1CA31	Wound - Low	Early - Community	2	4
2CA11	Wound - Low	Early - Institutional	0	4
2CA21	Wound - Low	Early - Institutional	1	4
2CA31	Wound - Low	Early - Institutional	2	4
3CA11	Wound - Low	Late - Community	0	2
3CA21	Wound - Low	Late - Community	1	3
3CA31	Wound - Low	Late - Community	2	3
4CA11	Wound - Low	Late - Institutional	0	3
4CA21	Wound - Low	Late - Institutional	1	3
4CA31	Wound - Low	Late - Institutional	2	3
1CB11	Wound - Medium	Early - Community	0	5
1CB21	Wound - Medium	Early - Community	1	5
1CB31	Wound - Medium	Early - Community	2	5
2CB11	Wound - Medium	Early - Institutional	0	5
2CB21	Wound - Medium	Early - Institutional	1	5
2CB31	Wound - Medium	Early - Institutional	2	5
3CB11	Wound - Medium	Late - Community	0	3
3CB21	Wound - Medium	Late - Community	1	3
3CB31	Wound - Medium	Late - Community	2	3
4CB11	Wound - Medium	Late - Institutional	0	4
4CB21	Wound - Medium	Late - Institutional	1	4
4CB31	Wound - Medium	Late - Institutional	2	4

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 2019 HH PPS proposed rule (83 FR 32415), 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). As outlined in previous sections of this final rule with comment period, we are finalizing this alternative case-mix adjustment methodology, called the PDGM. This new methodology results in 432 unique case-mix groups. These 432 unique case-mix payment groups are called Home Health Resource Groups (HHRGs).

To generate PDGM case-mix weights, we utilized a data file based on home health 30-day periods of care, as reported in Medicare home health claims linked to OASIS assessment data to obtain patient characteristics. The claims data provides visit-level data and data on whether non-routine supplies (NRS) was provided during the period and the total charges for NRS. 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 final rule with comment period. The model used in the PDGM payment regression generates outcomes that are statistically significant.

After best fitting the model on CY 2017 home health data, we used the estimated coefficients of the model to predict the expected average resource use of each 30-day period based on the five PDGM categories. In order to normalize the results, we divided the regression predicted resource use of each 30-day period by the overall average resource use used to estimate the model in order to calculate the case mix weight of all periods 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 impairment 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 impairment levels, section III.F.5 for admission source, section III.F.4 for timing, and section III.F.8 for the comorbidity adjustment.

TABLE 33 – COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURACE USE FOR PDGM PAYMENT GROUP

Variable	Coefficient	Coefficient Divided by Average Resource Use
Clinical Group and Functional Impairment Level (MMTA - Other - Low is excluded)		
MMTA - Other - Medium Functional Impairment	$220.79	0.1400
MMTA - Other - High Functional Impairment	$418.85	0.2656
MMTA - Surgical Aftercare - Low Functional Impairment	-$175.69	-0.1114
MMTA - Surgical Aftercare - Medium Functional Impairment	$83.62	0.0530
MMTA - Surgical Aftercare - High Functional Impairment	$329.50	0.2089
MMTA - Cardiac and Circulatory - Low Functional Impairment	-$34.25	-0.0217
MMTA - Cardiac and Circulatory - Medium Functional Impairment	$207.73	0.1317
MMTA - Cardiac and Circulatory - High Functional Impairment	$388.49	0.2463
MMTA - Endocrine - Low Functional Impairment	$153.49	0.0973
MMTA - Endocrine - Medium Functional Impairment	$413.53	0.2622
MMTA - Endocrine - High Functional Impairment	$606.21	0.3843
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional Impairment	-$97.99	-0.0621
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional Impairment	$159.99	0.1014
MMTA - Gastrointestinal tract and Genitourinary system - High Functional Impairment	$307.84	0.1952
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional Impairment	-$46.85	-0.0297
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional Impairment	$166.31	0.1054
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional Impairment	$341.89	0.2168
MMTA - Respiratory - Low Functional Impairment	-$70.73	-0.0448
MMTA - Respiratory - Medium Functional Impairment	$156.22	0.0990
MMTA - Respiratory - High Functional Impairment	$328.24	0.2081
Behavioral Health - Low Functional Impairment	-$139.38	-0.0884
Behavioral Health - Medium Functional Impairment	$140.70	0.0892
Behavioral Health - High Functional Impairment	$280.07	0.1776
Complex - Low Functional Impairment	-$66.09	-0.0419
Complex - Medium Functional Impairment	$260.06	0.1649
Complex - High Functional Impairment	$319.72	0.2027
MS Rehab - Low Functional Impairment	$128.07	0.0812
MS Rehab - Medium Functional Impairment	$329.00	0.2086
MS Rehab - High Functional Impairment	$554.71	0.3517
Neuro - Low Functional Impairment	$303.21	0.1922
Neuro - Medium Functional Impairment	$572.80	0.3632
Neuro - High Functional Impairment	$729.03	0.4622
Wound - Low Functional Impairment	$356.42	0.2260
Wound - Medium Functional Impairment	$596.96	0.3785
Wound - High Functional Impairment	$785.46	0.4980
Admission Source with Timing (Community - Early is excluded)		
Community - Late	-$637.39	-0.4041
Institutional - Early	$287.01	0.1820
Institutional - Late	$67.51	0.0428
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)		
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$94.05	0.0596
Comorbidity Adjustment - Has at least one interaction from interaction list	$291.27	0.1847
Constant	$1,567.71	0.9939
Average Resource Use	$1,577.26	
N	8,851,924	
Adj. R-Squared	0.2937	

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Table 34 presents the case-mix weight for each Home Health Resource Group (HHRG) in the regression model. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded. Weights are determined by first calculating the predicted resource use for episodes with a particular combination of admission source, episode timing, clinical grouping, functional impairment 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. The resulting ratio represents the case-mix weight for that particular combination of a HHRG payment group. 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.

Similar to the annual recalibration of the case-mix weights under the current HH PPS, we proposed to annually recalibrate the PDGM case-mix weights. 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 since we will implement the PDGM for 30-day periods of care beginning on or after January 1, 2020.

TABLE 34 - CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
1AA11	MMTA - Other - Low	Early - Community	0	0.9939
1AA21	MMTA - Other - Low	Early - Community	1	1.0536
1AA31	MMTA - Other - Low	Early - Community	2	1.1786
1AB11	MMTA - Other - Medium	Early - Community	0	1.1339
1AB21	MMTA - Other - Medium	Early - Community	1	1.1936
1AB31	MMTA - Other - Medium	Early - Community	2	1.3186
1AC11	MMTA - Other - High	Early - Community	0	1.2595
1AC21	MMTA - Other - High	Early - Community	1	1.3191
1AC31	MMTA - Other - High	Early - Community	2	1.4442
1BA11	Neuro - Low	Early - Community	0	1.1862
1BA21	Neuro - Low	Early - Community	1	1.2458
1BA31	Neuro - Low	Early - Community	2	1.3708
1BB11	Neuro - Medium	Early - Community	0	1.3571
1BB21	Neuro - Medium	Early - Community	1	1.4167
1BB31	Neuro - Medium	Early - Community	2	1.5418
1BC11	Neuro - High	Early - Community	0	1.4562
1BC21	Neuro - High	Early - Community	1	1.5158
1BC31	Neuro - High	Early - Community	2	1.6408
1CA11	Wound - Low	Early - Community	0	1.2199
1CA21	Wound - Low	Early - Community	1	1.2795
1CA31	Wound - Low	Early - Community	2	1.4046
1CB11	Wound - Medium	Early - Community	0	1.3724
1CB21	Wound - Medium	Early - Community	1	1.4321
1CB31	Wound - Medium	Early - Community	2	1.5571
1CC11	Wound - High	Early - Community	0	1.4919
1CC21	Wound - High	Early - Community	1	1.5516
1CC31	Wound - High	Early - Community	2	1.6766
1DA11	Complex - Low	Early - Community	0	0.9520
1DA21	Complex - Low	Early - Community	1	1.0117
1DA31	Complex - Low	Early - Community	2	1.1367
1DB11	Complex - Medium	Early - Community	0	1.1588
1DB21	Complex - Medium	Early - Community	1	1.2185
1DB31	Complex - Medium	Early - Community	2	1.3435
1DC11	Complex - High	Early - Community	0	1.1966
1DC21	Complex - High	Early - Community	1	1.2563
1DC31	Complex - High	Early - Community	2	1.3813
1EA11	MS Rehab - Low	Early - Community	0	1.0751
1EA21	MS Rehab - Low	Early - Community	1	1.1348
1EA31	MS Rehab - Low	Early - Community	2	1.2598
1EB11	MS Rehab - Medium	Early - Community	0	1.2025
1EB21	MS Rehab - Medium	Early - Community	1	1.2622
1EB31	MS Rehab - Medium	Early - Community	2	1.3872
1EC11	MS Rehab - High	Early - Community	0	1.3456
1EC21	MS Rehab - High	Early - Community	1	1.4053

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
1EC31	MS Rehab - High	Early - Community	2	1.5303
1FA11	Behavioral Health - Low	Early - Community	0	0.9056
1FA21	Behavioral Health - Low	Early - Community	1	0.9652
1FA31	Behavioral Health - Low	Early - Community	2	1.0902
1FB11	Behavioral Health - Medium	Early - Community	0	1.0832
1FB21	Behavioral Health - Medium	Early - Community	1	1.1428
1FB31	Behavioral Health - Medium	Early - Community	2	1.2678
1FC11	Behavioral Health - High	Early - Community	0	1.1715
1FC21	Behavioral Health - High	Early - Community	1	1.2311
1FC31	Behavioral Health - High	Early - Community	2	1.3562
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.8826
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9422
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.0672
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	1.0470
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.1066
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2316
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.2029
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.2625
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.3875
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9722
1HA21	MMTA - Cardiac - Low	Early - Community	1	1.0319
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.1569
1HB11	MMTA - Cardiac - Medium	Early - Community	0	1.1256
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.1853
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.3103
1HC11	MMTA - Cardiac - High	Early - Community	0	1.2403
1HC21	MMTA - Cardiac - High	Early - Community	1	1.2999
1HC31	MMTA - Cardiac - High	Early - Community	2	1.4249
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.0913
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.1509
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.2759
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2561
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.3158
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4408
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3783
1IC21	MMTA - Endocrine - High	Early - Community	1	1.4379
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5630
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.9318
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9914
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.1165
1JB11	MMTA - GI/GU - Medium	Early - Community	0	1.0954
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.1550
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.2800
1JC11	MMTA - GI/GU - High	Early - Community	0	1.1891
1JC21	MMTA - GI/GU - High	Early - Community	1	1.2487
1JC31	MMTA - GI/GU - High	Early - Community	2	1.3738
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9642
1KA21	MMTA - Infectious - Low	Early - Community	1	1.0239
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1489

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0994
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.1590
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2841
1KC11	MMTA - Infectious - High	Early - Community	0	1.2107
1KC21	MMTA - Infectious - High	Early - Community	1	1.2703
1KC31	MMTA - Infectious - High	Early - Community	2	1.3954
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9491
1LA21	MMTA - Respiratory - Low	Early - Community	1	1.0087
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1338
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0930
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.1526
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2777
1LC11	MMTA - Respiratory - High	Early - Community	0	1.2021
1LC21	MMTA - Respiratory - High	Early - Community	1	1.2617
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3867
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1759
2AA21	MMTA - Other - Low	Early - Institutional	1	1.2355
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3606
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.3159
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.3755
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.5006
2AC11	MMTA - Other - High	Early - Institutional	0	1.4415
2AC21	MMTA - Other - High	Early - Institutional	1	1.5011
2AC31	MMTA - Other - High	Early - Institutional	2	1.6261
2BA11	Neuro - Low	Early - Institutional	0	1.3681
2BA21	Neuro - Low	Early - Institutional	1	1.4278
2BA31	Neuro - Low	Early - Institutional	2	1.5528
2BB11	Neuro - Medium	Early - Institutional	0	1.5391
2BB21	Neuro - Medium	Early - Institutional	1	1.5987
2BB31	Neuro - Medium	Early - Institutional	2	1.7237
2BC11	Neuro - High	Early - Institutional	0	1.6381
2BC21	Neuro - High	Early - Institutional	1	1.6978
2BC31	Neuro - High	Early - Institutional	2	1.8228
2CA11	Wound - Low	Early - Institutional	0	1.4019
2CA21	Wound - Low	Early - Institutional	1	1.4615
2CA31	Wound - Low	Early - Institutional	2	1.5865
2CB11	Wound - Medium	Early - Institutional	0	1.5544
2CB21	Wound - Medium	Early - Institutional	1	1.6140
2CB31	Wound - Medium	Early - Institutional	2	1.7391
2CC11	Wound - High	Early - Institutional	0	1.6739
2CC21	Wound - High	Early - Institutional	1	1.7335
2CC31	Wound - High	Early - Institutional	2	1.8586
2DA11	Complex - Low	Early - Institutional	0	1.1340
2DA21	Complex - Low	Early - Institutional	1	1.1936
2DA31	Complex - Low	Early - Institutional	2	1.3187
2DB11	Complex - Medium	Early - Institutional	0	1.3408
2DB21	Complex - Medium	Early - Institutional	1	1.4004
2DB31	Complex - Medium	Early - Institutional	2	1.5255
2DC11	Complex - High	Early - Institutional	0	1.3786

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
2DC21	Complex - High	Early - Institutional	1	1.4382
2DC31	Complex - High	Early - Institutional	2	1.5633
2EA1I	MS Rehab - Low	Early - Institutional	0	1.2571
2EA2I	MS Rehab - Low	Early - Institutional	1	1.3167
2EA3I	MS Rehab - Low	Early - Institutional	2	1.4418
2EB1I	MS Rehab - Medium	Early - Institutional	0	1.3845
2EB2I	MS Rehab - Medium	Early - Institutional	1	1.4441
2EB3I	MS Rehab - Medium	Early - Institutional	2	1.5692
2EC1I	MS Rehab - High	Early - Institutional	0	1.5276
2EC2I	MS Rehab - High	Early - Institutional	1	1.5872
2EC3I	MS Rehab - High	Early - Institutional	2	1.7123
2FA1I	Behavioral Health - Low	Early - Institutional	0	1.0875
2FA2I	Behavioral Health - Low	Early - Institutional	1	1.1472
2FA3I	Behavioral Health - Low	Early - Institutional	2	1.2722
2FB1I	Behavioral Health - Medium	Early - Institutional	0	1.2651
2FB2I	Behavioral Health - Medium	Early - Institutional	1	1.3247
2FB3I	Behavioral Health - Medium	Early - Institutional	2	1.4498
2FC1I	Behavioral Health - High	Early - Institutional	0	1.3535
2FC2I	Behavioral Health - High	Early - Institutional	1	1.4131
2FC3I	Behavioral Health - High	Early - Institutional	2	1.5381
2GA1I	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.0645
2GA2I	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1241
2GA3I	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.2492
2GB1I	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2289
2GB2I	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.2886
2GB3I	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4136
2GC1I	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.3848
2GC2I	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.4444
2GC3I	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.5695
2HA1I	MMTA - Cardiac - Low	Early - Institutional	0	1.1542
2HA2I	MMTA - Cardiac - Low	Early - Institutional	1	1.2138
2HA3I	MMTA - Cardiac - Low	Early - Institutional	2	1.3389
2HB1I	MMTA - Cardiac - Medium	Early - Institutional	0	1.3076
2HB2I	MMTA - Cardiac - Medium	Early - Institutional	1	1.3672
2HB3I	MMTA - Cardiac - Medium	Early - Institutional	2	1.4923
2HC1I	MMTA - Cardiac - High	Early - Institutional	0	1.4222
2HC2I	MMTA - Cardiac - High	Early - Institutional	1	1.4818
2HC3I	MMTA - Cardiac - High	Early - Institutional	2	1.6069
2IA1I	MMTA - Endocrine - Low	Early - Institutional	0	1.2732
2IA2I	MMTA - Endocrine - Low	Early - Institutional	1	1.3329
2IA3I	MMTA - Endocrine - Low	Early - Institutional	2	1.4579
2IB1I	MMTA - Endocrine - Medium	Early - Institutional	0	1.4381
2IB2I	MMTA - Endocrine - Medium	Early - Institutional	1	1.4977
2IB3I	MMTA - Endocrine - Medium	Early - Institutional	2	1.6228
2IC1I	MMTA - Endocrine - High	Early - Institutional	0	1.5603
2IC2I	MMTA - Endocrine - High	Early - Institutional	1	1.6199
2IC3I	MMTA - Endocrine - High	Early - Institutional	2	1.7449
2JA1I	MMTA - GI/GU - Low	Early - Institutional	0	1.1138
2JA2I	MMTA - GI/GU - Low	Early - Institutional	1	1.1734

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.2985
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2773
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.3370
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4620
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3711
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.4307
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5558
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1462
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.2058
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3309
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2814
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.3410
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4660
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3927
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.4523
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.5773
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1311
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1907
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3157
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2750
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.3346
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4596
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3840
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.4436
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5687
3AA11	MMTA - Other - Low	Late - Community	0	0.5898
3AA21	MMTA - Other - Low	Late - Community	1	0.6495
3AA31	MMTA - Other - Low	Late - Community	2	0.7745
3AB11	MMTA - Other - Medium	Late - Community	0	0.7298
3AB21	MMTA - Other - Medium	Late - Community	1	0.7894
3AB31	MMTA - Other - Medium	Late - Community	2	0.9145
3AC11	MMTA - Other - High	Late - Community	0	0.8554
3AC21	MMTA - Other - High	Late - Community	1	0.9150
3AC31	MMTA - Other - High	Late - Community	2	1.0401
3BA11	Neuro - Low	Late - Community	0	0.7821
3BA21	Neuro - Low	Late - Community	1	0.8417
3BA31	Neuro - Low	Late - Community	2	0.9667
3BB11	Neuro - Medium	Late - Community	0	0.9530
3BB21	Neuro - Medium	Late - Community	1	1.0126
3BB31	Neuro - Medium	Late - Community	2	1.1377
3BC11	Neuro - High	Late - Community	0	1.0520
3BC21	Neuro - High	Late - Community	1	1.1117
3BC31	Neuro - High	Late - Community	2	1.2367
3CA11	Wound - Low	Late - Community	0	0.8158
3CA21	Wound - Low	Late - Community	1	0.8754
3CA31	Wound - Low	Late - Community	2	1.0005
3CB11	Wound - Medium	Late - Community	0	0.9683
3CB21	Wound - Medium	Late - Community	1	1.0279
3CB31	Wound - Medium	Late - Community	2	1.1530

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
3CC11	Wound - High	Late - Community	0	1.0878
3CC21	Wound - High	Late - Community	1	1.1475
3CC31	Wound - High	Late - Community	2	1.2725
3DA11	Complex - Low	Late - Community	0	0.5479
3DA21	Complex - Low	Late - Community	1	0.6076
3DA31	Complex - Low	Late - Community	2	0.7326
3DB11	Complex - Medium	Late - Community	0	0.7547
3DB21	Complex - Medium	Late - Community	1	0.8143
3DB31	Complex - Medium	Late - Community	2	0.9394
3DC11	Complex - High	Late - Community	0	0.7925
3DC21	Complex - High	Late - Community	1	0.8522
3DC31	Complex - High	Late - Community	2	0.9772
3EA11	MS Rehab - Low	Late - Community	0	0.6710
3EA21	MS Rehab - Low	Late - Community	1	0.7307
3EA31	MS Rehab - Low	Late - Community	2	0.8557
3EB11	MS Rehab - Medium	Late - Community	0	0.7984
3EB21	MS Rehab - Medium	Late - Community	1	0.8581
3EB31	MS Rehab - Medium	Late - Community	2	0.9831
3EC11	MS Rehab - High	Late - Community	0	0.9415
3EC21	MS Rehab - High	Late - Community	1	1.0012
3EC31	MS Rehab - High	Late - Community	2	1.1262
3FA11	Behavioral Health - Low	Late - Community	0	0.5015
3FA21	Behavioral Health - Low	Late - Community	1	0.5611
3FA31	Behavioral Health - Low	Late - Community	2	0.6861
3FB11	Behavioral Health - Medium	Late - Community	0	0.6790
3FB21	Behavioral Health - Medium	Late - Community	1	0.7387
3FB31	Behavioral Health - Medium	Late - Community	2	0.8637
3FC11	Behavioral Health - High	Late - Community	0	0.7674
3FC21	Behavioral Health - High	Late - Community	1	0.8270
3FC31	Behavioral Health - High	Late - Community	2	0.9521
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.4784
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.5381
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.6631
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6429
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7025
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8275
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.7987
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8584
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	0.9834
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5681
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.6277
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7528
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.7215
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7812
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.9062
3HC11	MMTA - Cardiac - High	Late - Community	0	0.8361
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8958
3HC31	MMTA - Cardiac - High	Late - Community	2	1.0208
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.6871

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.7468
3IA31	MMTA - Endocrine - Low	Late - Community	2	0.8718
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.8520
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9116
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.0367
3IC11	MMTA - Endocrine - High	Late - Community	0	0.9742
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0338
3IC31	MMTA - Endocrine - High	Late - Community	2	1.1588
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5277
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.5873
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7124
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6913
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7509
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8759
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7850
3JC21	MMTA - GI/GU - High	Late - Community	1	0.8446
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9697
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5601
3KA21	MMTA - Infectious - Low	Late - Community	1	0.6198
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7448
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6953
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7549
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8799
3KC11	MMTA - Infectious - High	Late - Community	0	0.8066
3KC21	MMTA - Infectious - High	Late - Community	1	0.8662
3KC31	MMTA - Infectious - High	Late - Community	2	0.9913
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5450
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.6046
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7297
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6889
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7485
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8735
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7979
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8576
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9826
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0367
4AA21	MMTA - Other - Low	Late - Institutional	1	1.0964
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2214
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1767
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.2364
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.3614
4AC11	MMTA - Other - High	Late - Institutional	0	1.3023
4AC21	MMTA - Other - High	Late - Institutional	1	1.3619
4AC31	MMTA - Other - High	Late - Institutional	2	1.4870
4BA11	Neuro - Low	Late - Institutional	0	1.2290
4BA21	Neuro - Low	Late - Institutional	1	1.2886
4BA31	Neuro - Low	Late - Institutional	2	1.4136
4BB11	Neuro - Medium	Late - Institutional	0	1.3999
4BB21	Neuro - Medium	Late - Institutional	1	1.4595

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
4BB31	Neuro - Medium	Late - Institutional	2	1.5846
4BC11	Neuro - High	Late - Institutional	0	1.4990
4BC21	Neuro - High	Late - Institutional	1	1.5586
4BC31	Neuro - High	Late - Institutional	2	1.6836
4CA11	Wound - Low	Late - Institutional	0	1.2627
4CA21	Wound - Low	Late - Institutional	1	1.3223
4CA31	Wound - Low	Late - Institutional	2	1.4474
4CB11	Wound - Medium	Late - Institutional	0	1.4152
4CB21	Wound - Medium	Late - Institutional	1	1.4749
4CB31	Wound - Medium	Late - Institutional	2	1.5999
4CC11	Wound - High	Late - Institutional	0	1.5347
4CC21	Wound - High	Late - Institutional	1	1.5944
4CC31	Wound - High	Late - Institutional	2	1.7194
4DA11	Complex - Low	Late - Institutional	0	0.9948
4DA21	Complex - Low	Late - Institutional	1	1.0545
4DA31	Complex - Low	Late - Institutional	2	1.1795
4DB11	Complex - Medium	Late - Institutional	0	1.2016
4DB21	Complex - Medium	Late - Institutional	1	1.2613
4DB31	Complex - Medium	Late - Institutional	2	1.3863
4DC11	Complex - High	Late - Institutional	0	1.2395
4DC21	Complex - High	Late - Institutional	1	1.2991
4DC31	Complex - High	Late - Institutional	2	1.4241
4EA11	MS Rehab - Low	Late - Institutional	0	1.1179
4EA21	MS Rehab - Low	Late - Institutional	1	1.1776
4EA31	MS Rehab - Low	Late - Institutional	2	1.3026
4EB11	MS Rehab - Medium	Late - Institutional	0	1.2453
4EB21	MS Rehab - Medium	Late - Institutional	1	1.3050
4EB31	MS Rehab - Medium	Late - Institutional	2	1.4300
4EC11	MS Rehab - High	Late - Institutional	0	1.3884
4EC21	MS Rehab - High	Late - Institutional	1	1.4481
4EC31	MS Rehab - High	Late - Institutional	2	1.5731
4FA11	Behavioral Health - Low	Late - Institutional	0	0.9484
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0080
4FA31	Behavioral Health - Low	Late - Institutional	2	1.1330
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1260
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.1856
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3106
4FC11	Behavioral Health - High	Late - Institutional	0	1.2143
4FC21	Behavioral Health - High	Late - Institutional	1	1.2739
4FC31	Behavioral Health - High	Late - Institutional	2	1.3990
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	0.9254
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	0.9850
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.1100
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.0898
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.1494
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.2744
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.2457
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3053
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.4303

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	CY 2019 Weight
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0150
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.0747
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.1997
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1684
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.2281
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3531
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2831
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.3427
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4677
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.1341
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.1937
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.3187
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.2989
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.3586
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.4836
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4211
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.4807
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6058
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	0.9746
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0342
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.1593
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1382
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.1978
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3228
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2319
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.2916
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4166
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0070
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.0667
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.1917
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1422
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.2018
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3269
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2535
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3131
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.4382
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	0.9919
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.0515
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.1766
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1358
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.1954
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3205
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2449
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.3045
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4295

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of June 30, 2018) 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, in the CY 2019 HH PPS proposed rule (83 FR 32420) we proposed 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 proposed 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 proposed 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.

We solicited public 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. The following is a summary of the public comments on the case mix weight methodology under PDGM and the updates to the HH PPS Grouper Software and our responses:

Comment: A few commenters urged CMS to formalize a transparent process and timeline to refine the case-mix weights soon after implementation of the PDGM, to assess whether various factors will influence the ability of the model to better predict resource use, such as additional secondary diagnoses or interactions between such diagnoses. The commenters noted that it is imperative that the case-mix weights reflect current care protocols and resource needs. A few commenters suggested that CMS provide further explanation of how the new model addresses the concerns for those patients with complex, chronic care needs (for example, an ALS patient is referenced). Another commenter questioned how the PDGM could address issues of access, since beneficiaries without access to home health are by definition not included in the analysis (which was done based on prior utilization records).

Response: As noted in the CY 2019 HH PPS proposed rule (83 FR 32416), we proposed to annually recalibrate the PDGM case-mix weights to reflect the most recent utilization data available at the time of rulemaking. Once the PDGM is finalized, we will also continue to analyze all of the components of the case-mix adjustment, and make refinements as necessary to ensure that payment for home health periods are in alignment with costs. We note that we provide a clinical example in section III.F.12 of this final rule with comment period, specifically relating to ALS, that shows how high cost periods of care could receive outlier payments under the PDGM.

Comment: Numerous commenters agreed that the October release of the Grouper should be discontinued (and only the January release be retained) as long as HHAs would not be at risk for violating HIPAA rules, if the agency were to potentially use an incorrect diagnosis code in the last quarter of the year (incorrect in the sense that the coding was made obsolete by ICD–10 refinements that were not reflected in the Grouper until the following January). A commenter expressed approval at this effort to reduce burdens on HHAs (although also expressed concern over the issue with HIPAA rules). Another commenter questioned how this would impact other Medicare claims and coding, noting that many agencies also operate hospice businesses, and the situation can be confusing if hospice still operates under the Fiscal Year guidance whereas Home Health operates under the Calendar Year guidance.

Response: We thank commenters for their support in findings ways to reduce regulatory burden and potentially streamlining the HH PPS Grouper into one annual release. However, upon further examination of this proposal, we recognize that this could lead to potential Health Insurance Portability and Accountability Act (HIPAA) violations for HHAs. HIPAA requires that covered entities use the current adopted code set (45 CFR 162.1000). If the ICD–10–CM code set is implemented in October then that would be the current code set and using outdated codes from October through the following January would be non-compliant with HIPAA requirements. However, in an effort to reduce provider burden associated with the release of two Groupers, we will continue to examine ways to minimize this burden. For example, if we do not update the functional impairment level points and thresholds on an annual basis, we could eliminate the need for a second Grouper release in January and instead update the Grouper for October 1 when ICD–10–CM code changes become effective. While we would continue to annually recalibrate the PDGM case-mix weights, we may not need to update the points and thresholds annually. Any changes to the Grouper releases or the updates to the functional points and thresholds would be proposed in future rulemaking.

Final Decision: We are finalizing the PDGM, with the modifications previously discussed, effective for 30-day periods of care that start on or after January 1, 2020. Additionally, we are finalizing our proposal to generate PDGM case-mix weights for each of the different PDGM payment groups by regressing resource use on a series of indicator variables for each of the five categories previously listed (timing, admission source, clinical grouping, functional level, and comorbidity) using a fixed effects model and annually recalibrating the PDGM case-mix weights to ensure that the case-mix weights reflect the most recent utilization data available at the time of annual rulemaking. We are not finalizing the discontinuation of the October release of the HH PPS Grouper software update given the potential for HIPAA violations. Therefore, we will continue to release Grouper software in both October and January of each year. Any proposals to discontinue any one of the Grouper software releases would be included in future rulemaking for public comment.

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

Currently, LUPA episodes qualify for an add-on payment when the 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 LUPA 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 proposed that the LUPA add-on factors will remain the same as the current payment system, described in the CY 2019 HH PPS proposed rule (83 FR 32372). We proposed to multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA 30-day periods that occur as the only 30-day period or an initial 30-day period in a sequence of adjacent periods of care 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 (the date of the first billable service) through and including the last billable service date under the original plan of care before an 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.

For 30-day periods of care, we proposed 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 a beneficiary elected transfer or there was a discharge and return to home health during the 30-day period, we proposed that 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 would be 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 would then be multiplied by the original case-mix and wage index to produce the 30-day payment.

We solicited public comments on the LUPA add-on payments and partial payment adjustments proposed for the PDGM and the associated changes in the regulations text. The following is a summary of the public comments and our responses:

Comment: Another commenter requested clarification on the use of the word ''episode' in the CY 2019 HH PPS proposed rule (83 FR 32421) and whether the first two 30-day periods (the former 60-day episode timeframe) would both receive the LUPA add-on payment or only the initial 30-day period. The commenter's expectation was that the add-on payment would only be paid to the initial 30-day period.

Response: The commenter's assumption was correct; the LUPA add-on payment amount under the PDGM will only be paid to LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of additional periods of care by the appropriate add-on factor.

Final Decision: We are finalizing our proposal to continue to multiply the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM. We are also finalizing our proposal to retain the current PEP policy and apply such policy to 30-day periods of care under the PDGM.

12. Payments for High-Cost Outliers Under the PGDM

As described in section III.E. of the CY 2019 HH PPS proposed rule (83 FR 32375), 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 the CY 2019 HH PPS proposed rule (83 FR 32375). We proposed that we would maintain the current methodology for payment of high-cost outliers upon implementation of the PGDM and that we would calculate payment for high-cost outliers based upon 30-day periods of care.

As discussed in the CY 2019 HH PPS proposed rule (83 FR 32421), we updated our outlier estimates for this final rule with comment period. Simulating payments using preliminary CY 2017 claims data and the CY 2019 payment rates, we estimated that outlier payments under the PGDM with 30-day periods of care would comprise approximately 4.77 percent of total HH PPS payments in CY 2019. Given the statutory requirement that estimated total outlier payments do not exceed the 2.5 percent of total payments (as required by section 1895(b)(5)(A) of the Act), we estimated that the FDL ratio under the PGDM would need to change to 0.71 to maintain compliance with statute. However, given the implementation of the PGDM 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 and would propose a change in the FDL ratio for CY 2020, if needed.

We solicited public comments on maintaining the current outlier payment methodology for the PGDM and the associated changes in the regulations text. The following is a summary of the public comments and our responses:

Comment: Several commenters indicated their support for the proposal to continue outlier payments under the PDGM.

Response: We thank the commenters for the support of this continued payment policy.

Comment: Several commenters suggested that we develop an outlier policy under the PGDM that is comparable to the existing system but modified to reflect the change to the 30-day payment period and also consider further refinement to ensure a smooth transition within the framework of the PGDM. Another commenter expressed concern regarding the potential for more providers to exceed the 10 percent outlier cap under a 30-day period of care and 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 a period's costs for outlier calculation purposes. A few commenters stated that they believed that the cap on outlier payments would prevent necessary care and cause providers to seek beneficiaries with profiles that could help maximize profits.

Response: We believe that our proposal to maintain the existing outlier policy under the PGDM, except that outlier payments would be determined on a 30-day basis to align with the 30-day unit of payment under the PGDM, is comparable to the existing system and would ensure a smooth transition within the framework on the PGDM. We plan to closely evaluate and model projected outlier payments within the framework of the PGDM and consider modifications to the outlier policy as appropriate. We note that the maximum of 2.5 percent of outlier payments to total payments and 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 amount.

Regarding the 8-hour limit on the amount of time per day counted toward the estimation of a period'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 CY2018 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 be furnished less than 8 hours each day. Therefore, we believe that maintaining the 8-hour per day cap is appropriate under the new PGDM. However, we plan to monitor for any unintended results of this policy as data become available.

Comment: Another commenter expressed concern regarding the change to 30-day payment periods and its impact to the outlier payment policy. The commenter believes that the 30-day periods and resultant adjustment to the fixed dollar loss ratio would then make it harder for beneficiaries to obtain outlier services.

Response: As described in detail in the CY 2019 HH PPS proposed rule (83 FR 32340), 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 higher 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. As we evaluate the final features of the PDGM for implementation in CY 2020, we will evaluate and consider the potential for impacts of a modified FDL. While a higher FDL value would potentially lessen the number of home health periods that qualify for an outlier payment, those periods that did qualify for an outlier payment could potentially receive a proportionally higher outlier payment amount. Additionally, we note that the 2.5 percent target of outlier payments to total payments and 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. Moreover, the forthcoming change to the 30-day payment period is also statutory in that it is required by the BBA of 2018. 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.

Comment: Several commenters suggested that eligibility for an outlier payment be updated to include NRS costs incurred and not just imputed costs of service visits. Commenters asserted that the outlier policy under the PDGM may not adequately cover the costs of wound care products necessary to achieve excellent patient outcomes and recommended that we design a more specific model that accurately pays for NRS separately and establish an outlier payment model for very complex wound-care patients.

Response: We appreciate the commenters' suggestion regarding the inclusion of supplies in the outlier calculation under the PDGM. In order to incorporate supply costs into the outlier calculation, significant claims payment systems modifications would be required. However, we will consider whether to add supply costs to the outlier calculations and evaluate whether such a policy change is appropriate for future rulemaking, potentially in conjunction with the implementation of the PDGM for CY 2020.

Comments: Commenters requested that we develop clinical examples illustrating how outliers would be paid under the proposed PDGM, similar to the examples provided for an ALS patient under the current payment system in the CY 2019 HH PPS proposed rule.

Response: In section III.D. of the CY 2019 HH PPS proposed rule (83 FR 32340), we described a clinical example of how care for a patient with amyotrophic lateral sclerosis (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. Using the same clinical scenario, in this final rule with comment period we provide an example 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 for the first two 30-day periods of care under the PDGM. We note that this example is provided for illustrative purposes only and does not constitute a specific Medicare payment scenario.

Example One: First 30-day Period under the PDGM:

An ALS beneficiary 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 of the sacrum, and pain status. In addition, a home health aide could provide services for three hours in the morning and three hours on Monday, Wednesday and Friday and two and a half hours in the morning and two and half 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 beneficiary's condition. Because of the patient's condition, the first 30-day period of care would be placed into the community early, neuro rehabilitation, high functional impairment, and low comorbidity group (1BC21). For the purposes of this example, we assume that services are rendered per week for a total of 4 weeks per 30-day period of care.

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TABLE 35: CLINICAL SCENARIO CALCULATION TABLE: FIRST 30-DAY PERIOD

HH Outlier CY 2019 30-Day Illustrative Values	Value	Operation	Adjuster	Equals	Output
National, Standardized 30-day Period Payment Rate	$1,753.68				
Case-Mix Adjustment for Payment Group	1.5158				
Case-Mix Adjusted Period Payment Amount	$1,753.68	*	1.5158	=	$2,658.23
Labor Portion of the Case-Mix Adjusted Period Payment Amount	$2,658.23	*	0.761	=	$2,022.91
Non-Labor Portion of the Case-Mix Adjusted Period Payment Amount	$2,658.23	*	0.239	=	$635.32
Wage Index Value (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.3055				
Wage-Adjusted Labor Portion of the Case-Mix Adjusted Period Payment Amount	1.3055	*	$2,022.91	=	$2,640.91
Total Case-Mix and Wage-Adjusted Period Payment Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Period Payment Amount plus the NRS Amount)					$3,276.23
Total Wage-Adjusted Fixed Dollar Loss Amount					
Fixed Dollar Loss Amount (National, Standardized 30-day Period Payment Rate*FDL Ratio)	$1,753.68	*	0.71	=	$1,245.11
Labor Portion of the Fixed Dollar Loss Amount	$1,245.11	*	0.761	=	$947.53
Non-Labor Amount of the Fixed Dollar Loss Amount	$1,245.11	*	0.239	=	$297.58
Wage-Adjusted Amount of the Fixed Dollar Loss Amount	$947.53	*	1.3055	=	$1,237.00
Total Wage-Adjusted Fixed Dollar Loss Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Fixed Dollar Loss Amount)	$1,237.00	+	$297.58	=	$1,534.58
Total Wage-Adjusted Imputed Cost Amount					
National Per-Unit Payment Amount - Skilled Nursing	$49.05				
Number of 15-minute units (45 minutes = 3 units twice per week for 4 weeks)	24				
Imputed Skilled Nursing Visit Costs (National Per-Unit Payment Amount * Number of Units)	$49.05	*	24	=	$1,177.20
National Per-Unit Payment Amount - Home Health Aide	$15.80				
Number of 15-minute units (28 hours per week = 112 units per week for 4 weeks)	448				
Imputed Home Health Aide Costs (National Per-Unit Payment Amount * Number of Units)	$15.80	*	448	=	$7,078.40
National Per-Unit Payment Amount – Occupational Therapy (OT)	$51.35				
Number of 15-minute units (45 minutes = 3 units twice per week for 4 weeks)	24				
Imputed OT Visit Costs (National Per-Unit Payment Amount * Number of Units)	$51.35	*	24	=	$1,232.40
National Per-Unit Payment Amount - PT	$51.55				
Number of 15-minute units (45 minutes = 3 units twice per week for 4 weeks)	24				
Imputed PT Visit Costs (National Per-Unit Payment Amount * Number of Units)	$51.55	*	24	=	$1,237.20
Total Imputed Costs for all Disciplines					$10,725.20
Labor Portion of the Imputed Costs for All Disciplines	$10,725.20	*	0.761	=	$8,161.88
Non-Labor Portion of Imputed Cost Amount for All Disciplines	$10,725.20	*	0.239	=	$2,563.32
CBSA Wage Index (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.3055				
Wage-Adjusted Labor Portion of the Imputed Cost Amount for All Disciplines	$8,161.88	*	1.3055	=	$10,655.33
Total Wage-Adjusted Imputed Cost Amount (Wage-Adjusted Labor Portion of the Imputed Cost Amount plus Non-Labor Portion of the Imputed Cost Amount)	$10,655.33	+	$2,563.32	=	$13,218.65
Total Payment for 30-Day Period					

HH Outlier CY 2019 30-Day Illustrative Values	Value	Operation	Adjuster	Equals	Output
Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Period Payment Amount)	$1,534.58	+	$3,276.23	=	$4,810.81
Total Wage-Adjusted Imputed Cost Amount - Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Period Payment Amount)	$13,218.65	-	$4,810.81	=	$8,407.84
Outlier Payment = Imputed Costs Greater Than the Outlier Threshold * Loss-Sharing Ratio	$8,407.84	*	0.8	=	$6,726.27
Total Payment for 30-Day Period = Total Case-Mix and Wage-Adjusted Period Payment Amount + Outlier Payment	$3,276.23	+	$6,726.27	=	$10,002.50

For the first 30-day period of this clinical scenario under the PDGM, the preceding calculation illustrates how HHAs would be paid by Medicare for providing care to patients with higher resource use in their homes.

Example Two: Second 30-day Period under the PDGM:

For the second 30-day period under the PDGM, the ALS beneficiary continues to require the home health services of skilled nursing, physical therapy, occupational therapy and a nurse's aide. The beneficiary continues to receive skilled nursing twice a week to assess dyspnea when transferring to a bedside commode, stage two pressure ulcer at the sacrum, and pain status. A home health aide could provide services for three hours in the morning and three hours on Monday, Wednesday, and Friday and two and a half hours in the morning and two and half 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 beneficiary's condition. Given the beneficiary's condition the second 30-day period of care would fall into the community late, neuro rehabilitation, high functional impairment, and low comorbidity group (3BC21).

TABLE 36: CLINICAL SCENARIO CALCULATION TABLE: SECOND 30-DAY PERIOD

HH Outlier CY 2019 30-Day Illustrative Values	Value	Operation	Adjuster	Equals	Output
National, Standardized 30-day Period Payment Rate	$1,753.68				
Case-Mix Adjustment for Payment Group	1.1117				
Case-Mix Adjusted Period Payment Amount	$1,753.68	*	1.1117	=	$1,949.57
Labor Portion of the Case-Mix Adjusted Period Payment Amount	$1,949.57	*	0.761	=	$1,483.62
Non-Labor Portion of the Case-Mix Adjusted Period Payment Amount	$1,949.57	*	0.239	=	$465.95
Wage Index Value (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.3055				
Wage-Adjusted Labor Portion of the Case-Mix Adjusted Period Payment Amount	1.3055	*	$1,483.62	=	$1,936.87
Total Case-Mix and Wage-Adjusted Period Payment Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Period Payment Amount plus the NRS Amount)					$2,402.81
Total Wage-Adjusted Fixed Dollar Loss Amount					
Fixed Dollar Loss Amount (National, Standardized 30-day Period Payment Rate*FDL Ratio)	$1,753.68	*	0.71	=	$1,245.11
Labor Portion of the Fixed Dollar Loss Amount	$1,245.11	*	0.761	=	$947.53
Non-Labor Amount of the Fixed Dollar Loss Amount	$1,245.11	*	0.239	=	$297.58
Wage-Adjusted Amount of the Fixed Dollar Loss Amount	$947.53	*	1.3055	=	$1,237.00
Total Wage-Adjusted Fixed Dollar Loss Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Fixed Dollar Loss Amount)	$1,237.00	+	$297.58	=	$1,534.58
Total Wage-Adjusted Imputed Cost Amount					
National Per-Unit Payment Amount - Skilled Nursing	$49.05				
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	24				
Imputed Skilled Nursing Visit Costs (National Per-Unit Payment Amount * Number of Units)	$49.05	*	24	=	$1,177.20
National Per-Unit Payment Amount - Home Health Aide	$15.80				
Number of 15-minute units (28 hours per week = 112 units per week for 8 weeks)	448				
Imputed Home Health Aide Costs (National Per-Unit Payment Amount * Number of Units)	$15.80	*	448	=	$7,078.40
National Per-Unit Payment Amount – Occupational Therapy (OT)	$51.35				
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	24				
Imputed OT Visit Costs (National Per-Unit Payment Amount * Number of Units)	$51.35	*	24	=	$1,232.40
National Per-Unit Payment Amount - PT	$51.55				
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	24				
Imputed PT Visit Costs (National Per-Unit Payment Amount * Number of Units)	$51.55	*	24	=	$1,237.20
Total Imputed Costs for all Disciplines					$10,725.20
Labor Portion of the Imputed Costs for All Disciplines	$10,725.20	*	0.761	=	$8,161.88
Non-Labor Portion of Imputed Cost Amount for All Disciplines	$10,725.20	*	0.239	=	$2,563.32
CBSA Wage Index (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.3055				

Wage-Adjusted Labor Portion of the Imputed Cost Amount for All Disciplines	$8,161.88	*	1.3055	=	$10,655.33
Total Wage-Adjusted Imputed Cost Amount (Wage-Adjusted Labor Portion of the Imputed Cost Amount plus Non-Labor Portion of the Imputed Cost Amount)	$10,655.33	+	$2,563.32	=	$13,218.65
Total Payment Per 30-Day Period					
Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Period Payment Amount)	$1,534.58	+	$2,402.81	=	$3,937.39
Total Wage-Adjusted Imputed Cost Amount - Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Period Payment Amount)	$13,218.65	-	$3,937.39	=	$9,281.26
Outlier Payment = Imputed Costs Greater Than the Outlier Threshold * Loss-Sharing Ratio	$9,281.26	*	0.8	=	$7,425.01
Total Payment Per 30-Day Period = Total Case-Mix and Wage-Adjusted Period Payment Amount + Outlier Payment	$2,402.81	+	$7,425.81	=	$9,827.82

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For the second 30-day period of this clinical scenario, the previous calculation demonstrates how outlier payments could be made for patients with chronic, complex conditions under the PDGM. 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 periods described here. The CMS Grouper would assign these groups based on information in the OASIS. In general, we expect that outlier payments for unusually high cost periods in PDGM will be comparable to those under the current system, but there may be a small increase or decrease in rates depending on each beneficiary's specific situation. 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, including the proposed outlier methodology under the PDGM.

Final Decision: We are finalizing our proposal to maintain the current methodology for payment of high-cost outliers upon implementation of the PGDM and that we would calculate payment for high-cost outliers based upon 30-day periods of care.

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

We are finalizing a number of revisions to the regulations to implement the PDGM for periods of care beginning on or after January 1, 2020, as outlined in sections through III.F.1 through III.F.12 of this final rule with comment period. We are finalizing 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 finalizing to restructure § 484.205. These revisions would be effective on January 1, 2020. Specifically, we are doing the following:

- Revising § 409.43, which outlines plan of care requirements. We are revising 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 are moving and revising paragraph (c)(2) to § 484.205 as paragraph (c)(2) aligns more closely with the regulations addressing the basis of payment.
- Revising 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.
- Restructuring § 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 are to revising § 484.205 to remove references to ''60-day episode'' and to refer more generally to the ''national, standardized prospective payment''. We are also revising § 484.205 as follows:

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

++ Moving language which addresses the requirement for OASIS submission from § 484.210 and inserting it into § 484.205 as new paragraph (c).

++ Moving 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.

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

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

- Removing § 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.
- Revising 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 are adding paragraph (f) to this section to describe when the national, standardized prospective 30-day payment rate applies.
- Revising 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 are removing the reference to ''national 60-day episode payment rate'' and replacing it with ''national, standardized prospective payment''.
- Revising 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 are revising § 484.225 to remove references to ''60-day episode'' and to refer more generally to the ''national, standardized prospective payment''. In addition, we are adding paragraph (d) to describe the annual update for CY 2020 and subsequent calendar years.

- Revising the section heading of § 484.230 from ''Methodology used for the calculation of low-utilization payment adjustment'' to ''Low utilization payment adjustment''. Also, we are designating the current text to paragraph (a) and inserting language such that paragraph (a) applies to claims beginning on or before December 31, 2019, using the current payment system. We are adding paragraph (b) to describe how low utilization payment adjustments are determined for claims beginning on or after January 1, 2020, using the PDGM.
- Revising the section heading of § 484.235 from ''Methodology used for the calculation of partial episode payment adjustments'' to ''Partial payment adjustments''. We are removing paragraphs (a), (b), and (c). We are removing paragraphs (1), (2), and (3) which describe partial payment adjustments from paragraph (d) in § 484.205 and incorporating them into § 484.235. We are adding 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 PDGM, that is, for claims beginning on or after January 1, 2020.
- Revising the section heading for § 484.240 from ''Methodology used for the calculation of the outlier payment'' to ''Outlier payments.'' In addition, we are removing language at paragraph (b) and appending it to paragraph (a). We are adding language to 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 are revising paragraph (b) to describe payments under the PDGM, that is, for claims beginning on or after January 1, 2020. In paragraph (c), we are replacing the ''estimated'' cost with ''imputed'' cost. Lastly, we are revising paragraph (d) to reflect the per-15 minute unit approach to imputing the cost for each claim.

We did not receive any comments on the corresponding regulations text changes regarding the PDGM; therefore, we are finalizing regulations text changes as proposed without modification.

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

1. 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),[31] and the Medicare Program Integrity Manual (Pub. 100–08, chapter 6 section 6.2.3).[32] The subregulatory 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 § 409.43, and/or the initial and/or comprehensive assessment of the patient required in accordance with § 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.

In the CY 2019 HH PPS proposed rule, we proposed to amend the regulations text at § 424.22(c) to align the regulations text with current sub-regulatory guidance that allows medical record documentation from the HHA to be used to support the basis for certification and/or recertification of home health eligibility, if the following requirements are met:

- The documentation from the HHA can be corroborated by other medical record entries in the certifying physician's and/or the acute/post-acute care facility's medical record for the patient, thereby creating a clinically consistent picture that the patient is eligible for Medicare home health services as specified in § 424.22(a)(1) and (b).
- 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 § 409.43 and/or the initial and/or comprehensive assessment of the patient required in accordance with § 484.55.

HHAs have the discretion to determine the type and format of any documentation used to support home health eligibility. Anecdotally, we have received reports from HHAs that they typically include this supporting information on the plan of care. In accordance with § 409.43(c)(3), the plan of care must be signed by the physician before the HHA submits its final claim for payment. In the CY 2019 HH PPS proposed rule, we stated that because 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 solicited comments on the proposal to amend the regulations at § 424.22(c) to align the regulations text with current sub-regulatory guidance to allow medical record documentation from the HHA to be used to support the basis for certification and/or recertification of home health eligibility under certain conditions and the comments received are summarized in this final rule with comment period.

Comment: Overall, commenters were supportive of incorporating existing sub-regulatory guidance into regulations text as it provides them with reassurance that HHA-generated documentation can play an important role in confirming eligibility for Medicare home health services.

Response: We appreciate commenter support about aligning regulations text with existing regulatory guidance. The goal of this proposal is to be flexible to allow HHA-generated documentation to support eligibility for home health services given that the home health

[31] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf.*

[32] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c06.pdf.*

CoPs at § 484.55 require that the HHA must verify the patient's eligibility for the Medicare home health benefit, including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. We agree that this proposal incorporates existing subregulatory 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. However, we remind commenters that the certifying physician's and/or the acute/post-acute care facility's medical record (if the patient was directly admitted to home health from such setting) for the patient must contain sufficient documentation of the patient's medical condition(s) to substantiate eligibility for home health services. The information may include, but is not limited to, such factors as the patient's diagnosis, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc. The certifying physician's and/or the acute/post-acute care facility's medical records can always stand alone in substantiating eligibility for home health services. Similarly, the certifying physician's/acute/post-acute care facility's medical record, in conjunction with appropriately incorporated HHA documentation (for example, plan of care, OASIS, etc.), may also substantiate the patient's eligibility for home health services. However, HHA-generated medical record documentation for the patient, by itself, is not sufficient in demonstrating the patient's eligibility for Medicare home health services. As noted earlier, in accordance with § 424.22(a) and (c), it is the patient's medical record held by the certifying physician and/or the acute/post-acute care facility that must support the patient's eligibility for home health services. Therefore, any documentation used to support certification that was generated by the HHA must be signed off by the certifying physician and incorporated into his/her medical record. The information provided to the certifying physician by the HHA and incorporated into the patient's medical record must be corroborated by the rest of the patient's medical record. This means that the 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. This could include, but is not limited to, the plan of care required in accordance with § 409.43, the initial and/or the comprehensive assessment of the patient required in accordance with § 484.55, the inpatient discharge summary, or multi-disciplinary clinical notes, etc., which must correspond to the dates of service being billed and not contradict the certifying physician's and/or the acute/post-acute care facility's own documentation or medical record entries. Once incorporated into the certifying physician's medical record for the patient, the HHA information can be used to support the patient's homebound status and need for skilled care.

Comment: A commenter expressed concern that this proposal would allow HHAs to have too much control over Medicare coverage decisions and provides an opportunity for the HHA to override the physician's opinion. This commenter went on to state that there may be a physician's order for care that subsequently has been reduced or discontinued by the HHA and that beneficiaries are forced to settle for less care for fear that the HHA will not provide any services at all. This same commenter stated that certifying physicians are busy and do not have the time to read hundreds of detailed home health agency records. This commenter recommended that the HHA-generated documentation should be used only to confirm eligibility and not to deny coverage for patients that home health agencies no longer want to serve.

Response: We note that coverage of Medicare home health services is dependent upon beneficiary eligibility for Medicare home health services as set forth at § 409.42. We remind commenters that the HHA-generated documentation may only be used to support the certifying physician and/or the acute/post-acute care facility's medical record documentation for eligibility for Medicare home health services. As such, the HHA-generated documentation is not meant to supersede, override or negate the physician's opinion or any physician orders in the established home health plan of care. The HHA-generated documentation is only meant to augment, as necessary, the certifying physician's and/or acute/post-acute care facility's medical documentation to create a clinically consistent picture that the patient is eligible for home health services. Any HHA-generated information provided to the certifying physician by the HHA and incorporated into the patient's medical record held by the certifying physician and/or the acute/post-acute care facility's medical record (if the patient was directly admitted to home health for such setting) must be corroborated by the rest of the patient's medical record. As such, we do not expect that HHAs would need to send voluminous clinical records to a certifying physician for his/her review when certifying a patient for home health eligibility as the certifying physician's and/or the acute/post-acute care facility's medical records are required to have sufficient information to serve as the basis for home health eligibility. Additionally, the certifying physician is responsible for establishing and periodically reviewing the home health plan of care in accordance with the home health CoPs at 42 CFR 484.60(a)(1). While the HHA is responsible for coordinating with the certifying physician regarding any revisions to the home health plan of care, drugs, services, and treatments are administered only as ordered by a physician. Therefore, it would be a violation of the home health CoPs for a HHA to revise the plan of care, including reducing or discontinuing any items or services identified on the plan of care, without specific orders from the certifying physician. Finally, the purpose of the supporting documentation is to confirm eligibility for Medicare home health services. However, if the certifying physician's and/or acute/post-acute care facility's documentation and the HHA-generated incorporated supporting documentation do not create a clinically consistent picture that the individual is eligible for Medicare home health services (for example, the individual is homebound and requires skilled services), this would not meet the requirements for coverage.

Comment: Another commenter asked if the certifying physician is required to sign every page of HHA-generated supporting documentation to demonstrate that the documentation from the HHA was considered when certifying patient eligibility for Medicare home health services.

Response: There are no specific regulations regarding physician signature on a document with multiple pages. In accordance with § 484.110(b) of our regulations, all patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided. Only when it is clear that an individual document

extends to multiple pages (for example, a notation on a multi-page document that identifies pagination—''page 2 of 4''), and that the entire document is then authenticated, would a signature on a single page suffice for other pages as well.[33] However, we recognize that there may be multiple variations in the way HHA documentation is incorporated into the certifying physician's and/or acute/post-acute care facility's medical records. As such, we will provide future sub-regulatory guidance to address any identified variations. We believe this will provide additional clarity for HHAs and decrease the likelihood that inconsistent decisions would be made by appeals adjudicators regarding certification of patient eligibility for home health services.

Comment: A commenter suggested that CMS should clarify that the patient's plan of care, with sufficient information to support eligibility and signed by the certifying physician, may be used as documentation from the physician's medical record to support eligibility for home health services. This commenter stated that CMS might consider revising the regulatory text at 42 CFR 424.22(c) to read:

''. . . . documentation can include, but is not limited to, the patient's plan of care and/or the initial or the comprehensive assessment''.

Response: We agree with this commenter's suggestion given we stated in the preamble of the CY 2019 HH PPS proposed rule that information from the HHA, such as the plan of care required in accordance with § 409.43 *and/or* the initial and/or comprehensive assessment of the patient required in accordance with § 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. We also agree the patient's plan of care could be the sole HHA documentation that is incorporated into the certifying physician's and/or the acute/post-acute care facility's medical record for the patient and used to support the basis for certification of home health eligibility if the plan of care provides sufficient information to support eligibility. We remind commenters that the CoPs at § 484.60 provide the content requirements for the plan of care including all pertinent diagnoses and functional limitations. Likewise, we remind commenters that the certifying physician's and/or the acute/post-acute care facility's medical documentation shall be used as the basis for home health eligibility. The documentation from the HHA serves only as supporting documentation for the purposes of certification if incorporated into the certifying physician's and/or the acute/post-acute care facility's medical record for the patient. We will revise the regulatory text at § 424.22(c) accordingly to reflect commenters' concerns.

Final Decision: We are finalizing the proposal to amend the regulations text at § 424.22(c) to align 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 the certain requirements are met as previously described.

2. 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.

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 CoP requirements for the content of the home health plan of care, set out at § 484.60(a)(2).

We 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 existing home health CoP requirements for the content of the home health plan of care, in the CY 2019 HH PPS proposed rule we proposed to eliminate the regulatory requirement, as set forth at § 424.22(b)(2), that the certifying physician, as part of the recertification statement, provide an estimate of how much longer skilled services will be required (83 FR 32424). All other recertification content requirements under § 424.22(b)(2) would remain unchanged. We noted that 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, resulting in an overall cost savings of $14.2 million. We provide a description of this burden reduction in section X.C.1.c. of this final rule with comment period.

We solicited 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).

Comment: Commenters overwhelmingly supported this proposal. Commenters stated that the elimination of this requirement would help to streamline documentation and make it easier for agencies to obtain necessary information from supervising physicians in a timely manner. Commenters also remarked that removing this requirement will also be consistent with the ''Patients over Paperwork'' initiative. Other commenters remarked that this would allow certifying physicians to focus more time on patient care.

Response: We appreciate commenter support on this proposal and we agree that elimination of this recertification requirement would reduce the amount of time certifying physicians would spend reviewing medical documentation. This change would reduce the time spent by physicians for recertification without diminishing existing documentation requirements and will allow greater emphasis to be placed on patient care.

Final Decision: Effective for recertifications made on and after January 1, 2019, we are finalizing our proposal to eliminate the regulatory requirement set forth at § 424.22(b)(2) that requires the certifying physician, as part of the recertification process, to 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.

[33] See, *https://med.noridianmedicare.com/web/jfb/cert-reviews/signature-requirement-q-a.*

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

In the CY 2019 HH PPS proposed rule (83 FR 32425), we acknowledged the potential benefit of the use of remote patient monitoring to augment the home health plan of care. We discussed how remote patient monitoring could enable the HHA to more quickly identify any changes in the patient's clinical condition, prompting physician review of, and potential changes to, the plan of care. For example, 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. Additionally, we discussed findings of our literature review that revealed that remote patient monitoring may improve patients' ability to maintain independence, improving their quality of life. Particularly 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.[34] Other benefits included fewer complications and decreased costs.

We explained that although 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, the statute does not define the term ''telecommunications system'' as it relates to the provision of home health care. While a service using a form of telecommunications, remote patient monitoring is not considered a Medicare telehealth service as defined under section 1834(m) of the Act. Additionally, there is no direct interaction between the patient and the practitioner. Remote monitoring, rather uses digital technology to relay information captured by the patient to the practitioner for review, and to potentially prompt changes to the plan of care. We explained that for these reasons it would not be subject to the telehealth restrictions on originating site and interactive telecommunications systems technology under section 1834(m) of the Act.

Therefore, because the statute does not define the term ''telecommunications system'' as it relates to the provision of home health care, we proposed to define remote patient monitoring in regulation 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.'' This definition aligns with the description for CPT code 99091, which 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). We recognized that HHAs cannot bill for this code (CPT code 99091); however, we believe the code's description accurately describes remote monitoring services. We also noted that CPT code 99091 includes the interpretation of the physiologic data, whereas the HHA would only be responsible for the collection of the data.

Currently home health 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. Allowing HHAs to report the costs of remote patient monitoring on the HHA cost report as part of their operating expenses, which are factored into the costs per visit, would have important implications for assessing home health costs relevant to payment, including HHA Medicare margin calculations. Therefore, we proposed 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.

We solicited comments on the proposed regulatory 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 welcomed comments regarding additional utilization of telecommunications technologies for consideration in future rulemaking. We also solicited 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) on the HHA cost report. The following is a summary of the public comments received and our responses.

Comment: Comments regarding the proposal to define remote patient monitoring in regulation for the Medicare home health benefit and to include the costs of remote patient monitoring as an allowable expense on the HHA cost report were overwhelmingly positive. Commenters stated that there are multiple benefits to integrating the costs of remote patient monitoring into home health, including providing clinicians with real-time updates on patient condition and providing patients with timely feedback, thereby encouraging patient engagement. Additionally, commenters stated that it allows for greater involvement with nurses and physicians, while decreasing travel, which may be advantageous not only in rural areas, but urban areas as well.

Response: We thank commenters for their positive feedback regarding these proposals. We agree that there are many benefits to remote patient monitoring and anticipate that defining it in regulation and allowing for more clear analysis of the associated costs through the cost report will encourage its use in home health and have a positive effect on patient outcomes.

Comment: Several commenters encouraged CMS to monitor utilization patterns to ensure that remote patient monitoring is not being used as a substitute for face-to-face visits. A commenter suggested that CMS require information about the frequency and duration of the use of remote patient monitoring services; specifically, that the HHA be required to report on the Medicare claim whether an episode included the use of remote patient monitoring.

Response: We agree with the recommendation to monitor utilization patterns to ensure appropriate use of the service under the home health benefit. We also agree that data concerning whether individuals received remote patient monitoring during the 30-day period of care could be informative. We will consider ways to obtain this information in the future.

Comment: Another commenter suggested that CMS clarify that if the remote monitoring service is a nursing service, it can help satisfy the skilled nursing requirement to trigger Medicare

[34] 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.*

coverage for other covered home health services such as home health aides and occupational therapy.

Response: In accordance with section 1861(m) of the Act, home health services must be furnished in the beneficiary's home. Additionally, § 409.48 defines a visit as an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA, for the purpose of providing a covered service. Finally, section 1895(e)(1)(B) of the Act states that services furnished via a telecommunications systems are not considered home health visits for purposes of eligibility or payment. Therefore, we do not consider the use of remote patient monitoring alone and/or a visit solely for the purpose of setting up and/or training the patient on remote monitoring equipment to meet the criteria for prompting coverage of home health services under the Medicare home health benefit.

Comment: Several commenters suggested adding the descriptions of two new proposed Physician Fee Schedule CPT codes: CPT codes 990X0, set-up and patient education on use of equipment and 990X1, device supply with daily recordings or programmed alerts transmission, to the proposed home health definition in order to allow for a more appropriate and complete description of allowable costs for remote patient monitoring services in the home health setting. Commenters suggested this would also help to establish consistency regarding remote patient monitoring across Medicare sites of service.

Response: We recognize that the descriptors for these two codes allows for greater specificity of the process of remote patient monitoring, which in turn would lead to more accurate analysis of the associated costs. While the proposed home health regulations text at § 409.46(e) would permit the cost and service of the equipment to be allowable administrative costs, we agree that set-up and patient education should be allowable expenses reported on the cost report. However, we wish to clarify that a visit to set up and/or train the patient on the equipment would not be allowed on the HHA claim when no other skilled service is provided. In other words, a visit cannot be reported when the sole reason is to set up and/or train the patient on the use of the remote monitoring equipment. Therefore, we are adding language to the regulations text to ensure a more complete description of remote patient monitoring services, with the qualification that such set-up and patient education services cannot be reported as a visit without the provision of another skilled service.

Comment: A commenter recommended that CMS describe how it plans to account for the adoption of new remote patient monitoring services as the agency monitors and evaluates the impact of previous or future rebasing adjustments made to the home health prospective payment rates since 2014. Another commenter stated that in order to implement in an effective and consistent manner, CMS needs to develop an appropriate corresponding payment methodology. Other commenters suggested CMS set up a demonstration project where HHAs have an incentive to make an investment in technologies, or incorporate telehealth waivers into all demonstration projects. Other commenters stated that CMS should have a more broad approach to telehealth and telemedicine to include virtual visits as a potential strategy to address workforce challenges. Others stated CMS should directly reimburse for remote patient monitoring, perhaps as a non-routine supply for agencies who are actually providing the service, as the proposal will indirectly provide increased reimbursement for all agencies, not specifically for those providing the service.

Response: We appreciate the commenters' suggestions. While we understand that these comments indicate that some commenters would like to see additional activities in incentivizing the use of remote patient monitoring in home health, we believe that allowing the costs associated with remote patient monitoring to be reported on the cost report is a necessary first step in determining the cost and frequency in which HHAs are currently utilizing this technology and whether the use of such technology improves health outcomes for home health patients. Additionally, we reiterate that 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. Thus virtual home health visits would not qualify for payment under the home health benefit. We plan to closely monitor remote patient monitoring costs and the impact that such technology may have on patient outcomes under the traditional Medicare home health benefit and we will consider ways to more broadly support such technology as part of home health.

Comment: A commenter suggested that rather than allowing the costs of remote patient monitoring to be included on the home health cost report, remote patient monitoring should be excluded from the home health episode and provided as a distinct and separately reimbursed service. The commenter stated that this would recognize the value of remote patient monitoring services while also recognizing home health agencies as providers of these services. Home health agencies would then be able to provide these services to patients within home health but also to those who do not qualify for home health but would benefit from RPM services, despite not having a mechanism for reimbursement. Similarly, another commenter suggested that a telehealth chronic care management program conceptualized as a ''step down'' program from an episode of care would benefit many patients greatly and may serve as an alternative to successive full episodes of care.

Response: We thank the commenters for these suggestions; however, we believe that these comments suggest the implementation of a separate remote patient monitoring benefit under Medicare and are therefore outside of the scope of this rule. Additionally, we note that beginning in CY 2018, separate payment is made under the Physician Fee Schedule for CPT code 99091 (Collection and interpretation of physiologic data (for example., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional). This code, billed directly by a practitioner, allow remote patient monitoring to be provided outside of the home health benefit for non-homebound patients.

Comment: Several commenters requested that CMS clarify whether the agency intends that all qualified health professionals, specifically physical therapists, speech language pathologists, and occupational therapists, acting within their scope of practice, may use remote patient monitoring to augment the plan of care during a home health episode.

Response: Our definition does not specify which skilled professionals may utilize remote patient monitoring under home health. As therapy goals must be established by a qualified therapist in conjunction with the physician when determining the plan of care, we believe therapists involved in care planning, as well as other skilled professionals acting within their scope of practice, may utilize remote patient monitoring to augment this process.

Final decision: We are finalizing our proposal to define remote patient

monitoring under the Medicare home health benefit as ''the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient or caregiver or both to the home health agency.'' We are adding the following language to the regulations text to ensure a more complete description of remote patient monitoring services, while also ensuring that such services cannot be reported as a visit without the provision of another skilled service: Visits to a beneficiary's home for the sole purpose of supplying, connecting, and/or training the patient on the remote patient monitoring equipment, without the provision of another skilled service are not separately billable. These services do constitute services included in the expense of providing remote patient monitoring allowed as administrative costs.

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

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

A. Background

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 (83 FR 32426), we proposed 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. Removal of 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 to be 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 [35] (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 OASIS-based measure, 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 proposed (83 FR 32426 through 32427) to remove two OASIS-based process measures, Influenza Immunization Received for Current Flu

[35] 2015 Annual Report to Congress, *http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm.*

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 proposed 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),[36] 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.[37] In 2014, the ACIP updated its guidelines to recommend that both vaccines, the PCV13 and the PPSV23, be given to all immunocompetent adults aged ≥65 years.[38] 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 proposed to remove this measure from the model beginning PY4.

We invited public comment on our proposal to remove these 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.

The following is a summary of the public comments received on these proposals and our responses:

Comment: The majority of commenters supported removing both OASIS-based process measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, citing concerns that process measures may be burdensome on providers to report while yielding limited information to support clinical improvement. Commenters also noted that removal of the measures aligns with the Meaningful Measure Initiative. Several commenters opposed any changes to the HHVBP model's applicable measure set and recommended that CMS complete testing of the HHVBP model prior to making any changes. A commenter opposed removal of the Pneumococcal Polysaccharide Vaccine Ever Received measure, stating that removal may lead to reductions in pneumococcal immunization rates. The commenter believes that CMS should retain this measure until it is updated to reflect the most current ACIP guidelines. The commenter noted that the measure aligned with Meaningful Measures criteria on high-impact conditions and patient-centered care, adding that retaining the measure would not be burdensome to HHAs, given their ability to establish standing orders to support immunization processes. Another commenter opposed removal of the Influenza Immunization Received for Current Flu Season measure as the commenter believes that it is an important safety measure that may be overlooked if it is no longer required to be reported.

Response: With regard to those comments that opposed changes to the HHVBP Model's applicable measure set until testing of the Model has concluded, we reiterate that one of the goals of the Model is to study new potential quality and efficiency measures for appropriateness in the home health setting. We indicated in the CY 2016 HH PPS final rule that the initial set of measures adopted for use in the Model would be subject to change during subsequent model years and, as summarized previously and in the proposed rule, we have finalized the removal of other measures included in the initial measure set in prior rulemaking. We continue to believe it is important to evaluate and consider changes to the measure set during the course of testing the Model because the relevance of certain quality measures may change over time (for example, a measure may become ''topped out''). We also note that we attempt to align with other CMS reporting programs, such as the Home Health Quality Reporting Program (HH QRP), to the extent possible, in order to minimize HHAs' reporting burden, as well as to focus on outcome-based measures where possible and align to clinical or best practice.

With respect to the commenter's concern that removal of the ''Influenza'' measure from the HHVBP model's applicable measure set would result in the vaccine not being given, we note that while the purpose of including these measures may be to drive certain outcomes or processes, such as administering a vaccine, removing the measure from the HHVBP Model's applicable measure set does not mean that HHAs will avoid providing appropriate care when needed. Moreover, although the ''Influenza'' measure was removed from the Quality of Patient Care Star Rating effective April 2018, HHAs will continue to report the measure in the HH QRP and it will continue to be displayed on Home Health Compare (HHC). As discussed in the proposed rule, we proposed to remove this measure from the HHVBP model's applicable measure set in response to concerns that it may not fully capture HHA performance in the administration of the influenza vaccine. However, we believe that HHAs will continue to have an incentive to provide the vaccine where appropriate.

With respect to the removal of the Pneumococcal Polysaccharide Vaccine Ever Received measure, we note that CMS is finalizing in this final rule with comment period the removal of this measure for purposes of the HH QRP beginning with the CY 2021 HH QRP and will publicly report the measure on HHC until January 2021. As we discuss in response to comments in section V. of this final rule with comment period, while we understand that assessing and appropriately vaccinating patients are important components of the care

[36] 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*).

[37] Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 1997;46:1–24.

[38] 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.

process, we also prioritize ensuring that quality measures can be used by practitioners to inform their clinical decision and care planning activities. The updated ACIP pneumococcal vaccination recommendations require information that is often not available to HHAs, including whether the patient has previously been vaccinated, the type of pneumococcal vaccine received by the patient, as well as the sequencing of vaccine administration. In addition, the physician issuing orders and responsible for the home health plan of care may not be the patient's primary care practitioner or other health care professional responsible for providing care and services to the patient before and after discharge from the agency, and therefore may not be best able to provide the HHA with such information. Finally, even if the pneumococcal vaccination status of the patient is available, OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received that are used in the calculation of this measure do not correspond to the updated ACIP pneumococcal vaccination recommendations and therefore may not accurately measure HHA performance in this area. However, we understand and value the role pneumococcal vaccines play in preventing pneumococcal disease [39] and we encourage that, whenever possible and as appropriate, HHAs provide pneumococcal vaccinations for their patients. As with the influenza vaccination measure, we do not believe that our removal of this measure from the HHVBP model will result in HHAs failing to provide appropriate care for beneficiaries.

Final Decision: After considering public comments, we are finalizing as proposed the removal of the Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received measures from the set of applicable measures beginning with PY4 and subsequent years of the model.

2. Replacement of 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 in the proposed rule (83 FR 32427 through 32429), we proposed 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. As we discussed in the CY 2019 HH PPS proposed rule, 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 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.

We indicated in the proposed rule that there are currently three ADL improvement measures in the HHVBP Model (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion). The maximum cumulative score across all three measures is 30. Because we proposed to replace these three measures with the two composite measures, we also proposed 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. That is, there would still be a maximum of 30 points available for ADL-related measures.

We stated that 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. We stated that both of these proposed composite measures combine several existing and endorsed HH QRP outcome measures into focused composite measures to enhance quality reporting. These proposed composite measures fit within the *Patient and Family Engagement* [40] 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. We indicated that 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

[39] CDC: Pneumococcal Disease. Retrieved from: *http://www.cdc.gov/pneumococcal/about/prevention.html.*

[40] 2017 Measures under Consideration List. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2017-CMS-Measurement-Priorities-and-Needs.pdf.*

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 37 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 proposed that the actual prediction models for the composite measures, if finalized, would use episodes of care that ended in CY 2017, which we proposed 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 CY 2017.

The following table (Table 37) 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. This same information was included in Table 50 of the CY 2019 HH PPS proposed rule (83 FR 32428 through 32429).

TABLE 37: OBSERVED VERSUS PREDICTED EPISODE-LEVEL PEFORMANCE FOR THE PROPOSED TOTAL NORMALIZED COMPOSITE CHANGE MEASURES

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

Table 37 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

We explained in the proposed rule that 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,[41] HHAs must provide responses to all OASIS items for

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

the OASIS assessment to be accepted into the CMS data repository. Therefore, while we believed the likelihood that a value for one of these items would be missing is extremely small, we proposed 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. We presented summary information for these two proposed composite measures in Table 51 of the proposed rule (83 FR 32429 through 32431). We explained that 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 of the proposed rule were replaced with columns describing ''Measure Computation'' and ''Risk Adjustment.''

We invited public comment on our 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.

Comment: Many commenters supported replacing the three OASIS-based measures, Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing, with the two composite measures, Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility. Some commenters, including MedPAC, expressed concerns with the composite measures, stating that such measures represent reporting elements completely within the control of HHAs and may incentivize them to change their coding practices in order to improve performance on such measures (and thus, positively affect risk-adjustment or payment adjustments in their favor). Another commenter questioned the methodology for the maximum possible change calculation, as each patient's maximum score for a specific question would be based upon the total number of responses possible for that OASIS question. The commenter was concerned that this methodology does not create an equal ability for HHAs to improve outcomes for certain populations of patients, such as those who benefit from home health physical therapy but have limited ability to improve upon scores on certain OASIS items such as transferring due to chronic musculoskeletal or neurological conditions. This same commenter questioned the use of a CY 2017 baseline year for these new composite measures, rather than the CY 2015 baseline year used for the other measures in the measure set, which it believed added complexity to the model. Another commenter expressed concern about the proposed Total Normalized Composite Change in Self Care measure, citing that the proposed composite measure uses outcome measures that are not currently included in the HHVBP Model and have not been a priority focus for quality improvement for agencies participating in the HHVBP Model.

Response: With regard to the concerns raised by MedPAC and others regarding the data elements that comprise the composite measures, we note that we are also finalizing our proposal (as discussed elsewhere in this final rule with comment period) to reduce the weight of the OASIS-based measures relative to the other measure areas (claims-based and HHCAHPS). Although we continue to believe that the OASIS-based measures yield reliable information for assessing HHAs' quality performance and capture important information about beneficiaries' function and improvement, our weighting methodology will increase the collective weight of the claims-based and HHCAHPS measures, which utilize data from claims and patient surveys and not self-reported data, relative to the OASIS-based measures. Regarding the commenter's concerns with the composite measure methodology, as discussed previously, our methodology uses normalized scores that take into account the difference in measure response scales, and result in a maximum possible change for any single OASIS item that is equal to ''1'' regardless of the possible range of response options for that particular OASIS item. This methodology accounts for changes to the scores on individual OASIS items while also taking into account that not all patients are able to significantly improve on all aspects of each composite measure. In the case of patients with certain chronic conditions where there is limited ability to improve on some areas of mobility, as the commenter noted, such beneficiaries may still benefit from home health care services such as physical therapy. We believe that including the composite measure (versus including one or more individual OASIS items related to transfers, which would place more weight on those individual items) will encourage HHAs to focus on improving overall mobility without penalizing HHAs that are unable to improve on OASIS scores for certain patients on a particular item. Regarding the comment that CMS is adding complexity to the model by using CY 2017 as the baseline year for the composite measures rather than the CY 2015 baseline year used for the remainder of the measures in the measure set, we note that, as we indicated in the CY 2016 HH PPS final rule, for the starter set of quality measures used in the model, 2015 would consistently be used as the baseline period in order to evaluate the degree of change that may occur over the multiple years of the model (80 FR 68681). These new composite measures were not part of the model's starter set. We believe that using more currently available calendar year data to assess HHA performance on these new composite measures will result in a more accurate performance score.

Finally, while not all of the OASIS items that comprise the Total Normalized Composite Change in Self Care composite measure are currently included in the measure set for the HHVBP Model, the composite measure would use data on these OASIS items that are already collected from the participating HHAs. All HHAs must report such data in order to meet the requirements for certification as an HHA, per the Medicare Conditions of Participation (CoP) requirements at § 484.55(c)(2). The individual OASIS items included in the Self-Care and Mobility composite measures focus on areas that target broad clinical goals related to therapy provided in the home setting: Improvement in ability to conduct activities of daily living for oneself (that is, dressing and bathing) and improvement in mobility (that is, ability to transfer). While not all of the individual OASIS items that comprise the composite measures are currently included in the HHVBP Model measure set, they reflect activities and goals that are consistent with the goals of the HHVBP Model: To encourage HHAs to improve the quality of care for beneficiaries. We expect that HHAs already focus on improvement in such areas not just because such items are included in the OASIS or are required

to be reported in order to become a Medicare-certified HHA, but also because self-care and mobility are areas of great importance to patients and families and improvement in such areas may allow beneficiaries to remain in the home setting (versus an institution) and contribute to beneficiaries' quality of life. Furthermore, we note that the Conditions of Participation require OASIS accuracy and that monitoring and reviewing is done by CMS surveyors. CMS also conducts activities to validate the same self-reported OASIS data that is used for payment.

Comment: Many commenters suggested that stabilization measures should be recognized in HHVBP as opposed to just focusing on improvement measures, given that stabilization is sometimes a more realistic goal than improvement for certain patients.

Response: We previously discussed our analyses of existing measures relating to stabilization in the CY 2016 HH PPS final rule. Specifically, we stated that while we considered using some of the stabilization measures for this model, we found that in contrast to the average HHA improvement measure scores which ranged from 56 to 65 percent, the average HHA stabilization measure scores ranged from 94 to 96 percent. Using measures where the average rates are nearly 100 percent would not allow for meaningful comparisons between competing HHAs on the quality of care delivered (80 FR 68669 through 68670). While the commenters did not suggest specific stabilization measures for our consideration, we note that in the years since the CY 2016 HH PPS final rule was published, we have continued to explore whether the inclusion of stabilization measures may be appropriate for the HHVBP Model, however we have not identified any such measures that we believe would allow for meaningful comparison of HHA performance. Although we appreciate commenters' concerns that some beneficiaries may have limited opportunity to improve and that stabilization may be a more realistic goal for such patients, based on these analyses, we do not believe these measures are appropriate for inclusion in the Model at this time.

Final Decision: After consideration of the public comments we received and for the reasons we discussed previously, we are finalizing our proposal to replace three OASIS-based measures, Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing, with two composite measures, Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility, for PY4 and subsequent performance years.

Table 38 reflects our finalized polices to remove the Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received measures and to replace the Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing measures with the new Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures. Table 38 identifies the applicable measures set for 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.

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TABLE 38: MEASURE SET FOR THE HHVBP MODEL BEGINNING PY 4*

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

NQS Domains	Measure Title	Measure Type	Identifier	Data Source	Numerator	Denominator
Patient & Caregiver-Centered Experience	Communications between Providers and Patients	Outcome		CAHPS	NA	NA
Patient & Caregiver-Centered Experience	Specific Care Issues	Outcome		CAHPS	NA	NA
Patient & Caregiver-Centered Experience	Overall rating of home health care	Outcome		CAHPS	NA	NA
Patient & Caregiver-Centered Experience	Willingness to recommend the agency	Outcome		CAHPS	NA	NA
Population/Community Health	Influenza Vaccination Coverage for Home Health Care Personnel	Process	NQF0431 (Used in other care settings, not Home Health)	Reported by HHAs through Web Portal	Healthcare personnel in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: (a) received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere; or b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other components of the vaccine or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; or (c) declined influenza vaccination; or (d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the previously mentioned numerator categories.	Number of healthcare personnel who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.
Population/Community Health	Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?	Process	NA	Reported by HHAs through Web Portal	Total number of Medicare beneficiaries aged 60 years and over who report having ever received zoster vaccine (shingles vaccine).	Total number of Medicare beneficiaries aged 60 years and over receiving services from the HHA.
Communication & Care Coordination	Advance Care Plan	Process	NQF0326	Reported by HHAs through Web Portal	Patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	All patients aged 65 years and older.

NQS Domains	Measure Title	Measure Type	Identifier	Data Source	Numerator	Denominator
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 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.

3. Reweighting 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 proposed to revise how we weight the individual measures and amend § 484.320(c) accordingly (83 FR 32431). Specifically, we proposed 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. We noted 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 in the proposed rule and in this final rule with comment period, we stated that we believe that this proposed reweighting, to allow more weight for the claims-based measures, would better support improvement in those measures.

We explained in the proposed rule that weights would also be adjusted under our 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 stated that 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 also proposed 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 stated that 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 proposed 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 1 and 2 (which were included as Figures 5 and 6 in the proposed rule) 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 stated that 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 our contractor's TEP.

FIGURE 1:

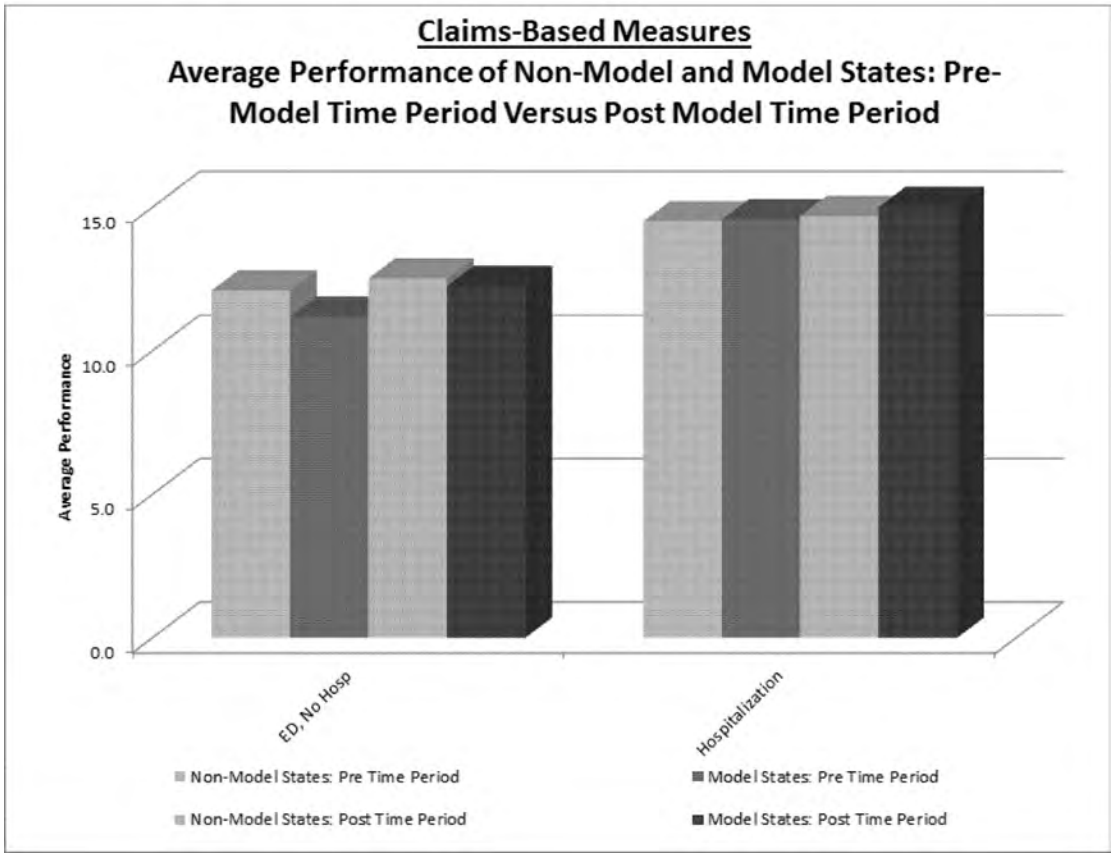
Claims-Based Measures
Average Performance of Non-Model and Model States: Pre-Model Time Period Versus Post Model Time Period
Average Performance
15.0
10.0
5.0
0.0
ED, No Hosp
Hospitalization
Non-Model States: Pre Time Period
Non-Model States: Post Time Period
Model States: Pre Time Period
Model States: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

FIGURE 2:

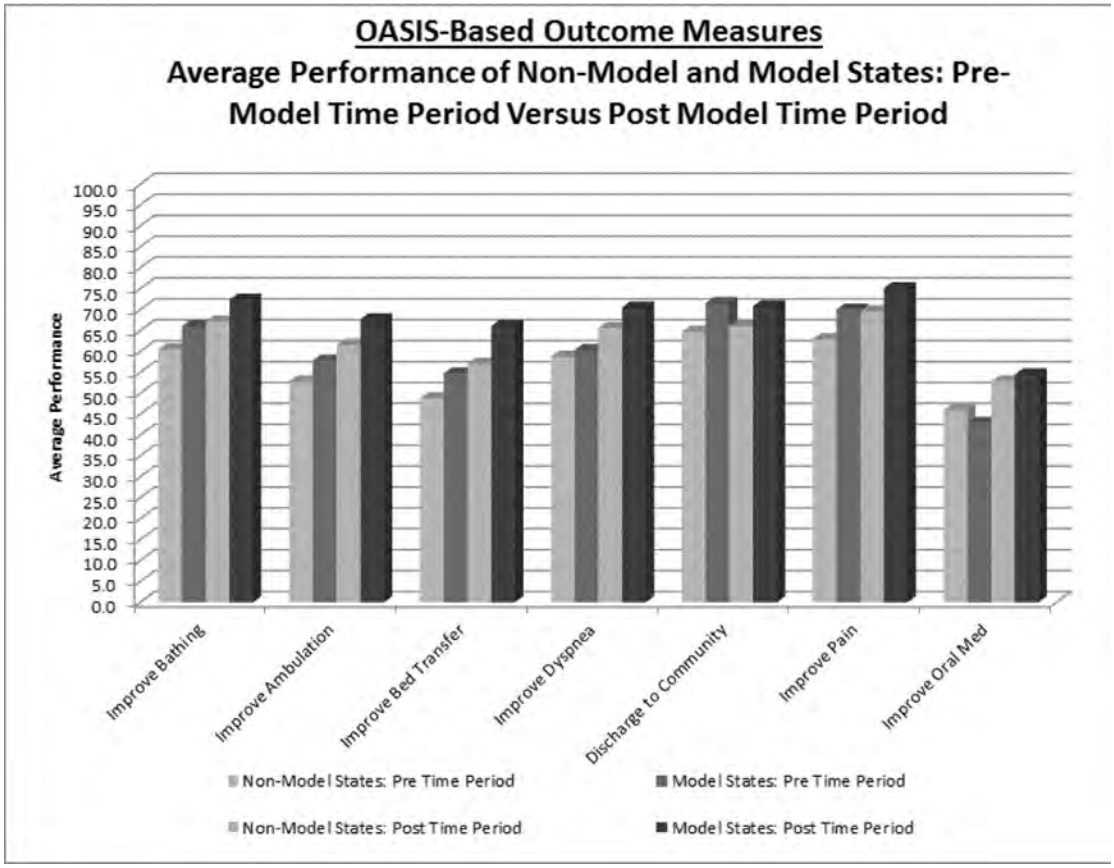

Table 52 of the proposed rule (83 FR 32434) showed the current weighting and the proposed revised weighting for each measure based on our proposal to change the weighting methodology from weighting each individual measure equally to weighting the OASIS, claims-based, and HHCAHPS measure categories at 35-percent, 35-percent and 30-percent, respectively. Table 52 of the proposed rule also showed the proposed weighting methodology based on various scoring scenarios. This same information is presented in Table 39 of this final rule with comment period. 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 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. The OASIS- and claims-based measure categories would have equal weights in this scenario because the weight for each remaining category when one category is missing is based on the relative weight of the category when all three are present. Because both the OASIS- and claims-based categories would have a weight of 35% when HHCAHPS data is reported, each would have a 50% weight if HHCAHPS data is not available. However, if no claims-based measure data is available, the OASIS-based measures would have a higher weight than the HHCAHPS category, because their weights when all three categories are available are 35% and 30%, respectively. Finally, both Table 52 of the proposed rule and Table 39 of this final rule with comment period show the change in the number of HHAs, by size, that would qualify for a TPS and payment adjustment under the current and proposed reweighting methodologies, using CY 2016 data. We noted in the proposed rule that Table 52 only reflects 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 (and Table 39 of this final rule with comment period). We referred readers to Table 65 of the proposed rule (83 FR 32506) which reflected the weighting that would apply if all of our proposed changes, including the proposed changes to the applicable measure set, were adopted for CY 2019. We indicated that 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. For purposes of this final rule with comment period, we refer readers to Table 50 of this final rule with comment period, which reflects the weighting that will apply beginning in CY 2019 based on all of our finalized proposals, including the finalized reweighting and our finalized changes to the applicable measure set. As reflected in Table 50 of this final rule with comment period, the two finalized composite measures will have weights of 7.5 percent when all three measure categories are reported.

TABLE 39: 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 proposed (and finalized) to be removed from the applicable measure set beginning CY 2019/PY 4.

**Measures proposed (and finalized) to be removed from the applicable measure set and replaced with two new composite measures beginning CY 2019/PY 4.

***The weights of the measure categories, when one category is removed, are based on the relative weight of each category when all measures are used. For example, if the two measure categories, Claims and OASIS, are expressed then each category represents 50% because each of these categories has the same weight (35%) when all 3 categories are represented. However, if only OASIS and HHCAHPS are expressed, OASIS represents 53.85% while HHCAHPS represents 46.15%, which represents the same relative proportion as 35% and 30%, the OASIS and HHCAHPS weights, respectively, when all three categories are present.

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We invited public comments 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 also proposed to amend § 484.320 to reflect these proposed changes. Specifically, we proposed 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. We also included a sample calculation in Table 53 of the proposed rule (83 FR 32435) 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.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters generally supported the reweighting of the measure categories for the purpose of encouraging additional focus on the claims-based measures, and also supported the proposed revised weights. Some commenters were concerned that reweighting the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure to be three times the weight of the Emergency Department Use without Hospitalization claims-based measure would make one measure too impactful for the overall TPS, and that significant weight on a single measure would encourage HHAs to focus on that one measure at the expense of other measures. A commenter suggested that the claims-based measure category should be reweighted higher, such as 60 percent, because the commenter believed that claims-based measures were less likely to be subject to data manipulation than measures based on self-reported data. Another commenter recommended an increase in weighting for claims-based measures when HHCAHPS data are not available. MedPAC supported weighting claims measures more and recommended the OASIS measures be weighted less than the HHCAHPS measures because they believe that patient experience can be an important way to assess quality of care.

Response: We appreciate the comments supporting reweighting in general as well as our proposed reweighting percentages. We proposed to weight the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure three times the weight of the Emergency Department Use without Hospitalization claims-based measure because of our belief that HHAs have greater ability to improve upon the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure than the ED measure, given that beneficiaries can self-refer to the ED but a hospitalization requires more direct clinician involvement (from either HHA staff or a community clinician with whom the HHA should be coordinating care) for an admission. As noted in the proposed rule, because inpatient hospitalizations generally cost more than ED visits, we also believe quality improvement in the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure may have a greater impact on reducing Medicare expenditures. We plan to monitor and evaluate the impact of weighting the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure three times the weight of the Emergency Department Use without Hospitalization claims-based measure.

With regard to the commenter's suggestion to reweight the claims-based measures to 60 percent, we are concerned that such an approach would encourage HHAs to focus on the claims-based measures (and particularly the Unplanned Hospitalization measure) at the expense of other quality improvement efforts, such as patient experience and mobility improvement, which are assessed through HHCAHPS and the OASIS measures. We are attempting to balance encouraging HHAs to focus on measures that may more heavily impact Medicare expenditures (such as the claims-based measures) with ensuring that HHAs focus on quality improvement across various focus areas, including those which are not directly measured through the claims-based measures, such as patient experience and mobility. As such, we do not believe we should increase the weight for claims-based measures above what we have proposed when HHCAHPS data are not available; rather, we believe a more gradual approach is appropriate for increasing HHAs' focus on claims-based measures. In addition, we continue to believe that OASIS-based measures provide important information about quality of care and want to continue to encourage HHAs to further improve on such measures. Finally, with regard to MedPAC's suggestion to weight the HHCAHPS higher than the OASIS-based measures, we agree with MedPAC that measuring patient experience during home health episodes is important. As discussed in this section, while we proposed to weight the HHCAHPS category less than the other two categories, the overall change in the weight for the HHCAHPS is not significant. As Table 50 reflects, HHCAHPS were reduced from 31.25 percent to 30.00 percent for the category and from 6.25 percent to 6.00 percent for each individual HHCAHPS measure under our proposal. A greater reduction actually occurs for the OASIS-based measures (as shown in Table 50, total weight for OASIS measures goes from 56.25 percent to 35.00 percent for the category and 6.25 percent to 5.00 percent for individual OASIS measures, other than the two new composite measures). This is because under current policy each HHCAHPS, OASIS-based, and claims-based measure is weighted equally and because the number of measures in each category differs. We believe the proposed reweighting balances our interest in encouraging focus on claims-based measures as well as on the patient experience and OASIS-based measures.

Comment: Several commenters suggested the weight of the HHCAHPS measures category should not be reduced because they are concerned that HHAs may focus less on improving upon HHCAHPS. Another commenter suggested that the HHCAHPS measure category should not have a lower weight than the OASIS measures category because the commenter believes that a lower weight would suggest that patient experience is less important than the other measures.

Response: We acknowledge the importance of the HHCAHPS measures and gave them serious consideration when proposing measure category reweighting. In considering revisions to the weights for HHCAHPS versus the other measures, we attempted to balance placing more emphasis on claims-based measures (which may have a greater impact on Medicare expenditures) with continuing to encourage HHAs to focus on patient experience. We note that while the OASIS measures category will

be reweighted from 56.25 percent to 35.0 percent (a reduction of 21.25 percent), the HHCAHPS measures category will be reweighted from 31.25 percent to 30 percent (a reduction of only 1.25 percent). We believe this moderate reweighting of the HHCAHPS measures category is appropriate because smaller HHAs are not required to submit their HHCAHPS measure scores due to their limited episodes of care, and therefore we believe that more weight should be allotted to measure categories with broader HHVBP Model reporting across HHAs of all types. However, as noted, our proposal only reduces the HHCAHPS weights very slightly, which is consistent with our belief and the view expressed by several commenters that patient experience is a crucial component of quality measurement during home health episodes. Based on our examination of performance data, we proposed to increase the weight of the claims-based measures, while still seeking to encourage HHAs to focus on other measure categories. CMS will also monitor and evaluate the impact of the reweighting of the overall measure categories and determine if additional adjustments are necessary in future years through rulemaking.

Comment: Some commenters suggested that CMS should delay measure category reweighting or maintain the current weighting methodology because they believe that HHAs need more time to adapt to the HHVBP Model, and that CMS should wait for information on behavioral impacts from the new PDGM prior to making additional changes to HHVBP. Other commenters suggested that making changes, such as reweighting, would make the HHVBP Model difficult to evaluate and create an unfair environment for HHAs.

Response: We carefully considered the impact on HHAs of our proposed changes to reweight the measure categories, as well as the effects on quality improvement for beneficiaries. We proposed to reweight the measure categories to allow for more weight to the claims-based measures to encourage further improvement on those measures, and place increased focus on accountability for areas of significant Medicare spending, such as hospitalizations. Because these measures have been a part of the HHVBP model's applicable measure set from the start of the model, we believe HHAs will have sufficient time to appropriately adjust business practices and care methods as needed in light of the proposed reweighting. The evaluation of the HHVBP model will take into account changes in the model methodology and in the corresponding HHA environment, such as changes to the Home Health Prospective Payment System.

Comment: Some commenters believed that the proposed reweighting may disincentivize some HHAs from serving vulnerable populations that are at risk for hospitalizations. A commenter stated that the proposed reweighting may incentivize further hospital stays.

Response: We believe that the reweighting will encourage HHAs to further enhance their service structures to appropriately address the needs of Medicare beneficiaries of all types by using quality improvement processes that support the Model's quality measures, including processes intended to reduce hospitalizations. We do not believe that reweighting the measures would discourage HHAs from serving vulnerable populations or incentivize further hospital stays. Rather, we believe that reweighting the measures to increase the emphasis on the claims-based ED use and unplanned hospitalization measures would encourage HHAs to increase the coordination with other providers and suppliers such as physicians and inpatient facilities (hospitals and post-acute care (PAC) facilities) in order to reduce ED visits and hospital admissions. We note that the claims-based ED and hospitalization measures are included in the HH QRP and reflect goals consistent with other CMS initiatives that focus on reducing avoidable hospital admissions, such as the Hospital Readmissions Reduction Program. We expect the proposed increase in the weight of these ED and hospitalization measures to incentivize avoiding hospital stays, not additional hospitalizations. We also do not expect that the reweighting will cause HHAs to implement policies that do not serve vulnerable populations at risk of hospitalization, but will instead encourage care coordination between HHAs and other health care providers to avoid hospitalizations, which may result in improved care for all beneficiaries, including vulnerable populations. Moreover, in determining the reweighting percentages, we proposed a weight of 30 percent for HHCAHPS in order to ensure patient experience across all vulnerable populations is not negatively affected by the reweighting. Finally, we note that HHAs in the HHVBP Model have opportunities to share strategies for success under the model, including reducing hospitalizations, through specialized technical assistance and learning events provided through the Model.

Comment: A commenter suggested that the proposed reweighting was arbitrary and that providers should be evaluated based on the most important aspects of care.

Response: We disagree that the proposed reweighting was arbitrary. The HHVBP model examines a broad array of quality measures that address critical quality areas. The selected measures are intended to have a high impact on care delivery and support the combined priorities of HHS and CMS to improve health outcomes, quality, safety, efficiency, and experience of care for patients. As discussed in response to other comments, the claims-based ED and hospitalization measures are included in the HH QRP and reflect goals consistent with other CMS initiatives that focus on reducing avoidable hospital admissions, and we believe our proposed reweighting will encourage increased focus on accountability for areas of significant Medicare spending, such as hospitalizations.

Final Decision: For the reasons stated and after consideration of the comments received, we are finalizing the measure category reweighting as proposed. Specifically, we are finalizing our proposal 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 will each count for 35 percent and the HHCAHPS measure category will count for 30 percent of the 90 percent of the TPS that is based on performance on the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. We refer readers to Table 50 in section X. Regulatory Impact Analysis of this final rule with comment period, which reflects the weighting that will apply beginning in CY 2019 based on all of our finalized proposals, including the finalized reweighting and our finalized changes to the applicable measure set. We are also finalizing our proposed amendments to § 484.320 without change. Specifically, we are amending § 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 40 (which is identical to Table 53 of the proposed rule) is a sample calculation to show how this finalized policy, in connection with the finalized changes to the measure set, will affect the scoring under the model, as set forth in prior rulemaking (80 FR 68679 through 68686), when all three measure categories are reported.

TABLE 40: SAMPLE HHVBP TOTAL PERFORMANCE SCORE CALCULATION UNDER CURRENT AND FINALIZED NEW WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES

	Points for Current Measures	Current Weight	Points for Finalized Measures	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	**Finalized**
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. Rescoring the Maximum Amount of Improvement Points

In the CY 2016 HH PPS final rule, we finalized that an HHA could earn 0 to 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 will 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 proposed 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 the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which we proposed the maximum improvement points would be 13.5 (83 FR 32435). The maximum score of 13.5 represents 90 percent of the maximum 15 points that could be earned for each of the two composite measures. The HHVBP Model focuses on having all HHAs provide high quality care and we stated in the proposed rule that we believe that awarding more points for achievement than for improvement beginning with PY4 of the model would support this goal. We stated that 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. Furthermore, we stated that 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.

We also stated in the proposed rule that this proposal would be consistent with public comments from prior rulemaking, 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 noted in the proposed rule 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). We proposed that HHVBP would employ a similar scoring methodology where HHAs could earn a maximum of 9 improvement points.

We proposed 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. We stated that 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, or 13.5 points for the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures (an HHA with performance equal to or higher than the benchmark score could still receive the maximum of 10 points for achievement (or 15 points, for the composite measures));
- Greater than its baseline period score but below the benchmark (within the improvement range), the HHA could receive an improvement score of 0–9 based on the formula and as illustrated in the examples (except for the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which the maximum improvement score would be 13.5, as noted previously); [42] or,
- Equal to or lower than its baseline period score on the measure, the HHA could receive zero points for improvement.

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

We also presented 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 (83 FR 32426 through 32438). We invited 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. The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported rescoring in general and the proposed rescoring. A commenter suggested that HHVBP should reward agencies based on achievement only, and another commenter stated that the proposed rescoring did not go far enough and would still penalize high performing agencies.

Response: We appreciate the positive feedback on our proposed methodology. We believe that removing improvement scores from the Model could disadvantage smaller HHAs and those HHAs with limited resources. Although we proposed to reduce the maximum improvement points, we believe that the improvement points continue to play a necessary role in promoting the consistent improvement of HHAs within the Model states that are not performing equal to or above the state benchmark. We will monitor and evaluate the impact of reducing the maximum improvement points from 10 to 9 to determine if additional rescoring is necessary in future years through rulemaking.

Final Decision: For the reasons stated and after consideration of the comments received, we are finalizing the rescoring of the maximum amount of improvement points, as proposed. Specifically, we are finalizing the reduction of the maximum amount of improvement points, from 10 points to 9 points, for PY4 and subsequent performance years for all measures except for the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which the maximum improvement points will be 13.5.

2. Examples of Calculating Achievement and Improvement Scores

For illustrative purposes we present the following examples of how the changes to the performance scoring

[42] We note that in the proposed rule (83 FR 32436), we inadvertently stated that the HHA could receive a maximum improvement score of 15 for these composite measures. As explained elsewhere in the proposed rule (83 FR 32435), we proposed that the maximum improvement points for these composite measures would be 13.5.

methodology will 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). We note that the figures and examples presented in this final rule with comment period are the same figures and examples set forth in the proposed rule (83 FR 32436 through 32438). Figure 3 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.

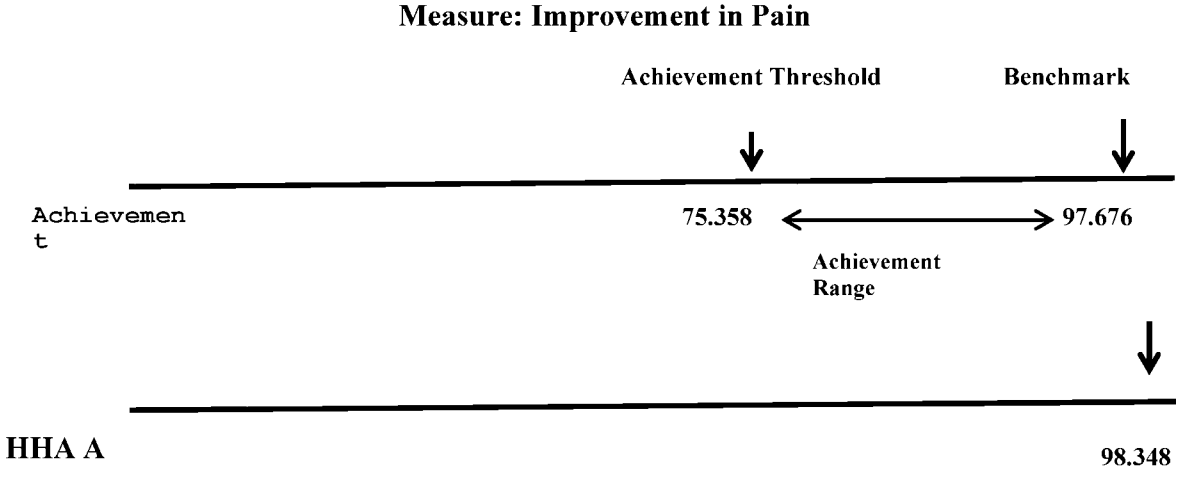
Figure 3 also shows the scoring for HHA 'B.' HHA B's performance on this measure went from 52.168 (which was below the achievement threshold) in the baseline period to 76.765 (which is above the achievement threshold) in the performance period. Applying the achievement scale, HHA B will earn 1.067 points for achievement, calculated as follows: 9 * (76.765 − 75.358)/(97.676 − 75.358) + 0.5 = 1.067.[43] 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 will earn 4.364 points, calculated as follows: 9 * (76.765 − 52.168)/(97.676 − 52.168) − 0.5 = 4.364.[44] Because the higher of the achievement and improvement scores is used, HHA B will receive 4.364 points for this measure.

In Figure 4, 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 will receive zero points based on achievement. It will also receive zero points for improvement, because its performance during the performance period was lower than its performance during the baseline period.

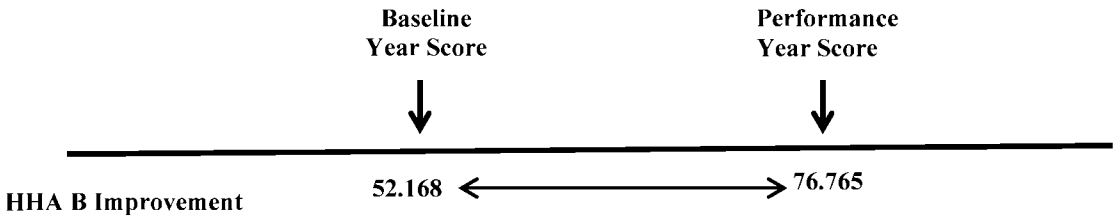
[43] Achievement points are calculated as 9 * (HHA Performance Year Score − Achievement Threshold)/(Benchmark − Achievement threshold) + 0.5.

[44] As finalized, the revised formula for calculating improvement points is 9 * (HHA Performance Year Score − HHA Baseline Period Score)/(HHA Benchmark − HHA Baseline Period Score) − 0.5. We note that in the proposed rule (83 FR 32436), we inadvertently included the achievement threshold of 75.358 in the denominator of this equation rather than HHA B's baseline period score of 52.168, however, the calculated figures were correct.

FIGURE 3: EXAMPLE OF AN HHA EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING

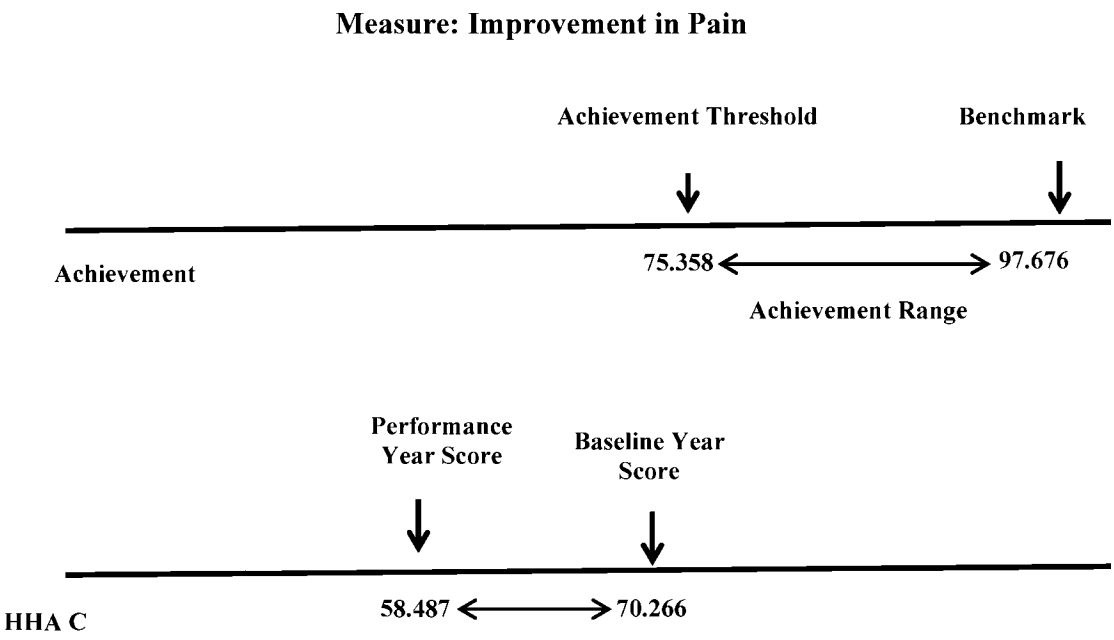


HHA A Score: 10 maximum points for achievement



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

FIGURE 4: EXAMPLE OF AN HHA NOT EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING



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

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 stated in the proposed rule that we were 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 a 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 did not make a specific proposal in the CY 2019 HH PPS proposed rule, we solicited 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 noted 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. We stated that 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.

Comment: Several commenters expressed support for publicly reporting information from the Annual Total Performance Score and Payment Adjustment Reports as they believe it would better inform consumers and allow for more meaningful and objective comparisons among HHAs. A commenter suggested that CMS consider providing an actual percentile ranking for HHAs along with their TPS as this would provide more information to both HHAs and the public. Another commenter expressed interest in publicly reporting all information

relevant to the HHVBP Model such as the agency's performance on the individual measures, percentile rankings, and comparison by state and cohort. Several commenters expressed concern with publicly displaying HHAs' TPSs citing that the methodology is still evolving and this data would only represent a subset of home health providers participating in the Model. Commenters also pointed out that consumers already have access to the quality measures in the Model as the measures themselves are already publicly reported on Home Health Compare. A commenter recommended not publicly reporting the data until all states are participating in the Model because it believes publicly reporting data for one state but not the other can be confusing for consumers.

Response: We appreciate the comments on when and what to publicly report and will work to ensure any data that are publicly reported from the Annual Total Performance Score and Payment Adjustment Reports are thoroughly explained and gives patients, physicians, discharge planners, and other referral sources the knowledge they need to choose higher-performing HHAs. We intend, if appropriate, to propose what would be publicly reported and when in future rulemaking.

We received a number of out-of-scope comments on policy areas not addressed by our proposals, including requests for us to expand the HHVBP Model to a national program. We thank the commenters for their input and would address any future changes through rulemaking.

V. Home Health Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of the (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, the comments we received on those proposals and our responses to those comments, and policies we are finalizing for future years of the HH QRP after consideration of the comments. We intend to use this approach in our rulemakings for the HH QRP 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 use 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).

Comment: A few commenters provided input on several topics associated with measure adoption the HH QRP. Specifically, a commenter expressed that the pace of removing historical OASIS items has not matched the addition of new measures that meet IMPACT Act requirements. The same commenter also requested that as IMPACT Act measures are added, along with the burden of data collection, the applicability of the measures to different settings be taken into consideration. Another commenter recommended that measures account for patients who do not have a goal of improvement and be tested to ensure their reliability and validity in the home setting.

Response: We appreciate the comments. The removal of historic OASIS items has been guided by our assessment regarding their continued need, as well as our goal to streamline reporting requirements for HHAs and minimize the reporting burden as much as possible. Adopting measures that meet IMPACT Act requirements at the same pace that we remove other OASIS items would not further our goal to reduce burden.

We interpret the comment regarding the applicability of quality measures across the post-acute care settings to mean that we should take into consideration the appropriateness of measures that would be used in both institutional and home-based settings. While we believe there can be overlap in patient populations across the four post-acute care (PAC) providers for which we are required to adopt measures that meet requirements under section 1899B of the Act, we recognize that each PAC provider setting also has unique attributes, and we take these differences into consideration during our measure development and maintenance work.

With regard to the comment that we should consider the adoption of measures that take into account patients who may not have goals for improvement, we agree that not all patients may have goals associated with improvement and we are interested in the utilization of such measures that address this population in the HH QRP and in post-acute care in general. Further, we agree that such measures should be tested to ensure their reliability and validity in the home setting.

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.[45] 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.[46] 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. 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,[47] 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 will 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 will be most useful to the public.

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

Comment: Several comments supported continued investigation of ways that social risk factors can be applied to quality measures. These commenters also provided recommendations for possible social risk factors, including family caregiver presence and degree of involvement, the Area Deprivation Index, patient preference, needs of specialty populations and disproportionate percentage of Medicaid patients. A commenter recommended collaboration with Accountable Health Communities to measure and eventually mitigate issues for those with advanced illness. Another commenter noted that there are statistical methods that can adjust for socioeconomic status (SES) factors that are independent of quality of care and will not adjust away actual quality disparities. The commenter also suggested that we explore the influence of neighborhood factors that could be available from other data sources and linked to a patient using address information. MedPAC noted that CMS should account for social risk factors in quality programs by adjusting payment through peer grouping and targeting technical assistance to low-performing providers. A few commenters expressed support for rewarding better outcomes for beneficiaries with social risk factors. Commenters also expressed support for the reporting of stratified outcomes measures to providers.

Response: We thank the commenters for their comments and will take them into account as we further consider how to appropriately account for social risk factors in the HH QRP. We also refer the reader to the CY 2018 HH PPS final rule (82 FR 51713 through 51714), where we discussed many of the issues raised by these commenters.

C. Removal Factors for Previously Adopted HH QRP Measures

As a part of our Meaningful Measures Initiative, discussed in section I.D.1 of this final rule with comment period and in the CY 2019 HH PPS proposed rule (83 FR 32440 through 32441), we strive to put patients first, ensuring that they,

[45] See 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.

[46] 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.*

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

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 stated that we began reviewing the HH QRP measure set in accordance with the Meaningful Measures Initiative discussed in section I.D.1 of this final rule with comment period and in the CY 2019 HH PPS proposed rule (83 FR 32440 through 32441), and that 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 stated our belief that 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 stated that we had 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 noted that we had adopted a process for retaining, removing, and replacing previously adopted HH QRP measures. To be consistent with other established quality reporting programs, in the CY 2019 HH PPS proposed rule (83 FR 32440 through 32441), we proposed 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.

As we stated in the proposed rule, we believe these measure removal factors are substantively consistent with the criteria we previously adopted (but noted that we would be changing the terminology to call them ''factors'') and appropriate for use in the HH QRP. However, we stated that even if one or more of the measure removal factors applies, we might nonetheless choose to retain the measure for certain specified reasons. We stated that 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 noted that consistent with other quality reporting programs, we would 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 is causing concern for patient safety. Specifically, in the case of a HH QRP measure for which there is a reason to believe that the continued collection raised possible safety concerns, we stated that 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 stated that we would immediately notify HHAs and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings. We stated that 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 the CY 2019 HH PPS proposed rule (83 FR 32440 through 32441), we also proposed 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 the CY 2019 HH PPS proposed rule (83 FR 32344 through 32345, 32440 through 32441), 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 stated our belief that 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 also stated that we had 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, we stated that 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 stated our belief that 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 proposed that we would remove measures based on 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. We stated that 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 invited 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 also invited 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.

Comment: The majority of commenters supported the proposal to replace the current six criteria with the seven factors to create alignment with the other PAC settings. The majority of commenters also supported the addition of Factor 8. A few commenters strongly agreed that quality measure reporting is important, but noted that the costs of such reporting can at times exceed the value of the data.

Response: We thank these commenters for their support.

Comment: With respect to Factor 1, a commenter noted support but added that automatically removing topped out measures creates a risk of decreased adherence to those evidence-based measures. The commenter urged CMS to consider continuing to require data reporting on topped out measures for a certain period time to ensure that performance in certain areas of quality, such as depression and fall risk, does not decline. Another commenter recommended that CMS periodically reassess any measure removed under Factor 1 to determine if there has been a decline in performance since the time the measure was removed.

Response: We thank these commenter for their comments. We do not automatically remove topped out measures, and wish to reiterate that a topped out measure may be retained for specified reasons. We may retain a particular measure with high performance rates if the measure addresses a topic related to quality that is so significant that we do not want to risk a decline in quality that could result if we removed the measure, or if the measure addresses a topic that is statutorily required. In response to the commenters' concern about a decline in performance that could result if a measure is removed based on Factor 1, we currently monitor for gaps in the quality of care related to the topic which a removed measure addressed, and we would consider whether to reintroduce a measure on that topic if we discovered such a gap.

Comment: A commenter raised concerns about the rationale of removing relatively precise measures in favor of more broadly applicable ones, noting that broader applicability and reportability do not necessarily equate to better measures. This commenter recommended choosing measures on the basis of their clinical significance.

Response: We agree that replacing a narrow measure with one that is more broadly applicable would be problematic if the more broadly applicable measure did not correlate with high quality outcomes. We intend to only consider measure replacement under Factor 4 if the more broadly applicable measure is at least comparable in terms of how well it addresses quality outcomes as the measure it is replacing.

Comment: A commenter recommended that CMS change the wording of Factor 2 from ''Performance or improvement on a measure does not result in better patient outcomes'' to ''Performance or improvement on a measure is not associated with better patient outcomes'' so that the factor does not suggest that causality.

Response: We thank the commenter for its suggestion. We believe that there is a direct correlation between performance improvement on a measure and better patient outcomes. We would apply Factor 2 when our data analysis indicates that, despite performance improvement on a measure, there is no improvement in patient outcomes.

Comment: A few commenters expressed specific support for the adoption of the new measure removal Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program for the HH QRP. Other commenters noted that Factor 8 was consistent with CMS' Patients over Paperwork initiative.

Response: We appreciate the support of the addition of this measure removal factor for the HH QRP.

Comment: Another commenter recommended that Factor 8 be applied on a case-by-case basis, and another commenter recommended that CMS consider a variety of costs in Factor 8's application, including costs to providers and clinicians participating in multiple quality programs. Another commenter opposed the adoption of Factor 8, citing the difficulty of measuring benefits to patients when comparing costs and benefits.

Response: We note that there are challenges in weighing the overall benefits for patients against the associated costs. We also recognize that various stakeholders may have different perspectives on such benefits and costs. In light of these challenges, we intend to evaluate each measure on a case-by-case basis, taking into account the input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, data vendors, and other stakeholders with insight into the benefits and costs (financial and otherwise) of maintaining the specific measure in the HH QRP. Because for each measure the relative benefit to each stakeholder may vary, we believe that the benefits to be evaluated for each measure are specific to the measure and the original rationale for including the measure in the program. Therefore, when evaluating whether a measure should be removed under Factor 8, we intend to assess and take into consideration issues including the holistic balance of the costs, benefits, data, input from stakeholders, and our policy objectives.

Final Decision: After consideration of the public comments, we are finalizing our proposal to replace the six criteria used when considering a quality measure for removal with the seven measure removal factors currently adopted in other CMS programs, including LTCH QRP, IRF QRP, and SNF QRP. We are also finalizing our proposal to add to the HH QRP 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 30 [48] measures for the CY 2020 program year, as outlined in Table 41.

[48] In the CY 2019 HH PPS proposed rule (83 FR 32441) we incorrectly stated that there are 31 measures for the CY 2020 program year. The current

TABLE 41: MEASURES CURRENTLY ADOPTED FOR THE CY 2020 HH QRP

Short Name	Measure Name & Data Source
	OASIS-based
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Bathing	Improvement in Bathing (NQF #0174).
Bed Transferring	Improvement in Bed Transferring (NQF # 0175).
Depression Assessment	Depression Assessment Conducted.
Diabetic Foot Care	Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care (#0519).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Dyspnea	Improvement in Dyspnea.
Falls Risk	Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537).
Influenza	Influenza Immunization Received for Current Flu Season (NQF #0522).
Oral Medications	Improvement in Management of Oral Medications (NQF #0176).
Pain	Improvement in Pain Interfering with Activity (NQF #0177).
PPV	Pneumococcal Polysaccharide Vaccine Ever Received.
Pressure Ulcer/Injury	Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), removed as of January 1, 2019. Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure, effective January 1, 2019.
Surgical Wounds	Improvement in Status of Surgical Wounds (NQF #0178).
Timely Care	Timely Initiation Of Care (NQF #0526).
	Claims-based
ACH	Acute Care Hospitalization During the First 60 Days of HH (NQF #0171).
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP).
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173).
ED Use without Readmission	Emergency Department Use without Hospital Readmission During the First 30 Days of HH (NQF #2505).
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
Rehospitalization	Rehospitalization During the First 30 Days of HH (NQF #2380).
	HHCAHPS-based
Communication	How well did the home health team communicate with patients.
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. Removal of HH QRP Measures Beginning With the CY 2021 HH QRP

To address the Meaningful Measures Initiative discussed in the CY 2019 HH PPS proposed rule in the CY 2019 HH PPS proposed rule (83 FR 32442 through 32446) we proposed to remove seven measures from the HH QRP beginning with the CY 2021 HH QRP. We received a few general comments on the proposed removal of these measures.

Comment: Most commenters, including MedPAC, supported CMS' proposal to remove all seven measures.

Pressure Ulcer/Injury measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), will be replaced by a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, effective January 1, 2019.

Response: We thank the commenters for their support of all of our measure removal proposals.

Comment: While supportive of the proposals to remove the seven measures, two commenters urged CMS to consider not waiting until the CY 2021 HH QRP program year to remove them from the HH QRP. These commenters also noted that if CMS continues to collect data through the OASIS on process measures that have been removed from the HH QRP but still represent best practices, HHAs can continue to monitor their performance on those measures without being concerned about having to report them for the HH QRP.

Response: We thank the commenters for their support of the measure removal proposals and note that we are finalizing all of them. We are unable to update the OASIS submission system before January 1, 2020, which is midway through the data collection period that we use for the HH QRP (see 81 FR 76783). As a result, with respect to the five HH QRP measures that are calculated using OASIS data (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, and Improvement in the Status of Surgical Wounds), HHAs will be required to continue submitting data on those measures with respect to home health quality episodes that begin during the first two quarters of the CY 2021 program year (that is, for home health episodes that occur during the 3rd and 4th quarters of CY 2019). With respect to the two HH QRP measures we are removing that are calculated using claims data (Emergency Department Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) and Rehospitalization During the First 30 Days of HH (NQF #2380)), we will stop collecting claims data for the calculation of these two measures beginning with home health quality episodes that begin on or after July 1, 2019.

We remind HHAs that the removal of a measure from the HH QRP does not prevent HHAs from continuing to incorporate the quality process addressed by that measure in their own quality monitoring activities, and we would encourage HHAs to do so.

1. Removal of the Depression Assessment Conducted Measure

In the CY 2019 HH PPS proposed rule (83 FR 32442), we proposed to remove the Depression Assessment Conducted Measure from the HH QRP beginning with the CY 2021 HH QRP under 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,[49] and mortality.[50] 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.[51] 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.[52]

We stated in the CY 2019 HH PPS proposed rule that 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) [53] 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 proposed to remove the Depression Assessment Conducted Measure from the HH QRP beginning with the CY 2021 HH QRP under our Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

We stated in the proposed rule that if we finalized this proposal, 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.[54] We also stated that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: A commenter expressed general support for the removal of the Depression Assessment Conducted measure but encouraged CMS to consider how else mood could be assessed in the HH setting, noting that behavioral health is a key aspect of patient outcomes.

Response: We agree that behavioral health is a key aspect of patient outcomes and wish to clarify that the

[49] Beekman AT, Deeg DJ, Braam AW, et al.: Consequences of major and minor depression in later life: a study of disability, well-being and service utilization. Psychological Medicine 27:1397–1409, 1997.

[50] 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.

[51] 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*).

[52] 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).

[53] 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.

[54] 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).

removal of this measure would not eliminate mood assessment in the HH setting. HHAs will continue to report OASIS Item M1730, Depression Screening at the time point of SOC/ROC as part of their reporting of data for other OASIS-based outcome measures currently used in the HH QRP. In addition, we continue to develop and test standardized patient assessment data elements that, if adopted, would assess the cognitive function and mental status of patients in PAC settings.[55]

Final Decision: After considering public comment, we are finalizing our proposal to remove the Depression Assessment Conducted Measure from the HH QRP. HHAs will no longer be required to submit OASIS Item M1730, Depression Screening at SOC/ROC for the purposes of this measure beginning with Home Health quality episodes of care that begin on or after January 1, 2020. HHAs will, 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. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

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

In the CY 2019 HH PPS proposed rule (83 FR 32442 through 32443), we proposed to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure beginning with the CY 2010 HH QRP. This process measure reports the percentage of HH quality episodes in which diabetic foot care and patient/caregiver education were included in the physician-ordered plan of care and implemented (at the time of or at any time since the most recent SOC/ROC assessment). The measure numerator is calculated using OASIS Item M2401 row a, Intervention Synopsis: Diabetic foot care.[56]

We stated in the CY 2019 HH PPS proposed rule (83 FR 32443) that 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 proposed 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.

We stated in the proposed rule that if we finalized this proposal, 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. We also stated that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: Another commenter expressed general support for the removal of the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure, but encouraged CMS to provide clear updates to providers about how they should complete items until the next OASIS version is released.

Response: We thank the commenter for its support. We intend to provide further guidance and training on how to properly complete the OASIS.

Final Decision: After considering public comment, we are finalizing our proposal to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP. HHAs will 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. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

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

In the CY 2019 HH PPS proposed rule (83 FR 32443), we proposed 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 [57]

[55] Development and Maintenance of Standardized Cross Setting Patient Assessment Data for Post-Acute Care: Summary Report of Findings from Alpha 2 Pilot Testing. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Alpha-2-SPADE-Pilot-Summary-Document.pdf.*

[56] 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*).

[57] At the time, this measure was adopted as ''Falls risk assessment for patients 65 and older.'' The

Continued

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.[58]

We stated in the proposed rule (83 FR 32443) that 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 proposed 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.

We stated in the proposed rule that if we finalized this proposal, 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. We also stated that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: Another commenter expressed general support for the removal of the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure, but encouraged CMS to consider whether it is appropriate to adopt measures when performance is high initially.

Response: We thank the commenter for its support. We agree that it is important to evaluate whether the measure rates on a measure being considered for adoption are already high because that analysis bears on the question of whether the measure is needed to address a gap in quality. However, we wish to note that there may be quality measures that address an important Meaningful Measure Area in which most providers will likely perform well. Examples of such measures include those that take into account ''never events,'' such as falls with major injury, or topics such as potentially preventable readmissions. In these instances, such performance information remains useful to consumers and providers even if the measure performance is high initially.

Final Decision: After considering public comment, we are finalizing our proposal to remove the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP. HHAs will 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. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

4. Removal of the Pneumococcal Polysaccharide Vaccine Ever Received Measure

In the CY 2019 HH PPS proposed rule (83 FR 32443 through 32444), we proposed to remove the Pneumococcal Polysaccharide Vaccine (PPV) 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.[59]

At the time that this measure was adopted in the HH QRP, the Advisory Committee on Immunization Practices (ACIP),[60] which sets current clinical guidelines, recommended use of a single dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23) among all adults aged 65 years and older and those adults aged 19 to 64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection.[61]

Since this measure was added to the HH QRP, the ACIP has updated its pneumococcal vaccination recommendations.[62] 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).

name of this measure was updated in the CY 2018 HH PPS final rule (82 FR 51717).

[58] 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*).

[59] 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*).

[60] 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*).

[61] Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 1997;46:1–24.

[62] 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.

We stated in the proposed rule that 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 proposed 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.

We stated in the proposed rule (83 FR 32444) that if we finalized this proposal, 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. We also stated that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: A few commenters supported the measure removal because it does not reflect current Advisory Committee on Immunization Practices (ACIP) guidelines.

Response: We thank the commenters for their support.

Comment: A few commenters did not support the removal of the PPV measure from the HH QRP, citing concerns with patient care consequences that could occur as a result of its removal. Some of these commenters noted that HHAs play a valuable role in providing immunizations to home-bound patients who experience barriers to vaccination access. Another commenter recommended retaining the current PPV measure until it is updated to reflect the most recent ACIP guidelines for both pneumococcal vaccinations, adding that its removal may be confusing to HHAs and may also lead to reductions in pneumococcal immunization rates. This commenter stated that the measure is aligned with Meaningful Measures objectives on addressing high-impact and patient-centered measure areas, and that retaining the measure would not be burdensome to HHAs, given their ability to establish standing orders to support immunization processes.

Response: While we understand that assessing and appropriately vaccinating patients are important components of the care process, we also prioritize ensuring that quality measures can used by practitioners to inform their clinical decision and care planning activities. The updated ACIP pneumococcal vaccination recommendations require information that is often not available to HHAs, including whether the patient has previously been vaccinated, the type of pneumococcal vaccine received by the patient, and the sequencing of vaccine administration. In addition, the physician who is responsible for the home health plan of care may not be the patient's primary care practitioner or other health care professional responsible for providing care and services to the patient before and after discharge from the HHA, and therefore may not be best able to provide the HHA with such information. Also, even if the pneumococcal vaccination status of the patient is available, OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received, both of which are used in the calculation of this measure, do not correspond to the updated ACIP pneumococcal vaccination recommendations and therefore may not accurately measure HHA performance in this area. However, we understand and value the role pneumococcal vaccines play in preventing pneumococcal disease [63] and we encourage that, whenever possible and as appropriate, HHAs provide pneumococcal vaccinations to their patients.

Comment: A few commenters recommended that CMS consider using an alternative pneumococcal measure, Pneumonia Vaccination Status for Older Adults (NQF #0043).

Response: The specifications for the Pneumococcal Vaccination Status for Older Adults measure also do not fully reflect the current ACIP guidelines. Therefore, this measure would not be an appropriate measure to consider for adoption into the HH QRP.

Final Decision: After considering public comment, we are finalizing our proposal to remove the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP. HHAs will 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. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

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

In the CY 2019 HH PPS proposed rule (83 FR 32444 through 32445), we proposed 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.[64] 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.[65] 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.[66]

We stated in the proposed rule (83 FR 32444) that the Improvement in the

[63] CDC: Pneumococcal Disease. Retrieved from: *http://www.cdc.gov/pneumococcal/about/prevention.html.*

[64] 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*).

[65] 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).

[66] 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*).

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) [67] 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 proposed 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.

We stated in the proposed rule that if we finalized this proposal, 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,[68] and also at the time point of Discharge for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance [69] that is used by HH surveyors during the survey process. We also stated that if we finalized this proposal, data on this measure would be publicly reported on HH Compare until January 2021.

We invited public comment on this proposal.

Comment: A commenter supported removal of the Improvement in the Status of Surgical Wounds Measure, while encouraging CMS to monitor other skin integrity measures to ensure that the full range of patient skin integrity issues is captured. Another commenter opposed the removal of this measure, but did not clarify the reason.

Response: We thank the commenters for their feedback. We will continue to closely monitor the performance data of other skin integrity measures.

Final Decision: After considering public comment, we are finalizing our proposal to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP. HHAs will 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 January 1, 2020. However, HHAs will 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 and also 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. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

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

In the CY 2019 HH PPS proposed rule (83 FR 32445), we proposed 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 72297 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).

We stated in the proposed rule (83 FR 32444) that 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 5 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.

We stated in the proposed rule (83 FR 32445) that 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)

[67] 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.

[68] 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).

[69] 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*).

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 #0173) Measure will not result in a loss of the ability to measure the topic of ED utilization for HH patients.

For these reasons, we proposed 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. We stated in the proposed rule that if we finalized this proposal, data for this measure would be reported on HH Compare until January 2020.

We invited public comment on this proposal.

Comment: A commenter supported the removal of this measure and expressed appreciation that CMS identified measures for removal in favor of more widely applicable ones.

Response: We thank the commenter for its support.

Final Decision: After considering public comment, we are finalizing our proposal as proposed 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. Data for this measure will be publicly reported until such data are no longer available for public reporting of this measure on HH Compare.

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

In the CY 2019 HH PPS proposed rule (83 FR 32445 through 32446), we proposed 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.[70] The Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) Measure also addresses the topic of acute care hospital utilization during a HH stay. This measure reports the percentage of HH stays in which Medicare FFS patients were admitted to an acute care hospital during the 60 days following the start of the HH stay. The Acute Care Hospitalization during the First 60 Days of HH (NQF #0171) Measure includes Medicare FFS patients irrespective of whether or not they had an acute inpatient hospitalization in the 5 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.

We stated in the proposed rule (83 FR 32446) that 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 proposed 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. We stated in the proposed rule that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until January 2020.

We invited public comment on this proposal.

Comment: A commenter supported the removal of this measure and expressed appreciation that CMS identified measures for removal in favor of more widely applicable ones.

Response: We thank the commenter for its support.

Final Decision: After considering public comment, we are finalizing our proposal as proposed 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. Data for this measure will be publicly reported on HH Compare until January 2020.

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 will satisfy

[70] 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.

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 intended to propose to adopt them for the CY 2021 HH QRP, with data collection beginning on or about January 1, 2020.

We stated in the proposed rule that 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 proposed 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.*

Comment: A commenter supported the continued development of measures to satisfy the IMPACT Act domain of transfer of health information and care preferences, noting its belief that these measures will improve continuity of care and care transitions. Another commenter did not express support or opposition, but encouraged CMS to consider data collection burden across settings prior to adopting cross-setting measures that satisfy the requirements of the IMPACT Act.

Response: We thank the commenters for their feedback.

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. In the CY 2019 HH PPS proposed rule (83 FR 32446), we proposed 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 invited 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.

Comment: A commenter supported all proposed changes to the HH QRP, including updated regulations clarifying OASIS data collection requirements. Another commenter noted that the clarification confirms its understanding of the regulations.

Response: We thank the commenters for their support.

Final Decision: After considering public comment, we are finalizing our proposal as proposed 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. Policies Regarding Public Display for the HH QRP

Section 1899B(g) of the Act requires that data and information regarding 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 will publicly display the Medicare Spending Per Beneficiary (MSPB)–PAC HH QRP beginning in CY 2019 based on 1 year of claims data on discharges from CY 2017.

In the CY 2019 HH PPS proposed rule (83 FR 32446), we proposed 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. We also stated that increasing the measure calculation and public display periods from 1 to 2 years of data would increase 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 1, 2014–July 31, 2015 Medicare FFS claims data) to 94.9 percent (based on August 1, 2014–July 31, 2016 Medicare FFS claims data). We further stated that increasing the measure public display periods to 2 years would align with the public display periods of these measures in the IRF QRP, LTCH QRP, and SNF QRP.

We invited 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.

Comment: Most commenters supported changing the reporting period for the MSPB–PAC HH QRP measure from 1 year to 2 years.

Response: We thank the commenters for their support.

Comment: Several commenters opposed changing the reporting period for the MSPB measure from 1 to 2 years. A commenter opposed the 2-year reporting period for the MSPB measure, noting that measurement may be ''smoothed'' and current performance diluted by relying on 2 years of data instead of 1 year. This commenter recommended using two years of historical data only for low-volume home health agencies that would otherwise report insufficient data, and retaining the one-year reporting period for larger home health agencies. Two other commenters opposed the change to a 2-year reporting period, noting that measures should reflect recent data and performance. Another commenter questioned the rationale for using a 2-year measure period, noting that while this may increase the denominator, measure accuracy might be compromised by any changes that occurred during the measurement period.

Response: We appreciate the commenters' concern about the impact of aggregating data across 2 years on the ability to demonstrate improvement in a 1-year period. However, we believe that the benefit of increasing the number of HHAs in public reporting outweighs the expressed concern associated with increasing the measurement period to 2 years because it enables us to provide more information to consumers who may have a limited number of HHAs in their area. Further, improvements in performance in a measure over a 1-year period will also be included in the 2 years of data, so providers' improvement efforts can still be reflected in their 2-year measure scores.

We disagree with the recommendation to use 2 years of data for low-volume HHAs but 1 year of data for larger HHAs because HHA performance may no longer be comparable using different time periods for data collection. Finally, there is no

evidence to support that increasing the number of years of data used for the calculation of measure scores of all HHAs from 1 year to 2 years might compromise the accuracy of a measure.

Final Decision: After consideration of public comments we received, we are finalizing our proposal as proposed to increase the number of years of data used to calculate the MSPB–PAC HH QRP measure for purposes of display from 1 year to 2 years.

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

In the CY 2019 HH PPS proposed rule (83 FR 32446), we did not propose 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 professional services, including nursing services, patient training and education, and monitoring services associated with administering infusion drugs by an item of durable medical equipment (DME) in a patient's home. This final rule with comment period will establish health and safety standards for home infusion therapy and provide consistency in coverage for home infusion therapy services. In addition, this final rule with comment period establishes regulations for the approval and oversight of accrediting organizations that provide accreditation to home infusion therapy suppliers. This rule also provides information on the implementation of the home infusion therapy services temporary transitional payments for CYs 2019 and 2020, as mandated by section 50401 of the BBA of 2018, and finalizes a regulatory definition of ''Infusion Drug Administration Calendar Day.''

A. General Background

1. Overview

Infusion drugs and administration services can be furnished in multiple health care settings, including inpatient hospitals, skilled nursing facilities (SNFs), hospital outpatient departments (HOPDs), physicians' 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 physicians' 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.[71] The MACs update Self-Administered Drug (SAD) exclusion lists on a quarterly basis.[72]

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 assess the infusion site and provide dressing changes. 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.

[71] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

[72] *www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D.*

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.[73] 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 how to operate the equipment in order to administer the infusion safely and effectively.[74] 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 section 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, 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 furnished. 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 (MA) 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)(1) of the Act requires the Secretary to implement a payment system under which, beginning January 1, 2021, 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). 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 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 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the HH PPS beginning on January 1, 2021.

B. 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,

[73] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html.*

[74] 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.''

as added by section 5012 of the Cures Act, sets forth four elements for home infusion therapy in the following areas: (1) Requiring that the patient be under the care of a physician, nurse practitioner, or physician assistant; (2) requiring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient specific needs; (3) providing patients with education and training on the effective use of medications and equipment in the home (not otherwise paid for as durable medical equipment); and (4) providing monitoring and remote monitoring services associated with administering infusion drugs in a patient's home.

The Journal of Infusion Nursing standards of practice specifically address patient education, and state that it is the clinician's role to educate the patient, caregiver, and/or surrogate about the prescribed infusion therapy and plan of care including, but not limited to, purpose and expected outcome(s) and/or goals of treatment, infusion therapy administration; infusion device-related care; potential complications; or adverse effects associated with treatment. (Infusion Therapy Standards of Practice, 2015).[75]

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 will be required to meet or exceed. We proposed 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 21st 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 final rule with comment period. 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).[76]
- 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).[77]
- 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).[78]
- 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 will 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 concluded that it was appropriate 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 solicited public comment on this approach and invited comments related to the home infusion therapy standards.

2. Home Infusion Therapy Supplier Requirements (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. Final 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 (§ 486.500)

We proposed 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 proposed 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, section 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.

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

[76] 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.

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

[78] 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.*

b. Definitions (§ 486.505)

At proposed § 486.505, we define certain terms that would be used in the home infusion therapy requirements. We 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 health and safety requirements set forth in this final rule with comment period. In accordance with the Act, we proposed the following definitions:

- ''Applicable provider'' would mean a physician, a nurse practitioner, and a physician assistant.
- ''Home'' would mean a place of residence used as the home of an individual, including an institution that is used as a home. However, an institution that is used as a home may not be a hospital, CAH, or SNF as defined in sections 1861(e), 1861(mm)(1), 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 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 (§ 486.520)

Proposed § 486.520(a), requires that all patients must be under the care of an ''applicable provider'' as defined at § 486.505. Proposed § 486.520(b) requires 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 proposed, 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 did not propose to establish a specific timeframe 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.

(2) Required Services (§ 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 proposed to require the provision of professional services, including nursing services, furnished in accordance with the plan of care. We proposed 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 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 proposed 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 requirement is consistent with section 1861(iii)(2)(B) of the Act. In addition, the 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 proposed 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) of the Act. Monitoring the patient receiving infusion therapy in their home is an important standard of practice that is an integral part of providing medical care to patients in their home.[79] 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 final rule with comment period.

Comment: We received a few comments related to whether we should include specific timeframes for review of the plan of care. Most comments suggested that CMS should align the physician review of the plan of care with State laws where they exist, while another commenter suggested that we require the plan of care be reviewed

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

every 30 days. Most commenters also stated that they believed adding additional reviews could conflict with the State laws and would create undue burden on home infusion therapy suppliers.

Response: We agree with the commenters that establishing timeframe requirements for the physician review of the patient plan of care could create duplicative requirements and add burden to home infusion therapy suppliers. Therefore, we are not including specific timeframes for the review of the plan of care, and will defer to existing State laws and regulations.

Comment: We received several comments requesting that the proposed home infusion therapy health and safety standards include various requirements for pharmaceutical standards, such as drug preparation and dispensing procedures. Specifically, commenters recommended compliance with sterile compounding standards and those requirements enforced by the United States Pharmacopeia and Food and Drug Administration.

Response: We agree it is important that all health care providers and suppliers, including home infusion therapy suppliers, provide services to patients in a safe and professional manner, and in accordance with professional standards of practice. To address these concerns, we have amended the regulation text at § 486.525 Required services, by adding § 486.525(b) which requires that all home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations. This could include the applicable provisions in the Federal Food, Drug, and Cosmetic Act.

Comment: Several commenters suggested we expand the standard under proposed § 486.525, Required services, (a) Professional services. Specifically the comments requested that CMS define the term ''Professional services,'' and to specify the specific services that would be applicable. Commenters suggested that the term ''professional services'' could be defined to include things such as clinical care planning, care coordination, pharmacy services, and nursing services to name a few.

Response: We agree various professional services may be necessary in the care of beneficiaries utilizing the Medicare home infusion therapy benefit. As stated in the proposed rule preamble, we have mirrored the language in section 1861(iii)(2)(A) that requires the provision of professional services, including nursing services, furnished in accordance with the plan of care by the home infusion therapy supplier. By specifically enumerating a specific list of services we would risk inadvertently excluding services that may be necessary for the care of a specific patient as part of the required services under the home infusion therapy benefit. We acknowledge that pharmacy services are closely related to the home infusion therapy benefit; however, at this time pharmacy services associated with the preparation and dispensing of home infusion therapy drugs are covered under the Medicare Part B DME benefit and are not part of this specific home infusion therapy benefit.

Comment: We received several comments that did not appear to support the proposed regulation. However, the comments were non-specific in nature, and did not provide any detailed information to which we could provide an appropriate response.

Response: We believe the proposed home infusion therapy health and safety standards are important and essential because they provide the essential basis for establishing a robust accreditation program that will protect the health and safety of Medicare beneficiaries. Therefore, we are finalizing, with modifications, the home infusion therapy health and safety regulations. As previously described, we received several public comments regarding the home infusion therapy supplier health and safety regulations proposed at § 486.520, Plan of care and § 486.525, Required services. We are finalizing these regulations, and are adding the following requirement to § 486.525(b): All home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations.

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

1. Background

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

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021. In the proposed rule we stated that, there are six AOs that are currently providing accreditation to home infusion therapy suppliers, which 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. However, since the publication of the proposed rule, we have learned that there are two additional organizations that provide accreditation to home infusion therapy suppliers. These organizations are: (1) The Centers for Pharmacy Practice Accreditation (CPPA) and (2) URAC.

Five of these AOs are providing accreditation to home infusion therapy suppliers as part of the overall accreditation of home health agencies. The remaining AOs are pharmacy associations that have home infusion therapy accreditation programs that have not been approved by Medicare.

We proposed to publish a solicitation notice in the **Federal Register**, in which we would invite national AOs to submit an application to CMS for approval of their home infusion therapy accreditation program. We proposed 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. We further proposed that the application submitted by any AOs that respond to the solicitation notice would be required to meet all requirements set forth in proposed § 488.1010 and demonstrate that their substantive accreditation 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 proposed that, in order for the home infusion therapy suppliers accredited by the eight AOs that currently provide non-Medicare

approved home infusion therapy accreditation to continue receiving payment for the home infusion therapy services they provide, the eight existing home infusion therapy AOs must submit applications to CMS for Medicare approval of their home infusion therapy accreditation programs. We made this proposal because the accreditation currently being provided by these AOs has not been approved by CMS as required by section 1861(iii)(3)(D) of the Act. More specifically, five of these existing home infusion AOs are home health agency (HHA) AOs that have been approved by CMS to provide HHA accreditation to home health agencies. (HHAs). These HHA AOs started offering home infusion therapy accreditation as part of their HHA accreditation program, but none of these HHA AOs have received separate CMS approval for their home infusion therapy accreditation programs. The remaining 3 of the existing home infusion AOs are pharmacy association that offer a non-CMS approved home infusion therapy accreditation programs. As noted, all these existing home infusion AOs would have to submit an application to CMS for Medicare approval of their home infusion therapy accreditation program.

We proposed that the home infusion therapy accreditation program be a separate and distinct accreditation program from the HHA AO's home health accreditation program. This would mean that AOs currently surveying HHAs would have a separate accreditation program with separate survey processes and standards for the accreditation of home infusion therapy suppliers. In addition, we proposed to require that the applications submitted by all HHA and pharmacy AOs that currently provide accreditation to home infusion therapy suppliers meet the application requirements set forth in the proposed home infusion therapy AO approval and oversight regulations at § 488.1010 and meet or exceed the substantive home infusion therapy 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. In the proposed rule, we proposed to establish regulations for the approval and oversight of AOs that accredit home infusion therapy suppliers to 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 a home infusion therapy AOs application for CMS approval of its home infusion therapy accreditation program; and (3) the process for ongoing monitoring and oversight of the CMS-approved home infusion therapy AOs.

Comment: Another commenter stated that they were slightly confused by the use of this proposed rule as the appropriate forum for these significant changes.

Response: The issues presented in the proposed rule involve the payment for home infusion therapy services, the accreditation of suppliers that provide home infusion therapy services to patients in their homes and the approval and oversight of AOs that accredit home infusion therapy suppliers. Most of the AOs that currently provide accreditation for home infusion therapy suppliers are AOs that also accredit Home Health Agencies (HHAs). Further, the home infusion therapy accreditation offered by these HHA AOs is currently provided as part of these HHA AO's home health accreditation program. Therefore, we believe that the Home Health Prospective Payment System (HH PPS) rule is an appropriate venue in which to present these issues.

Comment: Several commenters stated general support for the establishment of an accreditation program for home infusion therapy suppliers. One of these commenters stated that home infusion therapy is a service that can be safely and effectively provided in the home setting, when provided by an accredited home infusion therapy supplier under a physician ordered plan of care. Several commenters stated general agreement with the AO approval and oversight provisions for home infusion therapy AOs but suggested that the health and safety standard regulations need to include additional provisions including pharmacy safety standards such the requirements for sterile compounding.

Response: We thank these commenters for their support of these proposals. We refer those commenter that suggested changes or additions to the home infusion therapy health and safety standards to section VI.B. of this for further discussion of these comments.

Comment: Several commenters stated that the accreditation section of the rule is silent as to when CMS plans on making accreditation a requirement of participation for reimbursement. These commenters requested that CMS provide clarity on the effective date of this requirement.

Response: Section 1834(u)(5)(B) of the Act requires that ''not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy''. The permanent home infusion therapy benefit provided under the 21st Century Cures Act is to begin on January 1, 2021. Therefore, all home infusion therapy suppliers must be accredited by no later than January 1, 2021 in order to receive Medicare payment for furnishing home infusion therapy services under the permanent home infusion therapy benefit. CMS plans to publish a solicitation notice in the **Federal Register** which will announce that we are seeking national AOs to accredit home infusion therapy suppliers and invite interested AOs to submit their applications to CMS. We plan to publish this solicitation notice very soon after publication of the final rule. We will be prepared to begin accepting applications from prospective AOs seeking CMS approval of a home infusion therapy accreditation program immediately after publication of the solicitation notice.

Comment: A commenter stated the opinion that ''the accreditation section of the rule is a statutory construct of the *21st Century Cures Act* as a requirement to become a qualified home infusion provider for the permanent home infusion services reimbursement.'' This commenter further stated the belief that ''the BBA does not require accreditation

to become a ''qualified'' home infusion therapy supplier and relies on a qualified home infusion provider to be a qualified home infusion provider and a pharmacy enrolled in the DME program and a pharmacy licensed in the state where applicable home infusion drugs are administered.''

Response: Section 50401 of the Bipartisan Budget Act (BBA) of 2018 does not specifically state accreditation is required to become a ''qualified'' home infusion therapy for payment of the temporary transitional home infusion therapy services. However for the permanent home infusion therapy services benefit, section 5012 of the 21st Century Cures Act added section 1861(iii)(3)(D)(i) to the Act that defines the term qualified home infusion therapy supplier as a ''pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that . . . . ''(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5) . . .''. Further, this statutory provision does not restrict ''qualified'' home infusion therapy suppliers to only pharmacies, but includes physicians, other providers of services and suppliers as possible types of home infusion therapy suppliers. However, section 50401(a) of the BBA of 2018, adding new section 1834(u)(7)(F) to the Act, requires that ''eligible home infusion suppliers'' for the temporary transitional payment be a pharmacy that provides external infusion pumps and external infusion pump supplies and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered. Accreditation for home infusion therapy services is not required for these pharmacies.

Comment: Another commenter requested that CMS clarify that all eligible accrediting organizations may submit an application to CMS for approval of a home infusion therapy accreditation program and not just the eight AOs listed in the proposed rule.

Response: Regarding comments on the eight AOs listed in the proposed rule, since publication of the proposed rule, we are made aware of two additional AOs for home infusion therapy suppliers. The eight existing AOs that provide home infusion therapy accreditation are: (1) The Joint Commission; (2)Accreditation Commission for Healthcare (ACHC); (3) Community Health Accreditation Partner (CHAP); (4) The Compliance Team (TCT); (5) National Association of Pharmacy Boards (NAPB); (6) Healthcare Quality Association on Accreditation (HQAA); (7) The Centers for Pharmacy Practice Accreditation (CPPA) and (8) URAC. In accordance with this final rule with comment period, any national AO that provides accreditation for home infusion therapy suppliers that meets the following requirements may submit an application to CMS requesting approval of their home infusion therapy accreditation program: (1) The AO must be national in scope; (2) the AO must have a home infusion therapy accreditation program that is separate and distinct from other accreditation programs they have; (3) the AO must have home infusion therapy accreditation standards that meets or exceeds the Medicare home infusion therapy health and safety standards to be codified at 42 CFR 486.500 to 486.525; and (4) the home infusion therapy AO must accredit only those home infusion therapy suppliers that provide all services required by the Medicare home infusion therapy health and safety and payment regulations.

Upon receipt of an application from a home infusion therapy AO seeking CMS approval of its home infusion therapy accreditation program, CMS will determine its completeness in accordance with the requirements set forth at § 488.1010(a). Once CMS has determined that an application is complete, CMS will then review it to determine whether the application meets the requirements set forth at § 488.1000 to § 488.1050 and whether the AOs accreditation standards meet or exceed the Medicare home infusion therapy health and safety accreditation requirements set forth at proposed § 486.500 to § 486.525. CMS will also assess whether the AO accredits only those home infusion therapy suppliers that provide all services required by the Medicare home infusion therapy health and safety and payment regulations. Pursuant to § 488.1010(d), CMS must complete the application review process and issue a decision within 210 days from the date that CMS determines that the application is complete. In accordance with § 488.1020(b), CMS will publish a final notice in the **Federal Register** announcing our decision to approve or deny a national accrediting organization application. The notice will specify the basis for the CMS decision.

Comment: Several commenters raised the question of whether the National Association of Boards of Pharmacy (NABP), which is one of the existing AOs that provide accreditation to home infusion therapy suppliers, would qualify as a CMS-approved home infusion therapy AO. These commenters stated that the NABP's survey process focuses only on pharmacy personnel education, practice of pharmacy including sterile compounding, patient counseling. These commenters further stated that the NABP addresses sterile compounding in their standards but does not address the plan of care process, the complexities of patient care monitoring or any professional staff components. These commenters further stated that they do not consider NABP a full-service home infusion accreditation organization and few third party payers in the private sector accept or recognize NABP alone as sufficient accreditation for home infusion. These commenters expressed the opinion that they want the industry to be held to a higher standard than what NABP accreditation provides.

Response: Any national AO that provides accreditation for home infusion therapy suppliers that meets the requirements set forth previously may submit an application to CMS requesting approval of a home infusion therapy accreditation program. In addition, we cannot predetermine whether the NABP would qualify as a CMS-approved home infusion therapy AO nor can we prohibit any organization from applying to be an AO.

Upon receipt of an application, CMS will determine its completeness in accordance with the requirements set forth at § 488.1010(a). Once CMS has determined that the application is complete, CMS will review it to determine whether the application meets the requirements set forth at § 488.1000 to § 488.1050 and whether the AOs accreditation standards meet or exceed the Medicare home infusion therapy health and safety accreditation requirements set forth at proposed § 486.500 to § 486.525. CMS will also assess whether the AO accredits only those home infusion therapy suppliers that provide all services required by the Medicare home infusion therapy health and safety and payment regulations. Pursuant to § 488.1010(d), CMS must complete the application review process and issue a decision within 210 days from the date CMS determines that the application is complete. In accordance with § 488.1020(b), CMS will publish a final notice in the **Federal Register** announcing our decision to approve or deny a national accrediting organization's application. The final notice will specify the basis for CMS' decision.

If the NABP were to submit an application to CMS for approval of a home infusion therapy accreditation program, we would be required to give the same consideration to that

application as we would give to any other application we receive. We would be required to review the application to determine whether the NABP's home infusion therapy accreditation program meets the previously stated requirements. We would also be required to review the application to determine whether the NABP's application meets the requirements set forth is § 488.1010.

It is interesting to point out that these same commenters strongly advocated for CMS to ''grandfather'' in the existing eight home infusion therapy AOs which were recognized in the proposed rule. These commenter's argued that for CMS to do otherwise would be to defeat Congress's clear direction and understanding that the accreditation program be functional by January 1, 2019, and would severely disrupt care for patients. As the NAPB is one of eight existing home infusion therapy accrediting organizations, it would seem that these commenters have on one hand, advocated that the NABP should ''grandfathered'' in as one of the eight existing home infusion therapy AOs, while also advocating for their exclusion as a home infusion therapy AO. These arguments conflict with one another.

Comment: Several commenters expressed the belief that the HHA AOs with an existing home infusion therapy accreditation program should not be required to have a Home Infusion therapy accreditation program that is separate and distinct from their HHA accreditation programs because this would place unnecessary burden on these HHA AOs. These commenters stated their disagreement with CMS' proposal that the home infusion therapy benefit should fall under an entirely separate accreditation process from an existing home care program. These commenters strongly recommended that CMS allow HHA AOs to satisfy the specified home infusion therapy accreditation requirement within their home care programs. In support of this request, a commenter stated the belief that including home infusion therapy services as part of the larger home health accreditation would promote a higher quality of care as well as a more coordinated and comprehensive approach to care delivery.

Several commenters suggested that the accreditation of home infusion therapy suppliers should be allowed as part of an HHA AO's overall accreditation and not require a totally separate accreditation as long as the accreditation organization meets all the CMS mandated home infusion therapy accreditation health and safety standards. Some of these commenters stated the belief that requiring AOs with existing home infusion therapy accreditation programs to submit a home infusion therapy accreditation program that is separate and distinct from their HHA accreditation program could affect the quality of care provided by these AOs and that such a policy would further fragment care delivery.

Another commenter suggested that CMS should permit a separate home infusion therapy accreditation module, approved by CMS, under an existing accreditation program because CMS has already done considerable review of the existing HHA accreditation programs and could benefit from working with the AOs to build on already existing standards to establish a standard set of standards that could be included for all accreditation organizations rather than developing a totally separate, free-standing home infusion therapy accreditation program.

Several commenters stated the belief that the requirement for a distinct, freestanding accreditation program for home infusion therapy suppliers would place additional burden on home care programs that currently provide home infusion therapy services as well as on accrediting organizations (AOs). One of these commenters expressed the concern that a totally separate accreditation program for HIT only would involve excessive cost and personnel time for agencies and CMS.

Response: We believe that it would not be permissible for CMS to allow the Home Health accrediting organizations to maintain the home infusion therapy accreditation program as part of their overall HHA accreditation program for several reasons. First, sections 1861(iii)(3)(D)(i) and 1834(u)(5) of the Act are clear that an accreditation is required for qualified home infusion therapy suppliers and that CMS must approve AOs accrediting these suppliers. Pursuant to section 1834(u)(5)(B) of the Act, CMS is mandated to designate AOs to accredit home infusion therapy suppliers by no later than January 1, 2021. This statutory mandate does not include language that would allow CMS to approve existing home infusion therapy accreditation programs that are co-mingled with other accreditation programs.

Second, given that our review of the commenter's HHA accreditation program standards occurred prior to the passage of the statutory mandate for CMS to designate AOs to accredit home infusion therapy suppliers our review of AOs' HHA programs focus on and assess the AO's HHA accreditation program standards and adherence to the CMS Home Health Conditions of Participation. Therefore, the reliance on our previous review of the HHA accreditation program standards and survey processes would not be sufficient to ensure that a HHA AO's home infusion therapy accreditation program would meet or exceed Medicare home infusion therapy health and safety standards that we are finalizing in this rule.

In addition, in this rule, we have proposed to establish new home infusion therapy health and safety accreditation standards that each home infusion therapy AO must incorporate into their home infusion therapy accreditation standards. When we reviewed the HHA AOs previous application, this review would have occurred prior to the publication of the CY 2019 Home Health proposed rule. Therefore, the HHA AOs could not yet have incorporated the new home infusion therapy health and safety standards into the accreditation standards they submitted with their applications. The establishment of the Medicare home infusion therapy health and safety accreditation standards will require that the existing home HHA/home infusion therapy AOs revise their home infusion therapy accreditation standards to ensure that they meet or exceed these new home infusion therapy health and safety standards. Therefore, we must require that each of the existing HHA/home infusion therapy AOs submit for our review, a new application seeking approval for a separate and distinct accreditation program for home infusion therapy suppliers, to ensure that the accreditation standards used meet or exceed the Medicare home infusion therapy health and safety standards.

Comment: Several commenters have stated that CMS should allow home health agency AOs to continue to provide home infusion accreditation services as part of their larger home health accreditation program. These commenters believe that providing home infusion therapy accreditation services as part of the AO home health program would both promotes higher quality care for beneficiaries and reduce administrative burden.

Response: We respectfully disagree with these commenters, because the commenters have provided no specific facts or circumstances which would explain how having a separate and distinct home infusion therapy accreditation program would promote a higher quality of care.

Moreover, the statutory requirement of section 1834(u)(5) of the Act

contemplates an independent accreditation process for home infusion therapy suppliers.

Comment: Several commenters stated concern that it would be too burdensome to require HHA AOs with existing home infusion therapy accreditation programs to develop a new home infusion therapy accreditation program that is distinct from their existing HHA accreditation program.

Response: We respectfully disagree with these commenters. We believe the additional burden will be minimal. Moreover, the statute mandates an AO program and application process that is structurally separate from accreditation for HHAs. While these commenters may incur some initial burden to create a home infusion therapy accreditation program that is separate and distinct from their home health accreditation program, we believe that this burden would be limited for several reasons. First, these commenters have stated in their comments that they do have established home infusion therapy standards and survey processes but that they are co-mingled with the AOs home health accreditation standards and survey processes. As these home health AOs already have established home infusion therapy accreditation standards and survey processes, we believe that it would be an uncomplicated matter for these AOs to separate their home infusion therapy standards and survey processes from their home health accreditation standards and survey processes. What we mean by this is that the AO could simply take the documents which contains the combined home health/home infusion therapy accreditation standards and survey processes and cut and paste the home infusion therapy accreditation language into a separate document. This task would only need to be performed once. Further, we believe the benefits of having a home infusion therapy accreditation program that is separate and distinct from the home health AOs home health accreditation program far outweighs the burden associated with the initial separation of the home infusion therapy accreditation program and home health accreditation program standards and survey processes.

Comment: Another commenter pointed out that ''HHAs have historically provided professional services associated with home infusion to individuals under their care, and further stated that they applauded both Congress and CMS for moving forward in implementing this important benefit and the additional support and resources it represents.'' However, several other commenters stated that home health agencies do not own or operate pharmacies, prepare home infusion drugs, provide the care coordination necessary to manage drug infusion, or provide a home infusion benefit. These commenters further stated that home infusion providers are neither certified nor authorized to offer the myriad of care services required of a home health agency. Thus, there is no relationship, overlap or intersection between the two benefits. Home health agencies will continue to provide the home health benefit for Medicare patients, and home infusion pharmacies will provide the new separate home infusion benefit for their Medicare patients.

Response: We agree with this commenter and we believe that HHAs are in a unique position to provide both home infusion therapy services and home health services to patients in their homes. Under the Medicare home infusion therapy benefit in section 1861(iii) of the Act, as added by section 5012 of the Cures Act, home infusion therapy services are available for those individuals receiving eligible home infusion drugs. Eligible home infusion therapy drugs are defined under section 1861(iii)(3)(C) of the Act, as 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. The services that are to be provided and paid for by Medicare do not include the provision of the home infusion drug, DME infusion pump, or supplies therefore, it is not necessary for a home infusion therapy supplier to be a licensed pharmacy.

Comment: Several commenters expressed the opinion that CMS has delayed in proposing the home infusion therapy AO regulations, and that this has caused the likelihood that the home infusion therapy AOs will be unable to apply for CMS approval, much less that CMS will have completed the accreditation process for home infusion AOs, prior to January 1, 2019. These commenters urged CMS to ''grandfather'' in existing accreditations to entities such as the eight AOs recognized in the proposed rule. The commenters suggest that for CMS to do otherwise would be to defeat Congress's clear direction and understanding that the accreditation program be functional by such date, and would severely disrupt care for patients. These commenters stated the belief that such action would be consistent with section 1834(u)(7)(F) of the Act, as added by section 50401 of the BBA of 2018, where Congress expressed its acceptance of such accreditation as sufficient on January 1, 2019 when the Transition benefit will begin.

Response: We respectfully disagree with these commenters' contention that CMS delayed in proposing the home infusion therapy AO regulations. The 21st Century Cures Act, which is the legislation that established the requirement for accreditation of home infusion therapy suppliers, was signed into law December 13, 2016. Thereafter, time was required to develop our plan for implementation, which occurred through mid to late 2017. By the time that the implementation planning phase was completed, the CY 2018 Home Health Prospective Payment proposed and final rules had already been published. Therefore, the CY 2019 Home Health Prospective Payment System Proposed Rule was the first appropriate venue in which CMS could make these proposals. Moreover, section 1834(u)(5)(B) of the Act, as added by the 21st Century Cures Act, requires that ''[n]to later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy.'' This means that it was intended that CMS would have until January 1, 2021 to solicit and approve AOs to accredit home infusion therapy suppliers for the permanent Medicare home infusion therapy services benefit for which payment to qualified home infusion therapy supplier will begin on January 1, 2021.

As stated in the proposed rule, we plan to publish a solicitation notice seeking national AOs to accredit home infusion therapy suppliers shortly after publication of the final rule. In addition, § 488.1010(d) requires 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 an application is complete. If we publish the solicitation notice by December 31, 2018 and receive applications from prospective home infusion therapy AOs during the first 5 months of 2019, we would be required to complete our review of these applications and issue our decisions by December 31, 2019, which is 1 full year before the January 1, 2021 deadline. Assuming we publish the solicitation notice by December 31, 2018, and considering that we must complete review of the application within 210 days, there would be a 16-month period in which prospective home infusion therapy AOs could submit their application for CMS review and obtain approval by the January 1, 2021 deadline specified in section 1834(u)(5)(B) of the Act.

The existing AOs that have been providing accreditation of home infusion therapy suppliers already have established home infusion therapy accreditation programs and accreditation standards. A number of commenters have stated that their respective home infusion therapy standards already meet or exceed the CMS proposed home infusion therapy accreditation health and safety standards and therefore believe that they should not be required to submit an application to CMS for approval. However, if this is the case, we believe that it should not take these AOs long to prepare the information and documentation required to apply for CMS approval of their home infusion therapy accreditation programs.

Likewise, we do not believe that it would take a long period of time for the HHA AOs that accredit home infusion therapy suppliers to prepare and submit their applications for CMS approval of a separate and distinct home infusion therapy accreditation program. It is our understanding from the comments received that these AOs have home infusion therapy accreditation standards that already meet or exceed the CMS proposed home infusion therapy accreditation health and safety standards; however, these home infusion therapy accreditation standards are integrated into the AO's HHA accreditation program. We believe that it would be an uncomplicated matter for these HHA AOs to segregate their home infusion therapy accreditation program into an individual accreditation program. As these AOs have previously established one or more accreditation programs and survey processes in the past, and have prepared and submitted one or more applications to CMS for approval of these accreditation programs, we believe that it would take these AOs less time and effort to do so for a separate and distinct home infusion therapy accreditation program.

Comment: Several commenters expressed the opinion that the Congressional intent was for CMS to accept the accreditation provided by the existing home infusion therapy AOs as being sufficient as of January 1, 2019 when the transitional benefits begin. Several commenters suggested that section 1834(u)(5)(D) requires CMS to deem any home infusion supplier accredited by a home infusion therapy AO designated or otherwise recognized and accepted by CMS prior to January 1, 2019, to be deemed accredited through January 1, 2023.

Response: We do agree that the existing home infusion therapy accreditation provided by the 8 existing home infusion therapy accreditation organizations prior to or on January 1, 2019 and still in effect on January 1, 2021, would be deemed to meet our accreditation requirements through at least January 1, 2023, once the permanent program goes into effect on January 1, 2021. Accreditation is not required for the transitional program set out at 1834(u)(7) of the Act. CMS cannot designate AOs until after January 1, 2019 (when our standards and designation procedures become effective).

Section 1834(u)(5)(D) titled ''*Rule for Accreditations Made Prior to Designation*'' refers to accreditations of home infusion suppliers that occurred ''prior to the Secretary's designation'' of AOs. This provision applies only to those AOs that are ultimately approved by CMS; the eight AOs currently providing accreditation receive no special consideration. Should any of the eight apply and be approved, any supplier with an active accreditation as of January 1, 2019 that is still active on January 1, 2021, when the accreditation requirement goes into effect, will be deemed to have a recognized accreditation until at least January 1, 2023, and longer if their accreditation lasts for a longer period.

2. 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 proposed 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 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 proposed 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 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 health and safety standards (contained in 42 CFR part 486, subpart B) and the AO meets the requirements of the 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 488.13 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 we believe that 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 will apply to AOs that accredit home infusion therapy suppliers. For example, § 488.6, regarding accredited provider entities' participation in Medicaid, will not apply to home infusion therapy because home infusion therapy suppliers is not a benefit specified in our Medicaid regulations.

Section 488.7, titled ''Release and use of accreditation surveys'' and § 488.8 titled ''Ongoing review of accrediting organizations'' will have parallel provisions applicable to AOs that accredit home infusion therapy suppliers (§ 488.1025). However, § 488.9 titled ''Validation surveys'' will not have a parallel provision applicable to

AOs for home infusion therapy suppliers because the State Survey Agency (SA) only performs validation surveys for AOs that operate under the statutory authority of section 1865 of the Act. In addition, 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. Home infusion therapy suppliers are not included in this list.

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'' will also not have parallel provisions applicable 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 will also not have parallel provisions applicable 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 will not have parallel provisions applicable to AOs for 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.'' As noted previously, we will not be including a parallel provision applicable to AOs that accredit home infusion therapy suppliers because it involves the activities of the SAs, which will not be involved in the home infusion therapy supplier accreditation process.

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 have created a separate set of regulations that are specifically applicable to home infusion therapy AOs.

We sought comment on our decision not to use the existing regulation at §§ 488.1 through 488.13. We did not receive any comments on this topic.

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 did not propose 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, as mentioned previously, the SAs are not available to perform validation surveys for home infusion therapy AOs. This is because, pursuant to section 1864(a) of the Act, the SA, enters into an agreement with the Secretary to provides services to only a limited number of healthcare provider types (that is, 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.

We sought 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 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 carry out 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, 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 § 488.1005 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 would 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 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 changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process.

Comment: Several commenters agreed with CMS that validation surveys should not be required for home infusion therapy AOs. One of these commenters agreed with CMS' position that the performance reviews performed under proposed § 488.1030 would provide more objective and effective data about the AOs performance.

Response: We thank these commenters for their input.

Final Decision: In consideration of the comments received, we are finalizing this proposal without modification and

will perform ongoing monitoring as part of the approval and ongoing oversight process for home infusion therapy AOs.

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

We proposed to establish regulations for the approval and oversight of AOs for home infusion therapy suppliers. We also proposed 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 being set forth in this final rule with comment period 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 proposed 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 proposed to further require that the AOs home infusion therapy accreditation standards meet or exceed the 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.

e. Oversight of Home Infusion Therapy Accrediting Organizations

As noted previously, we proposed 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 final rule, we describe our regulatory provisions.

The following sections discuss the regulations, in their order.

(1) Basis and Scope (§ 488.1000)

We proposed at § 488.1000 to set forth the statutory authority related to this set of regulations. Sections 1834(u)(5) and 1861(iii) of the Act would be the statutory basis for these 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 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 proposed the following definitions:

- ''*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 will, 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 proposed 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 proposed provision 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) requires 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.

Proposed § 488.1010(a)(2) requires AOs to specifically identify the Medicare supplier type for which they are requesting CMS-approval or reapproval.

Proposed § 488.1010(a)(3) requires 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.

Proposed § 488.1010(a)(4) requires 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.

Proposed § 488.1010(a)(5) requires 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 proposed requirement would allow CMS to evaluate whether the accreditation program standards meet or exceed the applicable Medicare requirements.

Proposed § 488.1010(a)(6) requires 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 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).

Proposed § 488.1010(a)(7)(ii) requires 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.

We proposed 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.

We proposed 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 will 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.

We proposed 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.

Proposed § 488.1010(a)(11) requires each AO for home infusion therapy suppliers to describe the content, frequency and types of in-service training provided to survey and audit personnel.

We proposed 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 requirement will 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.

We proposed 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.

Proposed § 488.1010(a)(14) requires 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.

We proposed at § 488.1010(a)(15) requires 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.

We proposed 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.

We proposed 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.

We proposed 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.

We proposed 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.

We proposed 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.

We proposed 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.

We proposed 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.

We proposed at § 488.1010(a)(23) to 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) requires 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 180 calendar days in advance of the effective date of the home infusion therapy AOs decision to voluntarily terminate its CMS-approved accreditation program.

Proposed § 488.1010(a)(24) requires the home infusion therapy AOs to provide CMS with a listing of the organization's 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) requires 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 proposed 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 proposed § 488.1020(b). Proposed § 488.1020(b) requires that the final notice, published by CMS, specify the basis for our decision.

Proposed § 488.1010(d) requires 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 proposed that to determine completeness, each application would be assigned to a technical review team upon receipt by CMS.

We sought public comment on the application requirements set forth in § 488.1010. We further sought comments on the burden related to the requirements of the application procedure. We received the following public comments:

Comment: Several commenters expressed general concern about the time and cost burden that would be incurred by a home infusion therapy AO related to obtaining CMS approval for their accreditation program. Another commenter questioned what the additional time and cost burden to home infusion therapy AOs for the ongoing administration of their home infusion therapy accreditation program, after CMS approval is obtained.

Response: While we understand that there would be some time and cost burden associated with the accreditation process for home infusion therapy AOs, this burden is necessary because the CMS approval process is required by section 1834(u)(5)(B) of the Act which requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021.

Comment: Several home infusion therapy suppliers expressed concern that the additional or increased operational costs incurred by new of existing home infusion therapy AOs (such as training, staff wages, revision of accreditation standards to meet the new Medicare home infusion therapy health and safety standards, preparation of the application for CMS seeking CMS approval of the AOs home infusion therapy accreditation program meet new and/or different accreditation standards, etc.) are likely that these standards and associated costs will vary among AOs.

Response: While we understand that there would be some time and cost burden associated with the accreditation process for home infusion therapy AOs, this burden is necessary because the CMS approval process is required by section 1834(u)(5)(B) of the Act which requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021.

Comment: Several commenters urged CMS to amend proposed § 488.1010(a)(23)(i) to require an AO to provide home infusion therapy suppliers with a 180 day notice, rather than a 90 day notice of the AO's voluntary withdrawal from the CMS accreditation program. These commenters stated the belief that the 90 day notice requirement would be too short a period of time for an otherwise compliant home infusion therapy supplier to secure new accreditation from a different CMS-approved home infusion therapy AO.

Response: We believe that, in most cases, an home infusion therapy AO that has decided to voluntarily terminate their CMS-approved home infusion therapy accreditation program is likely make this decision at least 6 months prior to the date that they would completely cease operations, in order to give them time to wrap up their business affairs and wind down operations. For example, the AO would need to complete any surveys that had been scheduled or refer these clients to other AOs. They would also need to provide notice to their accredited home infusion therapy suppliers of their decision to voluntarily terminate their CMS-approved home infusion therapy accreditation program.

We agree with these commenters that the 90 day notice period may not be a sufficient period of time in which an otherwise compliant home infusion therapy provider could seek out another CMS-approved home infusion therapy AO, file the required application, and complete the accreditation process. Therefore, we have decided to increase the notice requirement specified in § 488.1010(a)(23)(i) from 90 days to 180 days as requested.

It is important to note that § 488.1010(a)(23) requires the home infusion therapy AOs to provide a written statement in their application to CMS, 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). However, the actual requirement that the home infusion therapy AO provide notice is set forth at § 488.1045(a). Since we will be increasing the notice requirement that is to be included in the statement that is to be provided in the application submitted by the home infusion therapy AO as a condition for approval as required by § 488.1010(a)(23)(i), we must also make a corresponding change to the notice requirement in § 488.1045(a).

Final Decision: Section 488.1010(23)(a)(i) will be amended by changing the notice requirement for home infusion therapy AOs that voluntarily terminate their CMS-approved accreditation program from 90 days to 180 days. This change requires that we also make a corresponding

change to the notice requirement of § 488.1045(a). (See the discussion of § 488.1045(a) in this final rule with comment period) for this corresponding change.

(4) Resubmitting a Request (§ 488.1015)

Proposed § 488.1015(a) requires that except as provided in paragraph (b), a home infusion therapy AO whose request for CMS' 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) provides that a home infusion therapy AO that has requested reconsideration of an application denial by CMS could not submit a new application until the pending reconsideration was administratively final. This proposed 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 sought public comments on the requirements of § 488.1015. We did not receive any comments regarding § 488.1015.

Final Decision: Having received no comments in regards to § 488.1015, this section will be finalized as drafted, without modification.

(5) Public Notice and Comment (§ 488.1020)

Proposed § 488.1020(a) requires 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, and because we believe that it is important for the public to have notice of accreditation organization activities.

Section 488.1020(b) requires that when CMS approves or re-approves an application for approval of a home infusion therapy AO's accreditation program, a final notice will be published in the **Federal Register**. This notice would have to specify the basis for CMS' decision. Section 488.1020(b)(1), requires 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 proposed 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 sought comment on the requirements of § 488.1020, including on the appropriate term for approval of an AO. We did not receive any comments regarding § 488.1020.

Final Decision: Having received no comments in regards to § 488.1020, this section will be finalized as drafted, without modification.

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

Proposed § 488.1025 requires 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) provides 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) prohibits 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 publicly 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 sought public comments on the requirements of § 488.1025. We did not receive any comments regarding § 488.1025.

Final Decision: Having received no comments in regards to § 488.1025, this section will be finalized as drafted, without modification.

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

Proposed § 488.1030 clarifies that a formal accreditation program review could be opened on an ongoing basis. Specifically, this proposed 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 AO's home infusion therapy accreditation programs: (1) Performance review; (2) comparability review; and (3) CMS-approved accreditation program review.

Proposed § 488.1030(a) allows 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) allows 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) allows CMS to perform a comparability review when CMS imposes new or revised Medicare accreditation requirements. When this occurs, proposed § 488.1030(b)(1) requires 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) requires 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 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) requires 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 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 will have continued CMS-approval without further review or consideration.

Proposed § 488.1030(b)(7) 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 proposed § 488.1010(d).

We proposed at § 488.1030(b)(8) that if a home infusion therapy AO failed to submit its changes within the required timeframe, or failed to implement the 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 proposed 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 changes. Proposed § 488.1030(c)(2) prohibits the home infusion therapy AO from implementing these changes before receiving CMS' approval except as provided in proposed § 488.1030(c)(4). Proposed § 488.1030(c)(3) requires 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 proposed §§ 488.1030(c)(2) and 488.10(c)(3) ensures that the home infusion therapy AO provides CMS with advance notice of any changes to their home infusion therapy accreditation requirements and survey processes. This notice would allow CMS time to review these 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 proposed section would also prohibit home infusion therapy AOs from implementing any of the changes in their home infusion therapy accreditation requirements and survey processes, until CMS approval has been received.

Proposed § 488.1030(c)(4) requires CMS to provide written notice to the home infusion therapy accrediting organization indicating whether the home infusion therapy accreditation program, including the 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 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.

Section 488.1030(c)(5) requires 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 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) permits CMS to open an accreditation program review, in accordance with § 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 proposed 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 home infusion therapy health and safety regulations contained in 42 CFR part 486, subpart B. Proposed § 488.1030(d)(1) requires 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) 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 will have to take to address the identified deficiencies, and the length of the accreditation program review probation period, which would 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 proposed that CMS reviews and approves the home infusion therapy AO's plan of correction for acceptability within 30 days after receipt. Proposed § 488.1030(d)(3) provides that CMS monitors 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 monitors 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 proposed 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 proposed § 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 would 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 proposed 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) requires 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) requires 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, § 488.1030(d)(4)(iii) requires CMS to publish a notice of its decision to withdraw approval of the accreditation program in the **Federal Register**. This notice will have to include the reasons for the withdrawal, and a notification that the withdrawal will become effective 60 calendar days after the date of publication in the **Federal Register**. The publication of this **Federal Register** notice is notice will 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) allows 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 proposed 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 proposed 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 sought public comments on the requirements and the burden associated with the requirements of § 488.1030.

We did not receive any comments related to the burden associated with requirements § 488.1030. However, we did receive the following comment related to the requirements of § 488.1030:

Comment: Several commenters have requested that CMS clarify that the non-compliance that triggers a review under § 488.1030 must not only be ''substantial'' but also be ''material.''

Response: The term ''substantial'' means ''of considerable importance, size or worth.'' The term ''material'' means ''important, relevant or essential.'' [80] We believe that these terms are similar enough in nature that adding the word ''material'' would be duplicative. Our goal, as stated in the proposed rule, is to make the AO approval and oversight regulations as consistent, as possible, with the AO approval and oversight regulations for Medicare-certified providers and suppliers at 42 CFR 488.5 to 488.13. The term ''substantial and material'' is not used in regulation § 488.8 titled ''Ongoing review of accrediting organizations.'' which is the comparable regulation to § 488.1030 regulations for Medicare-certified providers and suppliers. Therefore, we believe that to add a different standard for home infusion therapy AOs would be inconsistent and would result in different standards across the AO types.

Also, many AOs have accreditation programs for numerous types of providers and suppliers. If CMS were to use varying standards for different types of providers and suppliers, it would make it difficult for these AOs with multiple accreditation programs to administer these programs in a smooth

[80] Merriam Webster Online Dictionary.

and consistent manner. Therefore, we believe that it is important that CMS keep the language of § 488.1030 consistent with that of § 488.8. We would also note that we have broad discretion to monitor the performance of AOs and to take action when necessary.

Final Decision: After consideration on the comments received, we have decided to finalize § 488.1030 without modification.

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

Proposed § 488.1035 requires a home infusion therapy AO to provide certain information to CMS and carry out certain activities on an ongoing basis. More specifically § 488.1035(a) requires 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 changes in its home infusion therapy accreditation standards or requirements or survey process.

Proposed § 488.1035(b) requires 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. Section 488.1035(c) requires 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) requires 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. Section 488.1035(e) requires 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 sought public comment on the requirements and the burden associated with § 488.1035. We received no comments in regards to requirements and the burden associated with § 488.1035.

Final Decision: As no comments related to § 488.1035 were received, this section to the proposed regulations will be finalized as drafted and without modifications.

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

We proposed 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 proposed 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 sought public comments on the requirements of and the burden related to § 488.1040. However, we received no comments in regards to requirements and the burden associated with § 488.1040.

Final Decision: As no comments related to § 488.1040 were received, this section to the proposed regulations will be finalized as drafted and without modifications.

(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 § 488.1045. Proposed § 488.1045(a) addresses 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 180 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 § 488.1045(b) addresses 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) provides that the accreditation status of affected home infusion therapy suppliers will 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) provides 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 proposed 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) requires that the terminated home infusion therapy AO must provide a second written notification to all accredited suppliers 10 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 proposed 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 section 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. Section 488.1045(d)(3) requires the home infusion therapy AO to submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier 5 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) of the Act and the payment consequences of being unaccredited. If there is a lapse in the accreditation status of the home infusion therapy supplier, they would 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 solicited public comments on the requirements of and the burden related to § 488.1045.

Comment: A commenter expressed concern that the requirements of proposed § 488.1045(d) would be extremely burdensome for the home infusion therapy AO to implement. This section provides that if a home infusion therapy supplier requested a voluntary withdrawal from accreditation, it would not be possible for the withdrawal to become effective until the home infusion therapy AO completed the following three required steps: (1) The AO must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intended to voluntarily withdraw from the accreditation program; (2) the home infusion therapy AO must 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; and (3) the home infusion therapy AO must 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 5 business days after the request for voluntary withdrawal was ultimately processed and effective.

In support of this contention that the previous requirements would be too burdensome, the commenter stated the belief that the home infusion therapy supplier would be responsible for knowing the CMS rules of coverage. AO's should provide this information to the supplier in the form of the AO's accreditation process and/or procedures. The AO should not have the burden of producing documentation that they informed the supplier at 3 separate times of what could happen if they withdrew their accreditation.

Response: We disagree with this commenter's contention that the requirements of proposed § 488.1045(d) are burdensome for the home infusion therapy AO to implement with the business technology that is readily available to each AO. It is important to point out that all 3 of these previously discussed steps can be accomplished quickly and effectively and would take a relatively short period of time. We say this because this section merely requires that each of the 3 categories of information is obtained and disseminated to the home infusion therapy supplier. This section does not require them to be accomplished separately at different times or on different dates.

Similarly, we believe that this task can be accomplished by the AO sending one single correspondence to the home infusion therapy supplier and simple follow-up monitoring to ensure that the

home infusion therapy supplier returns the required written confirmation to the AO acknowledging that they do intend to voluntarily withdraw from the accreditation program. To simplify matters further and save even more time, we believe that the AO could create a pre-prepared home infusion therapy supplier notification letter and an acknowledgment of withdrawal from accreditation form in a fillable .pdf template format. Thereafter, when a home infusion therapy supplier notifies an AO that they are withdrawing from that AO, all the AO would need to do is open up the AO notification and home infusion therapy supplier acknowledgement templates on their computer, fill in the blanks on the fillable .pdf template forms, print the forms and send them HIT supplier via hand deliver, text, email, fax or U.S.P., federal Express, etc. Then AO would only have to await for the HIT supplier to return the signed acknowledgement form.

Comment: § 488.1045(c)(2) provides that if a home infusion therapy supplier, whose home infusion therapy AO's CMS approval has been voluntarily or involuntarily terminated by CMS wishes to continue to receive reimbursement from Medicare, that home infusion therapy supplier 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 proposed 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.

Several commenters have urged CMS to amend the notice requirement of proposed § 488.1045(c)(2). These commenters have requested that CMS decrease the minimum time period by which affected home infusion therapy suppliers must provide their written notice to CMS informing us that they have filed an application with another home infusion therapy AO from 60 days to 5 days prior to the effective date of the termination of the home infusion therapy suppliers current term of accreditation. These commenters stated the belief that the change to a 5 day notice requirement will ensure that the second AO termination notice to providers can be acted upon if, for any reason, the original termination notice was missed.

Response: We understand the concern on the part of home infusion therapy suppliers about possibly missing the first notice sent by their home infusion therapy AO when that AOs CMS-approval has been voluntarily or involuntarily withdrawn. We believe that in the event a home infusion therapy AO voluntarily or voluntarily has its CMS-approval terminated, there will be ample notice provided.

In the case of an involuntary termination of an AOs CMS approval, § 488.1045(b) as finalized requires that CMS publish a notice in the **Federal Register** announcing its decision to terminate the accrediting organization's home infusion therapy accreditation program, therefore, the home infusion therapy AO will 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 is published in the **Federal Register**. This notice must state that CMS is withdrawing its approval of the home infusion therapy AO's accreditation program, and also discuss the implications for the supplier's payment, should there be a lapse in their accreditation status. In the case of a voluntary termination of an AO's CMS approval, proposed § 488.1045(d) provides that it will not be possible for the withdrawal to become effective until the home infusion therapy AO completes three required steps: (1) The AO must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the accreditation program; (2) the home infusion therapy AO must advise home infusion therapy supplier, in writing, of the statutory requirement at section 1861(iii)(3)(D)(i)(III) of the Act for requiring accreditation for all home infusion therapy suppliers; and (3) the home infusion therapy AO must advise the home infusion therapy supplier of the possible payment consequence for a lapse in accreditation status. Furthermore, § 488.1045(d)(3) requires the home infusion therapy AO to submit a final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

In addition to the notices required by the regulatory provisions previously referenced, CMS will take all appropriate steps to ensure that the affected home infusion therapy suppliers are given timely notice about the termination of their home infusion therapy AO's CMS-approved home infusion therapy accreditation program. Some possible methods CMS would use to make this information available to these affected home infusion therapy suppliers include, but are not limited to posting of information on the Quality, Safety and Oversight Group (QSOG) web page, notification sent via email and email blasts, information published in the Medicare Learning Network newsletter, Medicare payment manual bulletin, newsletter and in Medicare Learning Network publications, and discussion during Open Door Forums.

We believe that the requirement that affected home infusion therapy suppliers provide CMS with written notice that they have filed an application for accreditation with another CMS-approved home infusion therapy AO at least 60 days prior to the expiration of their current term of accreditation is an essential requirement for several reasons. First, it ensures CMS that all home infusion therapy suppliers affected by a voluntary or involuntary termination of a particular AO's CMS-approved accreditation program have indeed filed applications with other CMS-approved home infusion therapy AOs in a timely manner.

Second, the required 60 day written notice to be provided by these affected home infusion therapy suppliers informs CMS that they have already filed an application and initiated the accreditation process with another CMS-approved home infusion therapy AO. This in turn, will trigger the CMS payment system not to continuing paying these home infusion therapy suppliers until their new accreditation information is received.

The requirement that written notice be submitted by all affected home infusion therapy suppliers at least 60 days prior to the expiration of their current terms of accreditation provides CMS with assurances that the accreditation process for each these affected home infusion therapy suppliers has already been initiated, is either substantially completed or will be completed prior to the expiration of the affected home infusion therapy suppliers current term of accreditation and that CMS can be assured that they are not going to be paying claims submitted by non-accredited home infusion therapy supplier.

The accreditation process takes several months, at a minimum. If CMS were to allow these home infusion therapy suppliers to wait until 5 days prior to the expiration date of their current term of accreditation to notify CMS that they have initiated the accreditation process (filed an application) with another AO, CMS would have no assurance that the

accreditation process will be completed or substantially completed by the time their current term of accreditation lapses. If this were the case, CMS would not be able to prevent a lapse in payment to these home infusion therapy suppliers that find themselves in the situation in which the CMS-approval of their AO has been withdrawn. Therefore, this requirement is intended to protect those otherwise compliant home infusion therapy suppliers, who find themselves, through no fault of their own, in the situation in which their current AO is no longer CMS-approved.

Final Decision: After consideration of the comments received, we have decided not to change the notification requirement set forth in § 488.1045(c)(2). Therefore, we are finalizing the provisions of section § 488.1045 without modification.

(11) Reconsideration (§ 488.1050)

We proposed 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. Proposed at § 488.1050(b)(1), the home infusion therapy AO will 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) requires 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) allows a home infusion therapy AO to withdraw their request for reconsideration at any time before the administrative law judge issues a decision.

We proposed 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. Proposed § 488.1050(c)(2) requires 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 proposed 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) provides that the legal conclusions of the hearing officer within 45 calendar days after the close of the hearing. Proposed § 488.1050(d)(6) requires 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 sought public comments on the requirements of § 488.1050. We received no comments on the requirements of § 488.1050.

Final Decision: Having received no comments in regards to § 488.1050, we are finalizing this provision without modification.

D. Payment for Home Infusion Therapy Services

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

In the CY 2019 HH PPS proposed rule (83 FR 32340) we discussed the implementation of the home infusion therapy services temporary transitional payment under paragraph (7) of section 1834(u) of the Act, as added by section 50401 of the BBA of 2018 (Pub. L. 115–123). This section provided for a temporary transitional payment for administration of home infusion drugs for 2019 and 2020. These services must be furnished by an eligible home infusion supplier 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. Section 1834(u)(7)(F) of the Act defines eligible home infusion suppliers as suppliers that are enrolled in Medicare as pharmacies that furnish 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 in Medicare as pharmacies that provide external infusion pumps and supplies are considered eligible home infusion suppliers. 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. Additionally, section 1834(u)(7)(C) of the Act specifies the HCPCS codes for the drugs and biologicals covered under the Local Coverage Determinations (LCDs) for External Infusion Pumps, and identifies 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. 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.

As set out at new section 1834(u)(7)(D) of the Act, each payment category will be paid amounts equal to amounts for statutorily specified codes for which payment is made under the Physician Fee Schedule for each infusion drug administration calendar day in the individual's home for drugs assigned to such category. No geographic adjustment applies to the payments. In accordance with section 1834(u)(7)(E)(ii) of the Act, 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.

In the CY 2019 HH PPS proposed rule, we outlined the billing procedure for the temporary transitional payment. We created a new HCPCS G-code for each of the three payment categories. We stated that the eligible home infusion supplier will submit, in line-item detail on the claim, a G-code for each infusion drug administration

calendar day, which would include the length of time for which professional services were furnished (in 15 minute increments). These G-codes can be billed separately from or on the same claim as the DME, supplies, and infusion drug. However, under the temporary transitional payment period, the eligible home infusion supplier is required to be enrolled as a pharmacy that provides external infusion pumps and external infusion pump supplies and maintains all pharmacy licensure requirements. Therefore, during this period, it is likely that the G-codes will be billed on the same claim as the equipment, supplies, and drug. However, for the full implementation of the benefit in 2021, there may be two different suppliers: One furnishing the home infusion therapy services in the home and one furnishing the DME, supplies, and drug. The claims for the temporary transitional payment will be processed through the DME MACs. In order to implement the requirements of section 1834(u)(7) of the Act for this temporary transitional payment, we will 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.

In general, section 1834(u)(7) specifies, in detail, the requirements of the temporary transitional payment for home infusion therapy services, and in most instances, we generally do not have the discretion to apply different policies. However, we proposed a regulatory definition of ''infusion drug administration calendar day'' to specify in more detail, the policy in the statute as to when Medicare should make a single payment for home infusion therapy services. As required by section 1834(u)(1)(A)(ii) of the Act, a unit of single payment under the home infusion therapy benefit payment system is for each infusion drug administration calendar day in the individual's home. Section 1834(u)(7)(E)(i) clarifies that 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)(A)) were furnished to administer such drugs to such individual. Therefore, we proposed to define in regulation that ''infusion drug administration calendar day'' refers to payment 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. As we stated in the proposed rule, we believe this to mean skilled services as set out at 42 CFR. 409.32. This regulation states that the skilled services furnished on such day must be so inherently complex that they can only be safely and effectively furnished by, or under the supervision of, professional or technical personnel.

The following is a summary of the public comments received on the ''Proposed Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020'' and our responses.

Comment: Several commenters supported the proposed definition of ''infusion drug administration calendar day'' and noted that the home infusion payment rates for 2019 and 2020 specified in the statute are generally comparable and, in some cases, higher than the payment rates for an in-home visit under the home health prospective payment system. MedPAC agreed with CMS' requirement that home infusion therapy providers report the length of home visits on their claims submissions, as it would allow the agency to consider this data as it establishes the payment rates for 2021, and could help to inform the agency's consideration of potential payment adjustments based on patient acuity or drug administration complexity.

Response: We thank the commenters for their review and support of both the temporary and permanent payment structures for home infusion therapy services. We agree that the data obtained by requiring the length of the visit on the claim will be helpful in establishing payment adjustments for the full implementation of the benefit in 2021.

Comment: In general, other commenters stated that the definition of ''infusion drug administration calendar day'', and the resulting payment limitation based on physical presence would be contrary to law and Congressional intent, and would inappropriately limit the number of days of payment for home infusion therapy professional services. Commenters expressed concern that tying payment to days for which a nurse provides in-person professional services, would limit payment only to a small subset of the many professional services furnished in connection with home infusion. Commenters stated that CMS should define infusion drug administration calendar day to include a broader set of professional services such as drug preparation, including sterile compounding; clinical care planning; care coordination; and other professional services that most often occur outside of the patient's home and remove the physical requirement that a nurse be in the home for payment to occur. Commenters also disagreed with the reference to the definition of ''skilled services'' as set out at § 409.32. Commenters stated that it seems inappropriate to define home infusion therapy professional services as skilled services in a skilled nursing facility (SNF).

Response: We agree that there are a variety of providers and professional services involved in home infusion therapy and recognize their significance in ensuring that therapy is safe and effective in the home.

However, in accordance with section 1861(iii)(1) of the Act, the term ''home infusion therapy'' means the items and services furnished by a qualified home infusion therapy supplier, which are furnished in the individual's home. Likewise, section 1834(u)(7)(B)(iv) establishes a single payment amount for each infusion drug administration calendar day in the individual's home. Additionally, 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 the BBA of 2018 includes this clarification of ''infusion drug administration calendar day'' in order to establish clear parameters so as to explicitly pay for services that occur in the patient's home when the drug is being administered. Our interpretation of the phrase ''only for the date on which professional services, as described in section 1861(iii)(2) of the Act, were furnished'' is that mere infusion without any professional services furnished cannot trigger a home infusion therapy services payment for any day the drug is infused by the DME pump. Thus, we believe that the language in the statute clearly delineates a subset of days on which professional services are provided in the patient's home in order for payment to occur.

Additionally, section 1834(u)(7)(A)(i) of the Act states that payment to an eligible home infusion supplier is for items and services furnished in coordination with the furnishing of transitional home infusion drugs. The language does not indicate that payment is for the furnishing of the home infusion drug, but for the services provided together and in cooperation

with the furnishing of the drug. The Medicare payment for the drug is made separately from home infusion therapy services. The statute also states that payment is for the professional services furnished ''to administer'' such drugs to such individual. As the term ''administered'' refers only to the physical process by which the drug enters the patient's body,[81] then the professional must be in the patient's home furnishing services specifically related to this process. We noted in the CY 2019 HH PPS proposed rule that we understand that there may be professional services furnished in the patient's home that do not occur on a day the drug is being administered (83 FR 32464). However, we note that the home infusion therapy services temporary transitional payment is a unit of single payment, meaning all home infusion therapy services furnished, which include professional services, training and education, remote monitoring and monitoring, are built into the payment for the day the professional services are furnished in the home and the drug is being administered. With the addition of the home infusion therapy services temporary transitional payment, suppliers will still receive payments for furnishing the equipment, the supplies, and the drug (technically considered a supply) under the DME benefit; but will also receive a separate payment when professional services are furnished in the patient's home under the home infusion therapy benefit.

Furthermore, we note that the payment for an infusion drug administration calendar day is a single payment amount covering: professional services, including nursing services, furnished in accordance with a plan of care; training and education (not otherwise paid for as durable medical equipment); remote monitoring; and monitoring services furnished by a qualified home infusion therapy supplier. Therefore, at § 486.525, we have mirrored the language in section 1861(iii)(2)(A) of the Act that requires the provision of professional services, including nursing services, furnished by the home infusion therapy supplier in accordance with the plan of care. Since the Medicare payment is a single payment amount, we do not believe it is necessary to define ''professional services'' in regulation. By specifically enumerating a specific list of services we would risk inadvertently excluding services that may be necessary for the care of a specific patient as part of the required services under the home infusion therapy benefit.

Section 1861(iii)(1)(B) requires the individual to be under a plan of care, established by a physician, prescribing the type, amount, and duration of home infusion therapy services that are to be furnished. Thus, it is the individual's physician who is responsible for establishing the type and scope of professional services needed in the home in order to ensure home infusion therapy is successful. In the proposed rule, we did state that the services on this day must meet the criteria for skilled services as set out at § 409.32. This criteria states that to be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel. Although this is a requirement for coverage of post-hospital SNF care, the definition of skilled services is not specific to skilled nursing services in a SNF. Section 409.42(c)(1) under the home health benefit also references § 409.32 as the criteria for intermittent skilled nursing services. Additionally, although both benefits require ''skilled services'' in reference to nursing, the definition is not exclusive to nursing services.

Finally, section 1834(u)(7)(D) of the Act sets the temporary transitional payment equal to 4 units at the amounts determined under the physician fee schedule (that is, equivalent to 4 hours of infusion in a physician's office). Payment for an infusion drug administered in a physician's office or outpatient center is made based on the occurrence of the professional services furnished during the visit. The professional services necessary for the infusion drug administration at these sites of care are factored into the payment for the visit, not separately payable. As such, it is not necessary to define the professional services required for infusion drug administration in a physician's office or outpatient center because payment is not dependent upon the individual services furnished, but rather the occurrence of the visit and the professional services furnished at the time. Likewise, the home infusion therapy services temporary transitional payment includes payment for any professional services furnished in the patient's home to administer the infusion drug.

Comment: A commenter recommended CMS add additional payment for visits exceeding a median visit time period such as 2 or 3 hours, as initial visits in particular can vary from 1 to 6 hours. The commenter stated that in the absence of these additional payments, home infusion suppliers may limit the types of patients they accept during the transitional period.

Response: Section 1834(u)(7)(D) of the Act sets the temporary transitional payment equal to 4 units at the amounts determined under the physician fee schedule (that is, equivalent to 4 hours of infusion in a physician's office). Although we do recognize that there may be some visits that exceed the number of units allowed, some visits may also be shorter. The temporary transitional payment is statutorily limited to the payment methodology as put forth in section 1834(u)(7)(D) of the Act.

Comment: Another commenter stated that many chronically ill patients depend on home health agencies for home infusion therapy services and supplies, and stated that home health agencies should continue to be paid as they currently are for home infusion. Another commenter stated that many home infusion suppliers do not actually provide the necessary skilled nursing support and must contract with home health agencies, which in turn, requires the home infusion company to assume responsibility for visits which may be unrelated to the patient's infusion therapy.

Response: It is important to emphasize that the home infusion therapy services temporary transitional payment is separate from the home health benefit. Home infusion therapy is excluded from the Medicare home health benefit, and separately payable, beginning January 1, 2019. Section 1842(u)(7)(F) of the Act requires eligible home infusion suppliers to be Medicare DME suppliers that are enrolled as pharmacies that supply external infusion pumps and supplies in order to receive the home infusion therapy services temporary transitional payment. Not until the full implementation of the benefit in 2021 will home health agencies have the option of becoming home infusion therapy suppliers.

It is unclear why the commenter states that the home infusion supplier would be required to assume responsibility for visits which may be unrelated to the patient's infusion therapy. We recognize that currently home infusion suppliers may contract with HHAs to furnish the nursing services; however, it is incumbent upon the home infusion supplier to negotiate appropriate contract terms in order to only assume responsibility for services related to home infusion therapy.

We also note that section VI.C.2.f. of the proposed rule discusses the

[81] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

potential relationship/interaction between the home infusion therapy benefit and home health benefit. We stated that although the patient is not required to be homebound in order to receive home infusion therapy services, we anticipate that there may be circumstances when a patient may utilize both the home health benefit and the home infusion therapy benefit concurrently. We will provide further discussion on this relationship, including how we anticipate HHAs that furnish both home health and home infusion therapy services would submit claims for each of these services, in future rulemaking.

Comment: A few commenters expressed support for the inclusion of requirements for remote monitoring in the home infusion benefit, and encouraged CMS to consider how to incorporate the use of telehealth into the final home infusion payment system. A commenter suggested that CMS include requirements that monitoring be performed using medical devices cleared by the FDA for remote monitoring purposes.

Response: As we do not have specific policies surrounding the technology used in remote monitoring, for now we choose not to be prescriptive regarding how remote monitoring, or which remote monitoring devices, are used in home infusion. Anecdotally, we have heard from many home infusion providers that monitoring in home infusion consists mainly of phone calls. Likewise, the consensus from TEP members was that physical assessment and in-person monitoring is more common in home infusion due to the importance of visualizing the access site.

Comment: Many commenters stated that the proposed definition of infusion drug administration calendar day assumes that a nurse would be present for each administration of the home infusion drug. Several comments stated that requiring a nurse to come for every infusion day was inefficient, unnecessary, and would put a tremendous financial burden on patients who could not afford to have a nurse come every day to administer the drug. Several commenters stated concern regarding the potential inability to receive their infusion drugs on those days in which a skilled professional is not present in the home during the administration of the infusion drug. Some commenters stated that this requirement would also cause an access issue for home infusion patients, possibly resulting in an increase in deaths among those who receive home infusion drugs, though no specific reason was provided as to why this would be the case. Another commenter stated that infusion suppliers would be forced to cut back on services, especially in rural areas, due to a limited supply of nurses. Additionally, this commenter stated that agencies will have to determine whether financially they are able to cover non-reimbursed costs associated with the benefit for Medicare patients, given that other payers do not require nurses to be present when drugs are infused in a patient's home.

Response: We wish to remind stakeholders that the provision of home infusion is not contingent upon a nurse being present each and every day a drug is being infused, nor that a nurse is present during the entire administration of the drug. An important goal of home infusion therapy services is to teach patients to safely, effectively, and independently self-administer the drug in the home. The home infusion therapy services paid under this benefit furnished in the patient's home help ensure that patients and/or their caregivers can reach this goal. The requirement that a skilled professional be in the home on a day an infusion drug is administered is only for purposes of determining the days for which the bundled payment for home infusion therapy services is made. We also note that there is no limit on the number of times that a home infusion therapy services payment would be made if a nurse needed to visit the beneficiary's home more than once a week.

The payment for professional services and training and education (not otherwise paid for under the Medicare Part B DME benefit), remote monitoring and monitoring services is only made when a skilled professional is physically present in a patient's home on a day of drug administration. This does not mean that that the external infusion pump, drug, and related supplies are not covered on days when there is not a skilled professional in the home. The home infusion therapy services temporary transitional payment is a separately paid amount from the external infusion pump, drug, and related supplies.

Additionally, we state in the proposed rule that the professional services covered under this benefit are not intended to provide on-going nursing supervision throughout each infusion. We do not expect a nurse to be present for every infusion, or to stay for the duration of each infusion once the patient and/or caregiver has been taught to operate the pump. In section VI.C.2.d. of the proposed rule, we outline the training and education services that we believe the home infusion therapy payment would cover. We state that these 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.

Furthermore, section 1861(iii)(2)(B) includes the provision of monitoring and remote monitoring as part of the home infusion therapy benefit. In the proposed rule, we indicated that we understand that some home infusion therapy patients may require daily monitoring, but generally do not need to be seen by a practitioner daily. In section VI.C.2.d. of the proposed rule, we state our belief that monitoring and remote monitoring can enable daily contact with, or assessment of certain patients without necessitating a visit.

Considering that we do not expect a visit to be made for each infusion drug administration, we also do not believe the supplier should be paid every day that the medication is infused regardless of whether or not direct care services are furnished. We should also emphasize that the patient is responsible for 20 percent coinsurance for every home infusion therapy services payment in addition to the 20 percent coinsurance charged for the DME infusion pump supplies and the drug. Therefore, we believe tying the payment to a visit in the beneficiary's home would ensure that the beneficiary is receiving direct care services for which he/she is paying 20 percent coinsurance. We state in the proposed rule that we generally anticipate that a home infusion therapy supplier would provide a visit approximately two times a week for the first week and then weekly thereafter over the course of infusion therapy depending on the drug and patient. Therefore, the proposed definition of infusion drug administration calendar day would result in payment only for these days when a visit occurs. Likewise, the beneficiary would be responsible for the 20 percent coinsurance amount only on these days. Section 1834(u)(7) requires that the temporary transitional home infusion therapy services payment be equal to 4 units at the amounts determined under the physician fee schedule (that is, the equivalent of 4 hours of infusion in a physician's office). This amount would range from $141 to $240 (using CY 2018 fee schedule amounts). If payment were to be made every day an infusion occurred, regardless of whether a visit was made, the beneficiary would be responsible for the home infusion therapy services coinsurance amount each and every day the infusion

occurred. For some patients on daily, continuous infusions, this would mean paying a 20 percent coinsurance amount every day (approximately $900 per month in cost-sharing and more than $10,000 annually). In accordance with CMS' proposed definition of infusion drug administration calendar day, the infusion therapy supplier would be paid every time a visit is made and a skilled service was furnished in the individual's home, which we anticipate would be at least weekly. Furthermore, we believe requiring that direct patient care services be made in order to receive payment promotes visits that provide direct care to the patient, which may help to mitigate any infusion related reactions or unplanned readmissions or ED visits. Similar to the physician office and the hospital outpatient setting, Medicare payment is made for direct care services furnished to a patient for infusion drug administration. We believe that, clinically, it is occasionally necessary for a nurse to visualize part of the administration of the infusion drug as this is part of his/her overall patient assessment while in the home. For instance, a nurse may observe dyspnea, tachycardia, or infiltration during an infusion and can appropriately intervene to ensure the safe and effective administration of the infusion.

We also do not anticipate that this requirement would lead to any additional home visits than are currently provided by home infusion suppliers. As many commenters pointed out, visits are often provided weekly, which aligns with what we stated in the proposed rule. Furthermore, we consider this benefit to be an additional payment for the direct care services associated in coordination with the furnishing of home infusion drugs.

Comment: Some commenters expressed concern regarding availability and categorization of specific infusions such as Total Parenteral Nutrition (TPN), intravenous hydration, or antiemetic drugs.

Response: While ''home infusion drug'' is defined under section 1861(iii)(3)(C) as 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, 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 for the temporary transitional payment specifies the HCPCS codes for the drugs and biologicals covered under the Local Coverage Determinations (LCD) for External Infusion Pumps. Therefore, only these drugs are covered under the home infusion therapy services temporary transitional payment. We intend to examine the criteria for home infusion drugs for coverage of home infusion therapy services, for implementation of the full home infusion therapy benefit in 2021.

Comment: A few commenters pointed out a technical edit regarding billing related to the creation of the G-codes and questioned whether our intent is to create three new G-codes for each of the three payment categories or one new G-code for each of the categories.

Response: We thank the commenters for bringing this to our attention. To clarify, we plan on creating one new G-code for each of the three payment categories.

Final Decision: We are finalizing the definition of infusion drug administration calendar day for the home infusion therapy services temporary transitional payment to mean payment 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. *We recognize the concerns from stakeholders and members of Congress on our interpretation of ''infusion drug administration calendar day'', including with respect to professional services that may be provided outside of the home and, as applicable, payment amounts for such services. It is our intention to ensure access to home infusion therapy services in accordance with section 50401 of the BBA of 2018. Therefore, we believe the best course of action is to monitor the effects on access to care of finalizing this definition and, if warranted and within the limits of our statutory authority, engage in additional rulemaking or guidance regarding this definition for temporary transitional payments. We seek comments on this interpretation and on its potential effects on access to care.''*

1. 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 will 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 the CY 2019 HH PPS proposed rule (83 FR 32340), we discussed the provisions of the law, and in anticipation of future rulemaking, solicited comments regarding the payment system for home infusion therapy services beginning in CY 2021. We discussed the relationship between the new home infusion therapy benefit and the existing Medicare DME and home health benefits; the definition of infusion drug administration day; payment basis, limitation on payment, required and discretionary adjustments, and billing procedures; the professional/nursing services and monitoring related to the administration of home infusion drugs; and the role of prior authorization. Specifically, we requested comments on retaining the definition of ''infusion drug administration calendar day'', as proposed in section IV.C.2. of the proposed rule for the full implementation of the home infusion therapy services benefit, and invited 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 solicited comments on ways to account for therapy type and complexity of administration, as well as ways to capture patient acuity, and requested feedback on situations that may incur an outlier payment and potential designs for an outlier payment calculation. And finally, we invited comments on the unit of single payment; limitations on payment; prior authorization; and required and discretionary adjustments, and solicited any additional suggestions as to how qualified home infusion therapy suppliers should bill and be paid for services under the home infusion therapy benefit, including whether it is reasonable to require two separate claims submissions to account for different components of home infusion therapy.

As there is overlap between the provisions of the home infusion therapy services temporary transitional payment and the full home infusion therapy benefit to be implemented in 2021, many of the proposed rule comments we received pertained to both. However, while we did not include proposals regarding payment for home infusion therapy services for CY 2021 and beyond, we did receive several comments related specifically to implementation of the full benefit. These comments included suggestions regarding billing, payment basis and adjustments, prior authorization, and

the relationship between the home infusion and home health benefits. We appreciate commenters' review of, and input regarding the discussion of the home infusion benefit, and will give careful consideration to all comments received when implementing the permanent Medicare payment structure for home infusion therapy services.

We did receive several technical comments regarding certain provisions that are addressed in the responses in this section of this final rule with comment period.

Comment: Several commenters expressed concern with retaining the proposed definition of ''infusion drug administration calendar day'' for the full implementation of the home infusion therapy benefit in 2021 as required by the 21st Century Cures Act.

Response: While we did not formally propose a definition of ''infusion drug administration calendar day'' in the discussion of the full implementation of the home infusion therapy benefit in 2021, we will note that the clarification in section 1834(u)(7)(E)(i) of the Act, as added by the BBA of 2018, regarding ''infusion drug administration calendar day'' provides that this definition is with respect to the furnishing of ''transitional home infusion drugs'' or ''home infusion drugs'' to an individual by an ''eligible home infusion supplier'' or a ''qualified home infusion therapy supplier.'' As ''home infusion drugs'' and ''qualified home infusion therapy supplier'' are terms for the permanent benefit in the 21st Century Cures Act, this definition of ''infusion drug administration calendar day'' would pertain to both the temporary benefit and the full benefit.

Comment: A few commenters expressed concern with the potential exclusion of particular drugs from the full implementation of the home infusion therapy services benefit. Another commenter stated the understanding that Intravenous Immune Globulin (IVIG) is covered under the legislation enacted by the 21st Century Cures Act. Additionally, this commenter expressed concern with the conclusion of the Medicare IVIG demonstration as it relates to the full implementation of the home infusion therapy benefit and encouraged CMS to expedite the final report prior to the implementation of the benefit. Another commenter expressed concern that, because the legislation excludes drugs and biologicals on a self-administered drug (SAD) exclusion list, some subcutaneous immune globulins (SCIG) that are covered under the temporary transitional payment would be excluded from the benefit in 2021.

Response: We appreciate the commenter's concern regarding the conclusion of the IVIG demonstration; however, the timeline of the demonstration's final report is out of the scope of this rule. While section 50401 of the BBA of 2018 defines ''transitional home infusion drug'' by identifying the HCPCS codes for drugs under the LCD that are for coverage under the home infusion therapy services temporary transitional payment, the full implementation of the benefit in 2021 is less specific with regard to particular home infusion drugs. Section 1861(iii)(3)(C) of the Act defines a ''home infusion drug'' as 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. Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list. We understand commenter concern regarding certain drugs and biologicals, specifically SCIG and IVIG, and will continue to examine the scope of drugs covered under Part B, along with the criteria for inclusion on the Self-Administered Drug Exclusion list for full implementation of the home infusion therapy benefit in 2021.

Comment: A commenter urged CMS to ensure that coverage guidelines for home infusion therapy make continued coverage available even if the beneficiary and/or family member is unwilling or unable to be trained to assume responsibility for the infusion themselves.

Response: We should reiterate that the home infusion therapy benefit is intended for drugs that are administered through an item of DME. As DME must be appropriate for use in the home, DMEPOS supplier standards require suppliers to document that they or another qualified party provided beneficiaries with instructions and education on safe and effective operation of the equipment (42 CFR 424.57(c)(12)). CMS convened a technical expert panel (TEP) in August of 2018, during which TEP members concurred that despite a physician's belief that home infusion may be medically acceptable and appropriate for a patient, success is very individualized and to a great extent, patient-dependent. We solicited comments regarding a reasonable number of visits needed to train the patient and caregiver on safe and effective use of the pump, and many commenters supported our assumption of two visits the first week and then weekly thereafter. We also acknowledged that there may be patients that are unable or unwilling to self-administer, in which case the home would not be the appropriate site of care.

We appreciate commenter feedback and will take all comments under consideration while implementing the permanent home infusion therapy services benefit. We encourage commenters to submit additional comments regarding the full implementation of the benefit to the home infusion policy mailbox at *HomeInfusionPolicy@cms.hhs.gov.*

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 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 6 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 proposed 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 also proposed to modify the AO oversight regulations at § 488.5 by adding new requirements for training for AO surveyors.

B. 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 proposed adding a new provision to the approval and oversight regulations for AOs that accredit Medicare certified providers and suppliers 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 made this proposal because we have received numerous complaints from accredited and deemed facilities in good standing with their then-current AO stating that once they provide notification to the AO of their intent to voluntarily withdrawal their accreditation business from that AO, the AO frequently terminated 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. We do not believe it is reasonable for AOs to penalize facilities because they choose to terminate the services of an AO.

Providers and suppliers may be left without an accreditation status that would allow them to continue to participate in Medicare.

Comment: Several commenters expressed general support for our proposal 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, 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. A commenter stated that ''we agree with this proposed change because when a provider/supplier is accredited in good standing their accreditation should be good for the full term of their agreement with the accreditor.'' Another commenter stated the opinion that ''we agree that it is unreasonable for AOs to penalize facilities who choose to terminate the services of that AO, and as such, support this proposal. Another commenter stated full agreement with this proposal and stated that this is the standard operating procedure for this commenter's AO.

Response: We thank these commenters for their input.

Comment: Another commenter expressed agreement with the proposal regarding § 488.5(a)(17)(iii) and in addition, expressed the opinion CMS should require all AOs for Medicare certified providers and suppliers to document the dates of accreditation as the dates of the actual survey and acceptance of the plan of correction. This commenter argued that the requirement was necessary because AOs that accredit large multiple site providers/suppliers use a corporate accreditation cycle where the dates of the accreditation cycle are the same for all sites.

Response: We thank this commenter for their support for our proposal. We further that this commenter for the suggestion that CMS should consider a policy applicable to AOs that accredit large multiple site providers/suppliers which utilize a corporate accreditation cycle where the dates of the accreditation cycle are the same for all sites. However, this is an issue that is outside the scope of the proposed rule. We will take this information under advisement. We thank this commenter for bringing this concern to our attention.

Comment: A commenter expressed disapproval of our proposal, stating the proposal, as written, undermines the autonomy of this and all other AOs to enforce their own policies. The commenter also stated that each AO develops its own policies and procedures related to accreditation termination effective dates, which CMS subsequently approves.

The commenter also stated that this proposal would allow facilities to circumvent the mechanisms AOs for Medicare certified providers and suppliers have had in place for ongoing review of accredited facilities. The commenter believes that the rule, as written, would require this AO to maintain a facility's accreditation status regardless of the commenter AO's

policies and procedures related to termination of a facility's accreditation status. The commenter noted that throughout the accreditation process, participating facilities are obligated to comply with an AO's standards, policies, and procedures until an awarded accreditation term expires or terminates; therefore, this proposal would conflict with an AO's operation of its accreditation program and its authority to make accreditation decisions. The commenter strongly urged CMS to withdraw this requirement.

Response: We respectfully disagree with the views expressed by this commenter. We do not agree that the requirement would undermine the autonomy of this AO to enforce its own policies or conflict with commenter's AOs operation of its accreditation program and its authority to make accreditation decisions. This commenter provided no examples or explanation for how the addition of the proposed policy would do so.

It is our position that if an accredited provider or supplier has paid the agreed upon accreditation fees, successfully gone through the survey process, and is in good standing with their AO, but has, for whatever reason, decided to switch accreditation to another AO or to submit to a survey by a state agency, there is no justifiable reason for the current AO to cancel that provider/suppliers accreditation prior to the expiration date.

CMS has seen cases in which shortly after an AOs has been informed by one of its accredited providers/suppliers in good standing that said provide/supplier wishes to withdraw their accreditation business from that AO and become accredited by another AO (or obtain state certification), the current AO terminates that provider/suppliers accreditation, regardless of how much time remains on that provider's or supplier's existing term of accreditation. We believe that these instances of early termination of the accreditation of a provider/suppliers in good standing, with no performance or complaint issues who has recently informed their AO that they were switching to another AO are either retaliatory in nature, or done because these providers were no longer considered a viable source of revenue. We agree that it is unreasonable for AOs to penalize facilities who choose to terminate the services of that AO, and as such, support this proposal.

Final Decision: In consideration of the comments received, this provision will be added to 42 CFR 488.5(a)(17)(iii) as drafted, without modification.

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

We proposed 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 proposed 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 will 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.

At the time of the writing of the proposed rule, we believed that the disparity in findings made by the AO surveyors and those of the SA surveyors could 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. In the proposed rule, we stated that because each AO is an independent entity, the surveyor training and education provided by each AO to its surveyor's varies and is not consistent. We further stated that CMS provides comprehensive online training to the SA surveyor staff on the CMS Surveyor Training website [82] which are specific to each type of provider of supplier type to be surveyed.

In the proposed rule, we stated that it was our belief that the AO's disparity rate would be decreased if all surveyors took the same training. We further stated the belief that 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 rate. Therefore, we proposed that all AO surveyors be required to take the CMS online surveyor training offered on the CMS website. We further proposed to require each AO to provide CMS with documentation which provides proof that each surveyors had completed the CMS online surveyor training. Finally, we proposed that if the AO fails to provide this documentation, CMS could place the AO on an accreditation program review pursuant to § 488.8(c). We received a number of comments in response to this proposals.

Comment: Several commenters stated strong support CMS' proposal to require consistent, comprehensive training for AO surveyors.

Response: We thank these commenters for their support of our proposal.

Comment: Another commenter who supported CMS' proposal to require consistent, comprehensive training for AO surveyors stated that they did not believe the proposal went far enough. This commenter recommended that CMS undertake a rigorous review of the entire ''deemed status'' system. This commenter further stated concern that since these deemed-status health care providers are not subject to routine state certification surveys, they are not subject to the civil monetary penalties that could result from surveys conducted by state agencies. This commenter urged CMS to fix the flaws and loopholes in the deemed status program.

Response: We thank this commenter for their support of the proposal to require AO surveyors to take the CMS online surveyor training. We further thank this commenter for the remainder of their suggestions. As these suggestions are outside the scope of the

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

topics discussed in the proposed rule they will not be discussed here. However, we will take this commenters suggestions under advisement.

Comment: Several commenters urged CMS to consider including a corresponding decrease in CMS validation surveys for those AOs whose surveyors have completed the training, since the CMS online surveyor training which is supposed to decrease the disparity rate. Another commenter suggested that CMS resources devoted to validation surveys could be reduced, saving taxpayer dollars and lessening HHA time and effort spend on largely redundant surveys.

In support of the request to decrease the number of validation surveys to be performed if this requirement for surveyor training is finalized, a commenter pointed out that there are other administrative reviews including the RAC, Pre Claim Review, Probe & Educate, and routine MAC ADR probes that could assess an AOs compliance and performance. Another commenter stated that while there are ample enforcement tools, CMS has not clearly targeted these efforts to bad actors and high-value HHAs have had to divert resources from direct care to administrative functions. This commenter suggestion that audit frequency should be determined using current data along with Program for Evaluating Payment Patterns Electronic Report (PEPPER) reports to identify underperforming and/or noncompliant agencies and that audits should be limited to topics within statutory and regulatory parameters.

Response: CMS is currently in the process of reviewing and redesigning the validation process in an effort to make it more accurate, effective and less burdensome for facilities. While outside the scope of the proposals made, we will take the suggestions made by these commenters under advisement.

Comment: In this section of this final rule with comment period is a summary of the remainder of the comments received in response to our response to our proposal to require surveyors for the AOs that accredit Medicare certified providers and suppliers to the take CMS online surveyor training:

- A commenter recommended that CMS make the online surveyor trainings available but not mandatory for all AO surveyor so that each AO could then evaluate its own training and education materials and make an independent decision regarding how best to use the CMS training tools.
- A commenter stated that they support the CMS aim of reducing disparity rates, but that they cannot support the proposal as written due to its vagueness.
- Another commenter stated that the proposed rule offers little guidance on CMS implementation of this new requirement. Another commenter expressed concern regarding how this requirement would be fully operationalized.
- A commenter noted that the proposed rule does not specify the CMS online training courses for which it expects completion. Another commenter expressed the concern that it is unclear from the text of this rule, how often surveyors would be required to participate in the training.
- Several commenters stated the belief that there are ambiguities in the proposal that essentially create further opportunity for non-uniformity in surveyor training across the industry. Any non-uniformity in training could reduce the meaningfulness of any presumed links between surveyor training mandates and disparity rates that CMS hopes to identify and impact.
- Another commenter requested more clarity concerning training requirements including course enrollment expectations, frequency of course completion, and clarification regarding whether CMS intends to implement a reporting mechanism for AOs to validate surveyor course completion. This commenter expressed concern that, while the proposed rule proposed completion of ''relevant program specific CMS online trainings established for state surveyor,'' the variety of online training programs offered and the lack of specificity over the precise training modules required per program could create confusion over which precise training elements would be required for full rule compliance.
- Another commenter expressed doubt that a mandatory requirement for AO surveyors to take CMS online surveyor training would improve AO the disparity rates, and that reviewing online training does not guarantee surveyors will retain and then apply all the information from the trainings during their surveys.
- Several commenters strongly suggested that CMS needs to establish a measurable correlation between the proposal and the expected outcome before CMS proposes to require AOs to implement any costly program.
- Several commenters suggested that if CMS has questions and concerns with the current surveyor education provided by AOs, it seems like this would be an issue to be addressed when reevaluating that AO's own accreditation from CMS.
- A commenter also made the suggestion that CMS should also evaluate the length of surveys and determine whether it would make sense to have a minimum (or standard) length for all individuals surveying for a specific provider or supplier type. Or have a minimum (or standard) number of surveyors participating in each survey. This commenter stated the belief that there could be a number of factors involved in the disparity rate.
- Several commenters stated that they do not agree with CMS' assumptions that inconsistent training between SA surveyors and AO surveyors is the reason for high disparity rates. One of these commenters stated that they fail to see the correlation between different AO surveyor training programs and disparity rates when the disparity rate is a comparison of an SA survey result against an AO survey result and not a comparison between AOs.
- Another commenter recognizes that disparity rates are a constant challenge for CMS and AOs, and that root-cause factors driving high disparity rates are complex and multi-faceted. Yet another of these commenters stated that while surveyor training may be a factor that influences disparity rates, it is unclear whether mandating that AOs to require that surveyors complete CMS training modules will actually reduce the disparity rate. The hypothesis that mandating additional AO surveyor training will lower disparity rates is untested and unproven, and the basis for the hypothesis is unclear.
- Several commenters expressed the belief that unknown or alternative factors may truly drive high disparity rates and that there are multiple explanations as to why the disparity rate could be elevated that are not related to surveyor training. For example, according to these commenters, it is possible that there could be variance or issues with the validation surveyors. Reviewing online training does not guarantee surveyors will retain and then apply all the information from the trainings during their surveys.
- A number of commenters raised the following points in objection to our proposal that AO surveys complete CMS-provided mandatory surveyor training:

++ CMS reviews and approves all AO training, verifying its adequacy.

++ State agency surveyors are not required to have actual experience in the health care field for which they survey. This commenter stated that at least one accreditor requires a minimum of 5 years' experience in the same field that they will survey, thus making them a subject matter expert.

++ State agencies send multiple surveyors for multiple days, where AOs

usually send one surveyor for 2 to 5 days. The length of the survey depends on the number of unduplicated admissions the facility bills over a 12 month period.

++ State agencies cite the same deficiencies multiple times. AOs normally do not.

++ There is not an appeal process for the AO in regard to a validation survey. When a validation survey comes back with deficiencies that the AO did not cite and does not agree with, CMS only accepts the state validation surveyors' deficiencies as accurate.

• Several commenters expressed concern that this new requirement would place significant new burden on AOs.

A commenter recommended that CMS delay implementation of the current proposal, and instead bring together accreditation organizations and providers and suppliers to more fully explore how to improve disparity rates between AO and validation surveys. Several other commenters encouraged CMS to engage the AOs directly in both the initiative to reduce disparity rates and on any initiatives that may impact AO accreditation program operations.

*General Respons*e: We agree with these commenters that the text of this section of the proposed rule may have been unclear about how the requirement for online surveyor training was to be operationalized and that it was not clear about the number and types of training the AO surveyor would have to take. While we do believe that the disparity rate would be decreased somewhat by the requirement that AO surveyors take the CMS online surveyor training, at this time CMS is not able to demonstrate that such training will significantly reduce the validation disparity rate. After consideration of the comments received, we acknowledge that root-cause factors driving high disparity rates are complex and multi-faceted and that there are a number of other factors that could have an impact on the disparity. We also acknowledge that while surveyor training may be a factor that influences disparity rates, it is unclear whether requiring that AOs require that surveyors complete CMS training modules will reduce the disparity rate. Therefore, after consideration of the comments received, we have decided not to finalize our proposal to require the surveyors for AOs that accredit Medicare certified providers and suppliers to take the CMS online surveyor training. However, it is important to note that many of the AOs' disparity rates have been consistently high. We are continuing to monitor these rates and look for ways to reduce them.

Final Decision: After consideration of the comments received, we have decided not to finalize our proposal to require the surveyors for AOs that accredit Medicare certified providers and suppliers to take the CMS online surveyor training.

VIII. Requests for Information

This section addressed two requests for information (RFI).

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

In the CY 2019 HH PPS proposed rule (83 FR 32471 through 32473), we included a Request for Information (RFI) related to promoting interoperability and electronic health care information exchange. We received approximately 28 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

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

In the CY 2019 HH PPS proposed rule (83 FR 32473 and 32474), we included a Request for Information (RFI) related to price transparency and improving beneficiary access to home health agency charge information. We received approximately 15 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

IX. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management 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 42 presents the mean hourly wage rate, fringe benefits costs and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 42: 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 final rule with comment period makes reference to associated information collections that are not discussed in the regulation text contained in this document. These final changes are associated with the information collection request (ICR)—Outcome and Assessment Information Set (OASIS) OASIS–C2/ICD–10 (CMS–10545), approved under OMB control number 0938–1279. We note that on March 12, 2018 (83 FR 10730) we published a notice in the **Federal Register** seeking public comment on a revision to CMS–10545 (OMB control number 0938–1279), which will 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 . We solicited public comment on additional changes related to when certain OASIS items are required to be completed by HHA clinicians due to the implementation of the patient-driven groupings model (PDGM) for CY 2020, as outlined in section III.F of this final rule with comment period; and the changes to due to the removal of HH QRP measures beginning with the CY 2021 HH QRP, as outlined in section V.E. of this final rule with comment period.

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 this final rule with comment period, we are removing the Depression Assessment Conducted Measure from the HH QRP under measure removal Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. Removing this measure will not impact our 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.[83]

In section V.E.2. of this final rule with comment period, we are removing the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP under measure removal 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 removing this one data element at the TOC and Discharge time points.

In section V.E.3. of this final rule with comment period, we are removing the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP under measure removal 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 removing this one data element at the SOC/ROC time point.

In section V.E.4. of this final rule with comment period, we are removing the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP, under measure removal 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 removing these two data elements at the TOC and Discharge time points.

In section V.E.5. of this final rule with comment period, we are removing the Improvement in the Status of Surgical Wounds Measure from the HH QRP under measure removal Factor 4: A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. Removing this measure will not impact our collection of information because OASIS Items M1340 and M1342 are 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.[84] [85]

In sections V.E.6. and V.E.7. of this final rule with comment period, we are removing the Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure and the Rehospitalization during the First 30

[83] 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).

[84] 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).

[85] 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*).

Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP under measure removal Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. Because these are both claims-based measures, removing them will not impact our collection of information.

In summary, we are finalizing 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 removals 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 final rule with comment period, to calculate the case-mix adjusted payment amount for the PDGM, we are finalizing our proposal to add collection of two current OASIS items (10 data elements) at the follow-up (FU) time point:

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

As outlined in section III.F of this final rule with comment period, several OASIS items will not be needed in case-mix adjusting the period payment for the PDGM; therefore, 19 current OASIS items (48 data elements) are 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 finalizing 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, as a net result of the policies we are finalizing in this final rule with comment period, we will be removing 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 removals from the HH QRP and the 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 is 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 physical therapists (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 41. Individual providers determine the staffing resources necessary.

Table 43 shows the total number of assessments submitted in CY 2017 and estimated burden at each time point.

TABLE 43: 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) x (clinician burden [min]/60) x ($70.75 [weighted clinician average hourly wage]).

Based on the data in Table 43 for the 11,623 active Medicare-certified HHAs in April 2018, we estimate the total average decrease in cost associated with 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 burden decrease will be accounted for in the information collection under OMB control number 0938–1279. We did not receive comments on collection of information requirements associated with the OASIS.

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 Century 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 requirement will 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. We did not receive any comments from the public, either in agreement or opposition, regarding our estimation of burden for information collection requirements in relation to the implementation of the home infusion therapy standards as delineated by section 5012 of the 21st Century Cures Act; therefore, we are finalizing this estimate without modification.

We did not receive any comments from the public, either in agreement or opposition, regarding our estimation of burden for information collection requirements in relation to the implementation of the home infusion therapy standards as delineated by section 5012 of the 21st Century Cures Act; therefore, we are finalizing this estimate without modification.

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

1. Background

We are finalizing 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 will impose burden on those new AOs that seek approval of their Home Infusion Therapy accreditation program. This burden will 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 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 a 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 will be imposed only on those national AOs that accredit home infusion therapy suppliers.

At this time, there are five CMS-approved HHA AOs that provide home infusion therapy accreditation as part of the deeming accreditation of home health agencies. These HHA AOs are The Joint Commission (TJC), the Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), the Community Health Accreditation Partner (CHAP), and the Healthcare Quality Association on Accreditation.

There are three pharmacy association AOs that provide non-CMS approved home infusion therapy accreditation. These non-CMS approved Home infusion AOs are the National Association of Boards of Pharmacy, the Centers for Pharmacy Practice Accreditation (CPPA) and URAC).

In this final rule with comment period, we have 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 will 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 will accredit home infusion therapy suppliers will 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 will 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.

We did not receive comments on these information collection requirements.

E. ICR Regarding Modifications to 42 CFR 488.5

We are modifying the AO approval and oversight regulations for Medicare certified providers and suppliers by adding a new requirement. Section 488.5(a)(17)(iii) will 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.

An AO would prepare this written statement as part of the preparation of the initial or renewal applications they submit to CMS seeking initial and renewal approval of the CMS approval

of their accreditation program. This statement would be included in a written document with other required written statements. As the AO would already be in the process of preparing the documentation for their application, we believe that there would be little, if any burden associated with the preparation of this statements.

We believe that it would take no more than 15 minutes for the AO to add this statement to the written document containing all the statements and affirmations that AO must submits as a condition of approval. We believe that this task would be performed 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 of the required statement in the amount of $14.28 ($28.56 × 15 minutes = $7.14) + ($7.14 for fringe benefits and overhead).

We had also proposed to add a new requirement at § 488.5(a)(7) to require surveyors for AOs that accredit non-certified providers and suppliers to take the CMS online surveyor training. However, after consideration of the public comments received regarding this proposal, we have decided not to finalize the proposal.

F. Submission of PRA-Related Comments

We have submitted a copy of this final rule with comment period 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–F) 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 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.

X. 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 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.D. of this final rule with comment period), the Secretary will establish three payment categories at amounts equal to the amounts determined under the Physician Fee Schedule established under section 1848 of the Act 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 $420 million (2.2 percent). The net transfer impact in CY 2020 related to the change in the unit of payment under the 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 $48 million. The savings impacts related to the HHVBP model as a whole are estimated at $378 million for CYs 2018 through 2022. Due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020, we estimate that this rule generates $60 million in annualized cost savings, or $46 million per year on an ongoing basis 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 $35,711. The cost of $12,453 would be incurred by the home infusion AO for the preparation and submission of their initial application to CMS seeking CMS approval of the AO's home infusion therapy accreditation program. The AO will incur this $12,453 cost with the submission of their initial application and then every 6 years thereafter, with the submission of their renewal application. The remaining costs of $23,258, which represents the costs associated with the home infusion therapy AO's participation in ongoing CMS AO overview, monitoring and program review activities will be incurred on a bi-yearly basis.

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 in this final rule with comment period will 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 final 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 604 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 final rule with comment period 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 final 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 final rule with comment period 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 final rule with comment period, 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 final rule would be the similar to the number of reviewers of last year's final 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 believe 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 final rule with comment period. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule with comment period, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. 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 final rule with comment period, 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 $420 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 final rule with comment period. Therefore, the estimated impact of the 2019 wage index and the recalibration of the case-mix weights for CY 2019 is $0 million. The $420 million increase reflects the distributional effects of the CY 2019 home health payment update of 2.2 percent ($420 million increase), a 0.1 percent increase in payments due to the new lower FDL ratio, which will increase outlier payments 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 $420 million in increased payments is reflected in the last column of the first row in Table 44 as a 2.2 percent increase in expenditures when comparing CY 2018 payments to estimated CY 2019 payments.

With regard 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 (PDGM)

We estimate no net impact of the 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. 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 final rule with comment period, we 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 final rule with comment period. 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.[86] 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 finalized 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 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 home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations (including the applicable provisions in the Federal Food, Drug, and Cosmetic Act).

All current standards established by AOs already address the 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 health and safety standards. Additionally, we assume that these 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 $48 million (not including $12 million in beneficiary cost-sharing) in increased Medicare payments to home infusion suppliers in CY 2019. This increase reflects the cost of providing infusion therapy services to existing Medicare beneficiaries who are receiving DME home infusion therapy (at a 4-hour rate), as the temporary transitional payment applies only to existing Medicare eligible 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). Prior to the implementation of the temporary transitional payment, home infusion suppliers have not been separately paid 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

[86] CY 2017 OASIS assessments matched to Medicare FFS claims (as of March 2, 2018).

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 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 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.

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 i§§ 488.1010 through 488.1050. The following is a discussion of the burden associated with specific sections of the home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050.

(a) Burden for Home Infusion Therapy AOs Associated With § 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 § 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 § 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 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 five HHA AOs that accredit home infusion therapy suppliers as part of the deeming accreditation of a home health accreditation program (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)). The other three home infusion therapy AOs are pharmacy associations that provide non-Medicare approved accreditation to home infusion therapy suppliers. (That is, the National Association of Boards of Pharmacy, the Center for Pharmacy Practice Accreditation (CPPA) and URAC). The home infusion therapy accreditation programs offers by these 8 AO have not been approved under the requirements of section 1834(u)(5)(A) of the Act. Therefore, 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 eight 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 $64,116 ($4,007.25 × 8 AOs = $32,058) + ($32,058 for fringe benefits and overhead).

To obtain this CMS approval, 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 new home infusion therapy AO approval and oversight regulations set forth at § 488.1010(a)(1) through (a)(24) and the new home infusion therapy health and safety regulations at 42 CFR part 466, subpart I. We have further 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 § 488.1030

In accordance with § 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.

Section 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. Section 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.

Section 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. There is uncertainty around our estimate of 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 five HHA AOs that accredit home infusion therapy suppliers as part of the deeming accreditation of a home health accreditation program (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)). The other three home infusion therapy AOs are pharmacy associations that provide non-Medicare approved accreditation to home infusion therapy suppliers (that is, the National Association of Boards of Pharmacy, the Center for Pharmacy Practice Accreditation (CPPA) and URAC). The home infusion therapy accreditation programs offers by these 8 AO have not been approved under the requirements of section 1834(u)(5)(A) of the Act. If all of these eight 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 $2,828.80 ($176.80 × 8 AOs = $1,414.40) + ($1,414.40 for fringe benefits and overhead). As provided by § 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 eight 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), National Association of Boards of Pharmacy), the Center for Pharmacy Practice Accreditation (CPPA) and URAC. If all of these eight 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 $114.24 ($7.14 × 8 AOs = $57.12) + ($57.12 for fringe benefits and overhead).

Section § 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 ($4,007.25 × 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 § 488.1030(c), CMS will perform a standards review when the home infusion therapy AO makes updates to its accreditation standards and surveys processes. Section 488.1030(c)(1) would require that when a home infusion therapy AO proposed 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 implementation date of the revised standards. Section 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. Section 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 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 changes. Section 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 § 488.1030(c) or (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 § 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 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.

Section 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. Section 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 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). Section 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. Section 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 home infusion therapy AO approval and oversight regulation or the 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 is unlikely to ever be a situation in which all 8 potential AOs would be under an accreditation program review at the same time.

(c) Burden for Home Infusion Therapy AOs Associated With § 488.1035

Section 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. Section 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 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 8 home infusion therapy AOs for these tasks would be $424.32 ($53.04 × 8 home infusion therapy AOs = $424.32).

Section 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 8 home infusion therapy AOs for these tasks would be $282.88 ($35.36 × 8 home infusion therapy AOs = $282.88).

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 8 home infusion therapy AOs for these tasks would be $141.44 ($17.68 × 8 home infusion therapy AOs = $141.44). The estimated yearly cost across the 6 potential home infusion therapy AOs would be $1,697.28 ($17.68 × 8 AOs = $141.44 per all AOs per month and $141.44 per year × 12 months per year = $1,697.28). Section 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 8 home infusion therapy AOs for these tasks would be $424.32 ($53.04 × 8 home infusion therapy AOs = $424.32). The estimated yearly cost across the 8 potential home infusion therapy AOs would be $5,091.84 ($53.04 × 8 AOs = $424.32 per all AOs per month and $424.32 per year × 12 months per year = $5,091.84).

Section 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 § 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 8 potential home infusion therapy AOs for this task would be $707.20 ($88.40 × 8 potential home infusion therapy AOs = $707.20).

Section 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 8 potential home infusion therapy AOs would be $707.20 ($70.72 × 8 = $565.76) + ($17.68 × 8 = $141.44).

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.

Section 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.

Section 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. Section 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) and (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 § 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.

(d) Burden for Home Infusion Therapy AOs Related to § 488.1040

Section 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. Section 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 eight home infusion therapy AOs would be $9,052.16 ($1,131.52 × 8 potential AOs = $9,052.16).

In this final rule with comment period, we have the eight 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 § 488.1045

Section § 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. Section 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.

Section 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 § 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.

Section 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.

Section 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 § 488.1050

Section 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.

Section 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. Section 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. Section 488.1050(c)(1) provides the opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and § 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 solicited comment on how to estimate this burden and receive none.

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 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 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 new home infusion therapy AO approval and oversight regulations and 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 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 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 are implementing 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 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 proposed to require the AOs for home infusion therapy suppliers to submit their 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 proposed to modify the AO approval and oversight regulations for Medicare-certified providers and suppliers by adding two new requirements. The first new requirement would have been to add to 42 CFR 488.5(a)(7) a requirement that in their application for CMS approval, the AOs that accredited Medicare-certified providers and suppliers 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. As stated previously, after consideration of the numerous comments we received in response to this proposal, we decided not to finalize this proposal. Therefore the burden estimates provided in the proposed rule regarding the proposed time and cost burden related to the requirement that AO surveyors take the CMS online surveyor training are no longer relevant.

The second requirement was to add § 488.5(a)(18)(iii) to 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. As stated previously, we have made a decision to finalize this proposal without change or modifications.

(1) Burden Associated With the Online Training Requirement for AO Surveyors

A number of commenters expressed concern that the requirement that AO surveyors take the CMS online training would impose significant burden on the surveyors. Other commenters stated the belief that the AO training was adequate and that it was similar to the CMS online training, therefore the training requirement would be duplicative. Therefore, after consideration of the comments received, we have decided not to finalize the proposal to require AO surveyors to take the CMS online surveyor training.

(2) Burden Associated With the Statement Requirement for AOs

We finalized 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.

Section 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 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 6 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 finalizes 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 final rule with comment period presents the estimated expenditure effects of policy changes in this final rule with comment period. 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 44 represents how HHA revenues are likely to be affected by the policy changes 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 44 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 in this rule. Overall, it is projected that aggregate payments in CY 2019 would increase by 2.2 percent. As illustrated in Table 44, 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.

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TABLE 44: 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	10,582	0.0%	0.0%	-0.1%	0.1%	2.2%	2.2%
Facility Type and Control							
Free-Standing/Other Vol/NP	1,062	-0.4%	0.0%	0.0%	0.2%	2.2%	2.0%
Free-Standing/Other Proprietary	8,432	0.1%	0.0%	-0.1%	0.1%	2.2%	2.3%
Free-Standing/Other Government	252	0.3%	0.2%	-0.1%	0.2%	2.2%	2.8%
Facility-Based Vol/NP	590	-0.1%	0.1%	0.0%	0.2%	2.2%	2.4%
Facility-Based Proprietary	64	-0.5%	0.2%	-0.2%	0.2%	2.2%	1.9%
Facility-Based Government	182	0.0%	0.2%	-0.3%	0.2%	2.2%	2.3%
Subtotal: Freestanding	9,746	0.0%	0.0%	-0.1%	0.1%	2.2%	2.2%
Subtotal: Facility-based	836	-0.1%	0.1%	-0.1%	0.2%	2.2%	2.3%
Subtotal: Vol/NP	1,652	-0.3%	0.0%	0.0%	0.2%	2.2%	2.1%
Subtotal: Proprietary	8,496	0.1%	0.0%	-0.1%	0.1%	2.2%	2.3%
Subtotal: Government	434	0.1%	0.2%	-0.2%	0.2%	2.2%	2.5%
Facility Type and Control: Rural							
Free-Standing /Other Vol/NP	255	-0.2%	0.2%	-0.3%	0.2%	2.2%	2.1%
Free-Standing /Other Proprietary	836	0.7%	0.1%	-0.7%	0.1%	2.2%	2.4%
Free-Standing /Other Government	167	0.4%	0.2%	-0.2%	0.2%	2.2%	2.8%
Facility-Based Vol/NP	263	0.2%	0.3%	-0.3%	0.2%	2.2%	2.6%
Facility-Based Proprietary	33	0.1%	0.4%	-0.5%	0.1%	2.2%	2.3%
Facility-Based Government	140	0.3%	0.3%	-0.4%	0.2%	2.2%	2.6%
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	807	-0.4%	0.0%	0.0%	0.2%	2.2%	2.0%
Free-Standing /Other Proprietary	7,596	0.0%	0.0%	0.0%	0.1%	2.2%	2.3%
Free-Standing /Other Government	85	0.2%	0.1%	0.0%	0.1%	2.2%	2.6%
Facility-Based Vol/NP	327	-0.2%	0.1%	0.0%	0.2%	2.2%	2.3%
Facility-Based Proprietary	31	-0.9%	0.1%	0.0%	0.2%	2.2%	1.6%
Facility-Based Government	42	-0.3%	0.1%	-0.1%	0.1%	2.2%	2.0%
Facility Location: Urban or Rural							
Rural	1,694	0.5%	0.2%	-0.6%	0.1%	2.2%	2.4%
Urban	8,888	-0.1%	0.0%	0.0%	0.1%	2.2%	2.2%
Facility Location: Region of the Country (Census Region)							
New England	364	-1.0%	0.0%	0.0%	0.2%	2.2%	1.4%
Mid Atlantic	483	-0.3%	-0.1%	0.0%	0.2%	2.2%	2.0%
East North Central	2,037	-0.3%	0.1%	0.0%	0.1%	2.2%	2.1%
West North Central	708	-0.1%	0.0%	0.0%	0.2%	2.2%	2.3%
South Atlantic	1,649	0.0%	-0.3%	0.0%	0.1%	2.2%	2.0%
East South Central	423	0.1%	-0.2%	-0.5%	0.1%	2.2%	1.7%
West South Central	2,777	0.7%	0.3%	-0.3%	0.1%	2.2%	3.0%
Mountain	682	-0.5%	0.0%	0.1%	0.2%	2.2%	2.0%
Pacific	1,419	0.3%	0.3%	0.0%	0.1%	2.2%	2.9%
Other	40	0.8%	-0.5%	0.0%	0.2%	2.2%	2.7%
Facility Size (Number of First Episodes)							

	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
< 100 episodes	2,866	0.0%	0.5%	0.0%	0.2%	2.2%	2.9%
100 to 249	2,266	0.1%	0.5%	-0.1%	0.1%	2.2%	2.8%
250 to 499	2,237	0.1%	0.3%	-0.1%	0.1%	2.2%	2.6%
500 to 999	1,678	0. 1%	0.1%	-0.1%	0.1%	2.2%	2. 4%
1,000 or More	1,535	-0.1%	-0.1%	-0.1%	0.1%	2.2%	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 final rule with comment period.
[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 final rule with comment period.
[3]The CY 2019 home health payment update percentage reflects the home health payment update of 2.2 percent as described in section III.C.2. of this final rule with comment period.

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 (PDGM)

Table 45 represents how HHA revenues are likely to be affected by the policy changes 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 45 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 PDGM as outlined in section III.F of this final rule with comment period. As illustrated in Table 45, the effect of the 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 final rule with comment period, 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 follow-up (FU) time point starting January 1, 2020. As also discussed in section III.F. of this final rule with comment period, 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 X. of this final rule with comment period provides a detailed description of the net decrease in burden associated with these changes in conjunction with the changes in burden that result from OASIS item collection changes due to the removal of certain measures required under HH QRP, also effective for January 1, 2020 as outlined in section V.E. of this final rule with comment period. Due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020, we estimate that this rule generates $60 million in annualized cost savings, or $46 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

TABLE 45: IMPACTS OF PDGM, CY 2020

	Number of Agencies	PDGM
All Agencies	**10,520**	**0.00%**
Facility Type and Control		
Free-Standing/Other Vol/NP	1,055	1.8%
Free-Standing/Other Proprietary	8,377	-0.9%
Free-Standing/Other Government	252	0.6%
Facility-Based Vol/NP	590	2.8 %
Facility-Based Proprietary	64	4.0%
Facility-Based Government	182	3.9%
Subtotal: Freestanding	9,684	-0.3%
Subtotal: Facility-based	836	3.0%
Subtotal: Vol/NP	1,645	2.1%
Subtotal: Proprietary	8,441	-0.8%
Subtotal: Government	434	2.3%
Facility Type and Control: Rural		
Free-Standing/Other Vol/NP	256	3.3%
Free-Standing/Other Proprietary	836	4.1%
Free-Standing/Other Government	167	0.7%
Facility-Based Vol/NP	263	3.1%
Facility-Based Proprietary	33	11.1%
Facility-Based Government	140	5.1%
Facility Type and Control: Urban		
Free-Standing/Other Vol/NP	799	1.7%
Free-Standing/Other Proprietary	7,541	-1.5%
Free-Standing/Other Government	85	0.5%
Facility-Based Vol/NP	327	2.8%
Facility-Based Proprietary	31	0.3%
Facility-Based Government	42	2.8%
Facility Location: Urban or Rural		
Rural	1,695	3.8%
Urban	8,825	-0.6%
Facility Location: Region of the Country (Census Region)		
New England	355	2.0%
Mid Atlantic	480	2.4%
East North Central	2,019	-1.3%
West North Central	706	-4.2%
South Atlantic	1,647	-5.1%
East South Central	423	1.0%
West South Central	2,753	4.6%
Mountain	679	-5.0%
Pacific	1,417	3.8%
Outlying	41	10.6%
Facility Size (Number of 60-day Episodes)		
< 100 episodes	2,804	2.4%
100 to 249	2,267	1.4%
250 to 499	2,237	1.0%
500 to 999	1,677	-0.1%
1,000 or More	1,535	-0.4%

	Number of Agencies	PDGM
Nursing/Therapy Visits Ratio		
1st Quartile (Lowest 25% Nursing)	2,630	-9.6%
2nd Quartile	2,630	-1.0%
3rd Quartile	2,630	6.2%
4th Quartile (Top 25% Nursing)	2,630	17.3%

Source: CY 2017 Medicare claims data (as of June 30, 2018) for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment.

Notes: The "PDGM" is the 30-day version of the model with no behavioral assumptions applied. From the impact file, this analysis omits 358,219 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 29 periods were excluded with missing NRS weights, and 2,439 periods with a missing urban/rural indicator. These excluded episodes results overall in 67 fewer HHAs being represented than in the standard impact tables. The standard 30-day payment amount used to achieve impact neutrality is $1,883.34, a 17.40% increase from the standard 2019 amount ($1,604.24).

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 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 46 which provides more information on the impact of the PDGM case-mix adjustment methodology for patients with selected clinical conditions.

TABLE 46: IMPACT OF THE PDGM FOR SELECTED PATIENT CHARACTERISTICS

	Ratio of Average PDGM Payment to Average Current (30-Day Equivalent) Payment
All Episodes (30-day Non-LUPA)	**1.00**
Clinical Group	
Behavioral Health	0.85
Complex	1.06
MMTA - Cardiac	0.99
MMTA - Aftercare	1.09
MMTA - Endocrine	1.09
MMTA - GI/GU	0.98
MMTA - Infectious	1.01
MMTA - Respiratory	0.97
MMTA - Other	0.96
MS Rehab	0.97
Neuro Rehab	0.93
Wound	1.25
Functional Impairment Level	
Low	0.95
Medium	0.99
High	1.06
Admission Source	
Community	0.89
Institutional	1.29
Timing	
Early	1.25
Late	0.87
Comorbidity Group	
No adjustment	0.97
Single Comorbidity	1.02
Comorbidity Interaction	1.15
Dual Status	
Not (Full) Dual Eligible	0.99
Yes (Full) Dual Eligible	1.03
Parenteral Nutrition	
No Parenteral Nutrition	1.00
Yes Parenteral Nutrition	1.12
Surgical Wounds	
No Known Surgical Wound	0.98
Yes Known Surgical Wound	1.10
Ulcers	
No Ulcers Recorded	0.99
Positive Number of Ulcers Recorded	1.15
Bathing	
Able to Bathe with some independence	0.98
Cannot bathe independently	1.08
Poorly-Controlled Cardiac Dysrhythmia	
No Poorly-Controlled Cardiac Dysrhythmia	1.00
Yes Poorly-Controlled Cardiac Dysrhythmia	1.05
Poorly-Controlled Diabetes	

	Ratio of Average PDGM Payment to Average Current (30-Day Equivalent) Payment
No Poorly-Controlled Diabetes	0.99
Yes Poorly-Controlled Diabetes	1.08
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
Yes Poorly-Controlled Pulmonary Disorder	1.01
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	0.99
No Fragile/Serious Health Risk	1.04

Notes: **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 ($1,604.24) to facilitate an understanding of reallocation of payments from the current system: for the ratio of PDGM to current payments in the right-most 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
Pulmonary Disorder: (I40-47, J84.01, J84.02, J84.03, J84.10, J96.0-J96.92, & J98.01-J98.3)

2. HHVBP Model

Table 47 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 finalized changes, each of which will 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);
- 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 will 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 will 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 of the changes finalized in this rule. 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 48 displays our analysis of the estimated impact of the policies finalized 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 47. 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 48 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 Linear Exchange Function 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 48, 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 48 shows the distribution of percentage change in payment adjustment percentage resulting from the policies finalized 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 finalized 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 changes would decrease their payment adjustment percentage by −2.5 percent or more while, for another 7 HHAs these 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 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 changes would be modest.

Table 49 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 policies finalized in this rule based on the 50th percentile of the impact of the changes on payment adjustment percentage.

Table 50 shows the current and revised weights, as finalized in this rule, 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 Finalized Weights columns show the revised weights for the individual performance measures based on the changes to the weighting methodology finalized in this final rule with comment period; specifically, to weight the measure categories so that the OASIS-based measure category and the claims-based measure category will each count for 35 percent and the HHCAHPS measure category will 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. For example, for HHAs with scores on All Measures, the OASIS-based measures account for 35 percent, with equal weighting given to the Improvement in Oral Medications, Improvement in Dyspnea, Improvement in Pain, and Discharge to Community measures. The Composite Self-Care and Composite Mobility measures will 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 are replacing (Improvement in Ambulation, Bathing and Bed Transferring). Under the revised weights, the two claims-based measures, which will collectively account for 35 percent, will not be weighted equally. We are finalizing that the weight of the acute care hospitalization measure will be three times higher than that of the ED Use measure. Thus, its weight will be 26.25 percent while the weight of the ED Use measure will be 8.75 percent for an HHA that reported on all measures. The HHCAHPS measures will account for 30 percent and each measure will be weighted equally.

Table 50 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 revised weighting methodologies. Most of the HHAs that would no longer receive a payment adjustment with the changes finalized in this rule are those with no claims or HHCAHPS measures. With only OASIS measures, these HHAs are more impacted by the finalized policy to remove the two immunization measures and the finalized policy to replace three OASIS functional measures with the two composite measures. The number of HHAs without claims or HHCAHPS measures that would have enough OASIS-based measures to receive a payment adjustment would drop from 99 to 73 (a decrease of 26 HHAs), and the majority of these HHAs would be smaller HHAs (16 of the 26 HHAs).

TABLE 47: 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 48: 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 Finalized 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 49: PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS FOR THE HHVBP MODEL

[Based on a 7-percent payment adjustment [1, 2]]

Cohort	Number of Eligible HHAs			Distribution of Percentage Change in Payment Adjustment Percentage Resulting From Finalized Changes				
	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-mix 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%.

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

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

Notes:

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

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

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

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. In section V.G. of this final rule with comment period, we revised 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. There are no changes in this final rule with comment period in our method for applying the 2 percentage point reduction to HHAs that fail to meet the HH QRP requirements. 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.

In section V.E. of this final rule with comment period, we are 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), and Rehospitalization during the First 30 Days of HH (NQF #2380). Their associated burden decreases are for CY 2020 because HHAs will no longer be required to submit data on these measures beginning CY 2020. As noted previously, section X. of this final rule with comment period provides a detailed description of the net decrease in burden associated with these changes in conjunction with the changes in burden that result from the implementation of the PDGM for CY 2020. Due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020; we estimate that this rule generates $60 million in annualized cost savings, or $46 million per year on an ongoing basis 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 51 represents the estimated increased Medicare costs of existing beneficiaries who are furnished DME and are 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.[87] At the time of publication, we did not have the 2019 Physician Fee Schedule rate in order to complete our impact analysis; however, actual payments starting on January 1, 2019 would be based on the Physician Fee Schedule amounts as specified in section 50401 of the BBA of 2018.

TABLE 51: ESTIMATED INCREASED MEDICARE COSTS OF EXISTING BENEFICIARIES WHO ARE FURNISHED DME AND ARE CURRENTLY USING HOME INFUSION THERAPY SERVICES, CY 2019

BBA of 2018 Category	Number of Beneficiaries	Total Weeks of Care	Estimated Total Visits of Care	Payment Rate	Estimated Cost
1	6,141	134,575	140,716	141.12	$19,857,842
2	6,713	256,177	80,556	224.28	$18,067,100
3	5,932	90,097	96,029	239.76	$23,023,913
Estimated Medicare Costs				80%	$48,759,084
Estimated Beneficiary Costs				20%	$12,189,771
Total	18,786				$60,948,855

Source: CY 2017 Medicare DME claims data as of June 30, 2018 containing HCPCS codes equal to one of the 37 codes listed in BBA of 2018.

Table 52 displays the estimated regional impacts using the beneficiary enrollment address reported in the Medicare Master Beneficiary Summary File. Table 53 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

[87] 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.

information in the Master Beneficiary Summary File. Additionally, the tables provide the estimated impacts by drug category.

TABLE 52: ESTIMATED IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES BY REGION, CY 2019

Census Division	Number of Home Infusion Patients	Total Estimated Costs [in $]				Estimated Medicare Costs (80% of Total) [in $]				Estimated Beneficiary Costs (20% of Total) [in $]			
		Category 1	Category 2	Category 3	Total	Category 1	Category 2	Category 3	Total	Category 1	Category 2	Category 3	Total
New England	748	$ 060,799.04	906,988.32	266,373.36	**2,234,160.72**	848,639.23	725,590.66	213,098.69	**1,787,328.58**	212,159.81	181,397.66	53,274.67	**446,832.14**
Mid-Atlantic	3,620	2,792,764.80	1,663,260.48	8,922,428.64	**13,378,453.92**	2,234,211.84	1,330,608.38	7,137,942.91	**10,702,763.13**	558,552.96	332,652.10	1,784,485.73	**2,675,690.79**
East North Central	2,606	3,297,409.92	1,851,655.68	3,478,438.08	**8,627,503.68**	2,637,927.94	1,481,324.54	2,782,750.46	**6,902,002.94**	659,481.98	370,331.14	695,687.62	**1,725,500.74**
West North Central	1,350	1,212,220.80	1,442,568.96	1,685,273.04	**4,340,062.80**	969,776.64	1,154,055.17	1,348,218.43	**3,472,050.24**	242,444.16	288,513.79	337,054.61	**868,012.56**
South Atlantic	4,620	4,508,925.12	5,178,176.64	4,685,150.16	**14,372,251.92**	3,607,140.10	4,142,541.31	3,748,120.13	**11,497,801.54**	901,785.02	1,035,635.33	937,030.03	**2,874,450.38**
East South Central	1,267	1,363,219.20	1,647,112.32	693,625.68	**3,703,957.20**	1,090,575.36	1,317,689.86	554,900.54	**2,963,165.76**	272,643.84	329,422.46	138,725.14	**740,791.44**
West South Central	1,796	2,616,082.56	1,924,322.40	973,185.84	**5,513,590.80**	2,092,866.05	1,539,457.92	778,548.67	**4,410,872.64**	523,216.51	384,864.48	194,637.17	**1,102,718.16**
Mountain	888	994,896.00	1,474,865.28	297,062.64	**2,766,823.92**	795,916.80	1,179,892.22	237,650.11	**2,213,459.13**	198,979.20	294,973.06	59,412.53	**553,364.79**
Pacific	1,821	1,983,723.84	1,937,779.20	1,917,600.48	**5,839,103.52**	1,586,979.07	1,550,223.36	1,534,080.38	**4,671,282.81**	396,744.77	387,555.84	383,520.10	**1,167,820.71**
Other	70	27,800.64	40,370.40	104,775.12	**172,946.16**	22,240.51	32,296.32	83,820.10	**138,356.93**	5,560.13	8,074.08	20,955.02	**34,589.23**
Total	**18,786**	**19,857,841.92**	**18,067,099.68**	**23,023,913.04**	**60,948,854.64**	**15,886,273.54**	**14,453,679.74**	**18,419,130.42**	**48,759,083.70**	**3,971,568.38**	**3,613,419.94**	**4,604,782.62**	**12,189,770.94**

Source: CY 2017 Medicare DME claims data as of June 30, 2018 containing HCPCS codes equal to one of the 37 codes listed in BBA of 2018.

TABLE 53: ESTIMATED URBAN/RURAL IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES, CY 2019

CBSA Urban/Rural	Number of Home Infusion Patients	Total Estimated Costs				Estimated Medicare Costs (80% of Total)				Estimated Beneficiary Costs (20% of Total)			
		Category 1	Category 2	Category 3	Total	Category 1	Category 2	Category 3	Total	Category 1	Category 2	Category 3	Total
Urban	15,369	$16,398,144.00	$15,399,961.92	$17,966,655.36	**$49,764,761.28**	$13,118,515.20	$12,319,969.54	$14,373,324.29	**$39,811,809.03**	$3,279,628.80	$3,079,992.38	$3,593,331.07	**$9,952,952.25**
Rural	3,367	$3,441,634.56	$2,626,767.36	$5,019,855.12	**$11,088,257.04**	$2,753,307.65	$2,101,413.89	$4,015,884.10	**$8,870,605.64**	$688,326.91	$525,353.47	$1,003,971.02	**$2,217,651.40**
Unknown	50	$18,063.36	$40,370.40	$37,402.56	**$95,836.32**	$14,450.69	$32,296.32	$29,922.05	**$76,669.06**	$3,612.67	$8,074.08	$7,480.51	**$19,167.26**
Total	18,786	**$19,857,841.92**	**$18,067,099.68**	**$23,023,913.04**	**$60,948,854.64**	**$15,886,273.54**	**$14,453,679.75**	**$18,419,130.44**	**$48,759,083.73**	**$3,971,568.38**	**$3,613,419.93**	**$4,604,782.60**	**$12,189,770.91**

Source: CY 2017 Medicare DME claims data as of June 30, 2018 containing HCPCS codes equal to one of the 37 codes listed in BBA of 2018.</PHOTO>

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 adjusted by changes in economy-wide productivity. The 0.8 percentage point multifactor productivity adjustment to the CY 2019 home health market basket update of 3.0 percent, is discussed in the preamble of this final rule with comment period 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 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 final rule with comment period, we revise the FDL ratio to 0.51. Simulations using CY 2017 claims data and the 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). Therefore, lowering the FDL ratio results in 2.32% in outlier payments that rises closer to but does not exceed the 2.5% in total outlier payments. 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 X. of this final rule with comment period, would be to either not implement the case-mix adjustment methodology changes 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 X. of this final rule with comment period 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 PDGM. As noted previously, we did not consider not implementing the case-mix methodology changes under the 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 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 final rule with comment period. Although the relationship in relative costs between the WWMC approach and the 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 final rule with comment period 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

We considered various alternatives to our proposals for the HHVBP Model. For the vaccination measures, we considered continuing to include them in the applicable measure set instead of removing them. However, for the reasons discussed in section IV of this final rule with comment period, we are finalizing our proposal to remove the two vaccination measures beginning with PY4.

With regard to our proposal to replace three OASIS-based measures with two composite measures, we also considered making no changes to the OASIS-based measures category.

Another alternative to this proposal would be to finalize one but not both composite measures. We discussed in the proposed rule the proposed scoring that would apply if we adopted this alternative. However, for the reasons discussed in section IV.B of this final rule with comment period, we are finalizing the replacement of the three OASIS-based measures with the two new composite measures.

An alternative to rescoring the maximum improvement points from 10 points to 9 points would be to keep the current scoring methodology. However, for the reasons discussed in section IV.B in this final rule with comment period, we are finalizing our proposal to rescore the maximum improvement points from 10 points to 9 points (or 13.5 points for the composite measures).

An alternative to reweighting the OASIS-based, claims-based and HHCAHPS measure categories would be to keep the current equally weighted methodology. For the reasons discussed in section IV.B of this final rule with comment period, we are finalizing reweighting of the OASIS-based measure category to 35 percent, the claims-based measure category to 35 percent and the HHCAHPS measure category to 30 percent in order to encourage increased focus on the claims-based measures.

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 final rule with comment period, would have been to retain these measures in the HH QRP.

4. Home Infusion Therapy

a. Health and Safety Standards

We considered establishing additional health and safety 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 some AOs that include requirements related to patient assessment, quality improvement, and infection control. To the extent that we subsequently determine that federal standards are necessary, we will propose them in subsequent notice and comment rulemaking.

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 54, 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 55 displays a transfer of zero. Table 56 provides our best estimates of the changes to OASIS item collection as a result of the implementation of the PDGM and changes to the HH QRP. Table 57 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 58 provides our best estimate of cost of AO compliance with our home infusion the Infusion Therapy application requirements.

TABLE 54: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS DUE TO THE NET MARKET BASKET INCREASE, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers	$420 million
From Whom to Whom?	Federal Government to HHAs

TABLE 55: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS DUE TO THE PDGM, FROM CY 2019 TO 2020 PDGM

Category	Transfers
Annualized Monetized Transfers	$0 million
From Whom to Whom?	HHAs to Federal Government

TABLE 56: 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 57: ACCOUNTING STATEMENT: TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers	$48 million
From Whom to Whom?	Federal Government to Home Infusion Therapy Suppliers

TABLE 58: 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 Regulations at §§488.1010 through 488.1050	$12,453 - for preparing and submitting application to CMS $23,258 – for participation in ongoing monitoring activities **$35,711 - Total**

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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 final rule with comment period, including limitations on the ability thus far to quantify some categories of impacts, can be found in the rule's economic analysis. This final rule with comment period is considered an E.O. 13771 deregulatory action. Details on the estimated cost savings of this final rule with comment period can be found in the rule's PRA and economic analysis. Due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020, we estimate that this rule generates $60 million in annualized cost savings, or $46 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

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 2.2 percent, or $420 million, in Medicare payments to HHAs for CY 2019. The $420 million increase reflects the effects of the CY 2019 home health payment update of 2.2 percent ($420 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 changes to the HH QRP and the 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.

In conclusion, due to the modifications to OASIS item collection as a result of the changes to the HH QRP and the changes to the HH PPS (PDGM), both effective on and after January 1, 2020, we estimate that this rule generates $60 million in annualized cost savings, or $46 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

4. Home Infusion Therapy

a. Health and Safety Standards

In summary, the 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 $48 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 finalized 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, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, 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 amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 is revised to read as follows:

Authority: 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, set-up, and service related to this system are allowable only as administrative costs. Visits to a beneficiary's home for the sole purpose of supplying, connecting, or training the patient on the remote patient monitoring equipment, without the provision of a skilled service are not separately billable.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 4. The authority citation for part 424 continues to read as follows:

Authority: 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, or 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 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh 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 revision 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 revision 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.

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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.

As used in §§ 486.520 and 486.525:

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.

(a) 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:

(1) Professional services, including nursing services.

(2) Patient training and education not otherwise paid for as durable medical equipment as described in § 424.57(c)(12) of this chapter.

(3) Remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs.

(b) All home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations.

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. In paragraph (a)(17)(i) by removing the word ''and'' at the end of the paragraph;

■ b. In paragraph (a)(17)(ii) by removing the period and adding in its place ''; and''; and

■ c. By adding paragraph (a)(17)(iii).

The additions read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(17) * * *

(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.

488.1000 Basis and scope.
488.1005 Definitions.

Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations

488.1010 Application and reapplication procedures for national home infusion therapy accrediting organizations.
488.1015 Resubmitting a request for reapproval.
488.1020 Public notice and comment.
488.1025 Release and use of home infusion therapy accreditation surveys.
488.1030 Ongoing review of home infusion therapy accrediting organizations.
488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accreditation organization.
488.1040 Onsite observations of home infusion therapy accrediting organization operations.
488.1045 Voluntary and involuntary termination.
488.1050 Reconsideration.

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 I, 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 home infusion therapy 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 reapproval.

(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 180 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) *Summary accreditation activity data and trends.* 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) *Termination of an accreditation organization.* 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) *Notification of proposed changes.* 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) *Response to a written notice from CMS.* 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 s 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 180 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: October 19, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 22, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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