DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 484

[CMS–1672–P]

RIN 0938–AT01

Medicare and Medicaid Programs; CY 2018 Home Health Prospective Payment System Rate Update and Proposed CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements

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

ACTION: Proposed rule.

SUMMARY: This proposed rule 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, 2018. This rule also: updates the HH PPS case-mix weights using the most current, complete data available at the time of rulemaking; implements the 3rd-year of a 3-year phase-in of a reduction to the national, standardized 60-day episode payment 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; and discusses our efforts to monitor the potential impacts of the rebasing adjustments that were implemented in CY 2014 through CY 2017. This rule proposes case-mix methodology refinements, as well as a change in the unit of payment from 60-day episodes of care to 30-day periods of care, to be implemented for home health services beginning on or after January 1, 2019; and finally, this rule proposes changes to the Home Health Value-Based Purchasing (HHVBP) Model and to the Home Health Quality Reporting Program (HH QRP).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 25, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1672–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four 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 instructions under the ''More Search Options'' tab.

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–1672–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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–1672–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

FOR FURTHER INFORMATION CONTACT: For general information about the HH PPS, please send your inquiry via email to: *HomehealthPolicy@cms.hhs.gov.*

For information about the HHVBP model, please send your inquiry via email to: *HHVBPquestions@cms.hhs.gov.*

Joan Proctor, (410) 786–0949 for information about the home health quality reporting program.

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 Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

In addition, because of the many terms to which we refer by abbreviation in this proposed rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ACH LOS Acute Care Hospital Length of Stay
ADL Activities of Daily Living
AM–PAC Activity Measure for Post-Acute Care
APU Annual Payment Update
ASPE Assistant Secretary for Planning and Evaluation
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)
BIMS Brief Interview for Mental Status
BLS Bureau of Labor Statistics
CAD Coronary Artery Disease
CAH Critical Access Hospital
CAM Confusion Assessment Method
CARE Continuity Assessment Record and Evaluation
CASPER Certification and Survey Provider Enhanced Reports
CBSA Core-Based Statistical Area
CCN CMS Certification Number
CHF Congestive Heart Failure
CMI Case-Mix Index
CMP Civil Money Penalty
CMS Centers for Medicare & Medicaid Services
CoPs Conditions of Participation
COPD Chronic Obstructive Pulmonary Disease
CVD Cardiovascular Disease
CY Calendar Year
DM Diabetes Mellitus
DRA Deficit Reduction Act of 2005, Public Law 109–171, enacted February 8, 2006
DTI Deep Tissue Injury
EOC End of Care
FDL Fixed Dollar Loss
FI Fiscal Intermediaries
FR Federal Register
FY Fiscal Year
HAVEN Home Assessment Validation and Entry System
HCC Hierarchical Condition Categories
HCIS Health Care Information System
HH Home Health
HHA Home Health Agency
HHCAHPS Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey
HH PPS Home Health Prospective Payment System
HHGM Home Health Groupings Model
HHQRP Home Health Quality Reporting Program
HHRG Home Health Resource Group
HHVBP Home Health Value-Based Purchasing
HIPPS Health Insurance Prospective Payment System
HVBP Hospital Value-Based Purchasing
IADL Instrumental Activities of Daily Living
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
IH Inpatient Hospitalization
IMPACT Act Improving Medicare Care Transformation Act of 2014 (Pub. L. 113–185)
IPR Interim Performance Report
IRF Inpatient Rehabilitation Facility
IRF–PAI IRF Patient Assessment Instrument
IV Intravenous
LCDS LTCH CARE Data Set
LEF Linear Exchange Function
LTCH Long-Term Care Hospital
LUPA Low-Utilization Payment Adjustment
MACRA Medicare Access and CHIP Reauthorization Act of 2015
MAP Measure Applications Partnership
MDS Minimum Data Set
MEPS Medical Expenditures Panel Survey
MFP Multifactor productivity
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, enacted December 8, 2003
MSA Metropolitan Statistical Area
MSS Medical Social Services
NQF National Quality Forum
NQS National Quality Strategy
NRS Non-Routine Supplies
OASIS Outcome and Assessment Information Set
OBRA Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–2–3, enacted December 22, 1987
OCESAA Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. 105–277, enacted October 21, 1998
OES Occupational Employment Statistics
OIG Office of Inspector General
OLS Ordinary Least Squares
OT Occupational Therapy
OMB Office of Management and Budget
PAC Post-Acute Care
PAC–PRD Post-Acute Care Payment Reform Demonstration
PAMA Protecting Access to Medicare Act of 2014
PEP Partial Episode Payment Adjustment
PHQ–2 Patient Health Questionnaire-2
PPOC Primary Point of Contact
PPS Prospective Payment System
PRA Paperwork Reduction Act
PRRB Provider Reimbursement Review Board
PT Physical Therapy
PY Performance Year
QAP Quality Assurance Plan
QIES Quality Improvement Evaluation System
QRP Quality Reporting Program
RAP Request for Anticipated Payment
RF Renal Failure
RFA Regulatory Flexibility Act, Pub. L. 96—354
RHHIs Regional Home Health Intermediaries
RIA Regulatory Impact Analysis
ROC Resumption of Care
SAF Standard Analytic File
SLP Speech-Language Pathology
SN Skilled Nursing
SNF Skilled Nursing Facility
SOC Start of Care
SSI Surgical Site Infection
TEP Technical Expert Panel
TPS Total Performance Score
UMRA Unfunded Mandates Reform Act of 1995.
VAD Vascular Access Device
VBP Value-Based Purchasing

I. Executive Summary

A. Purpose

This proposed rule would update the payment rates for home health agencies (HHAs) for calendar year (CY) 2018, as required under section 1895(b) of the Social Security Act (the Act). This proposed rule would update the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for CY 2018 and implement a 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for case-mix growth

unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014, under the authority of section 1895(b)(3)(B)(iv) of the Act. For home health services beginning on or after January 1, 2019, this rule also proposes case-mix methodology refinements under the authority set out at sections 1895(b)(4)(A)(i) and (b)(4)(B) of the Act, and a change in the unit of payment from a 60-day episode of care to a 30-day period of care under the authority set out at section 1895(b)(2) of the Act. Additionally, this rule proposes changes to: The Home Health Value Based Purchasing (HHVBP) model under the authority of section 1115A of the Act; and the Home Health Quality Reporting Program (HH QRP) requirements under the authority of section 1895(b)(3)(B)(v) of the Act.

B. Summary of the Major Provisions

Section III.A of this rule discusses our efforts to monitor for potential impacts due to the rebasing adjustments implemented in CY 2014 through CY 2017, as mandated by section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted March 23, 2010) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010), collectively referred to as the ''Affordable Care Act''. In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with the most current and complete data available at the time of rulemaking. In section III.B of this rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget neutral manner. Also in section III.B of this rule, as finalized in the CY 2016 HH PPS final rule (80 FR 68624), we are implementing a reduction to the national, standardized 60-day episode payment rate for CY 2018 of 0.97 percent 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.

In section III.C of this proposed rule, we would update the payment rates under the HH PPS by 1 percent for CY 2018 in accordance with section 411(d) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) which amended section 1895(b)(3)(B) of the Act. Additionally, section III.C of this rule, would update the CY 2018 home health wage index using FY 2014 hospital cost report data. In section III.D of this proposed rule, we note that the fixed-dollar loss ratio would remain 0.55 for CY 2018 to pay up to, but no more than, 2.5 percent of total payments as outlier payments, as required by section 1895(b)(5)(A) of the Act.

In section III.E of this rule we are proposing to implement case-mix methodology refinements and a change in the unit of payment from a 60-day episode of care to a 30-day period of care, effective for home health services beginning on or after January 1, 2019. The proposed home health groupings model (HHGM) relies more heavily on clinical characteristics and other patient information to place patients into meaningful payment categories, while eliminating therapy service use thresholds that are currently used to case-mix adjust payments under the HH PPS. This includes proposed changes in the episode timing categories, the addition of an admission source category, the creation of six clinical groups used to categorize patients based on their primary reason for home health care, revised functional levels and corresponding OASIS items, the addition of a comorbidity adjustment, and a proposed change in the Low-Utilization Payment Adjustment (LUPA) threshold. The LUPA add-on policy, the partial [episode] payment adjustment policy, and the methodology used to calculate payments for high-cost outliers would remain unchanged except for occurring on a 30-day basis rather than a 60-day basis.

In section IV of this rule, we are proposing changes to the Home Health Value-Based Purchasing (HHVBP) Model implemented January 1, 2016. We are proposing to amend the definition of ''applicable measure'' to specify that the HHA would have to submit a minimum of 40 completed surveys for Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) measures, for purposes of receiving a performance score for any of the HHCAHPS measures, and for performance year (PY) 3 and subsequent years, to remove the Outcome and Assessment Information Set (OASIS)-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures. We are also soliciting public comments on composite quality measures for future consideration.

In section V of this rule, we propose updates to the Home Health Quality Reporting Program, including: The replacement of one quality measure, the adoption of two new quality measures, the reporting of standardized patient assessment data in five categories described under the IMPACT Act, data submission requirements, exception and extension requirements, and reconsideration and appeals procedures.

C. Summary of Costs and Benefits

TABLE 1—SUMMARY OF COSTS AND TRANSFERS

Provision description	Costs	Transfers
CY 2018 HH PPS Payment Rate Update.	.....	The overall economic impact of the HH PPS payment rate update is an estimated −$80 million (−0.4 percent) in payments to HHAs.
CY 2018 HHVBP Model	.....	The overall economic impact of the HHVBP Model provision for CY 2018 through 2022 is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry (none of which is attributable to the changes proposed in this proposed rule). As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.
CY 2019 HH QRP	The overall economic impact of the HH QRP changes is a savings to HHAs of an estimated $44.9 million, beginning January 1, 2019.	

TABLE 1—SUMMARY OF COSTS AND TRANSFERS—Continued

Provision description	Costs	Transfers
CY 2019 HH PPS Case-Mix Adjustment Methodology Refinements.	.....	The overall impact of the proposed HH PPS case-mix adjustment methodology refinements, including a change in the unit of payment from 60-day episodes to 30-day periods of care, is an estimated −$950 million (−4.3 percent) in payments to HHAs in CY 2019 if the refinements are implemented in a non-budget neutral manner for 30-day periods of care beginning on or after January 1, 2019. The overall impact is an estimated −$480 million (−2.2 percent) in payments to HHAs in CY 2019 if the refinements are implemented in a partially budget-neutral manner.

II. Background

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare HH 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 HH 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 HH services paid under Medicare.

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount include 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; 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 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 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 HH 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 HH 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 HH 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 HH 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 links the quality data submission to the annual applicable percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the HH 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 MACRA amended section 421(a) of the MMA to extend the rural add-on for 2 more years. Section 421(a) of the MMA, as amended by section 210 of the MACRA, requires that the Secretary increase, by 3 percent, 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) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2018. Section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that for home health payments for CY 2018, the market basket percentage increase shall be 1 percent.

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 HH disciplines (skilled nursing, HH 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): 0–5; 6; 7–9; 10; 11–13; 14–15; 16–17; 18–19; 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 HH 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 HH 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 a 1.32 percent reduction to the payment rates for CY 2013 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 requires 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 must phase in any adjustment over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. The statute specifies that the maximum rebasing adjustment is to be no more than 3.5 percent per year of the CY 2010 rates. 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 2nd 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 3rd 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 above). 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 above). 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.

D. Report to Congress: Home Health Study on Access to Care for Vulnerable Patient Populations and Subsequent Research and Analyses

Section 3131(d) of the Affordable Care Act required CMS to conduct a study on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness and submit a report to Congress. As discussed in the CY 2016 HH PPS proposed rule (80 FR 39840) and the CY 2017 HH PPS proposed rule (81 FR 43744), 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'', found that payment accuracy could be improved under the current payment system, particularly for patients with certain clinical characteristics requiring more nursing care than therapy.[1]

The research for the Report to Congress, released in December 2014, consisted of extensive analysis of both survey and administrative data. The CMS-developed surveys were given to physicians who referred vulnerable patient populations to Medicare home health and to Medicare-certified HHAs.[2] The response rates were 72 percent and 59 percent for the HHA and physician surveys, respectively. The results of the survey revealed that over 80 percent of respondent HHAs and over 90 percent of respondent physicians reported that access to home health care for Medicare fee-for-service beneficiaries in their local area was excellent or good. When survey respondents reported access issues, specifically their inability to place or admit Medicare fee-for-service patients into home health, the most common reason reported (64 percent of respondent HHAs surveyed) was that the patients did not qualify for the Medicare home health benefit. HHAs and physicians also cited family or caregiver issues as an important contributing factor in the inability to admit or place patients. Only 17.2 percent of HHAs and 16.7 percent of physicians reported insufficient payment as an important contributing factor in the inability to admit or place patients. The results of the CMS-conducted surveys suggested that CMS' ability to improve access for certain vulnerable patient populations through payment policy may be limited. However, we are able to revise the case-mix system to minimize differences in payment that could potentially be serving as a barrier to receiving care. In this rule, we propose to better align payment with resource use so that it reduces HHAs' financial incentives to select certain patients over others.

However, we also performed an analysis of Medicare administrative data (CY 2010 Medicare claims and cost report data) and calculated margins for episodes of care. This was done because margin differences associated with patient clinical and social characteristics can indicate whether financial incentives exist in the current HH PPS to provide home health care for certain types of patients over others. Lower margins, if systematically associated with care for vulnerable patient populations, may indicate financial disincentives for HHAs to admit these patients, potentially creating access to care issues. The findings from the data analysis found that certain patient characteristics appear to be strongly associated with margin levels, and thus may create financial incentives to select certain patients over others. Margins were estimated to be lower for patients who required parenteral nutrition, who had traumatic wounds or ulcers, or required substantial assistance in bathing. For example, in CY 2010, episodes for patients with parenteral nutrition were, on average, associated with a $178.53 lower margin than episodes for patients without parenteral nutrition. Given that these variables are already included in the HH PPS case-mix system, the results indicated that modifications to the way the current case-mix system accounts for resource use differences may be needed to mitigate any financial incentives to select certain patients over others. Margins were also lower for beneficiaries who were admitted after acute or post-acute stays or who had certain poorly-controlled clinical conditions, such as poorly-controlled pulmonary disorders, indicating that accounting for additional patient characteristic variables in the HH PPS case-mix system may also reduce financial incentives to select certain types of patients over others. More information on the results from the Home Health Study required by section 3131(d) of the Affordable Care Act can be found in the Report to Congress on the ''Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations'' available at *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html*.

Section 3131(d)(5) of the Affordable Care Act allowed for the Secretary to determine whether a Medicare demonstration project is appropriate to conduct based on the result of the Home Health Study. If the Secretary determined it was appropriate to conduct the demonstration project under this subsection, the Secretary was to conduct the project for a four year period beginning not later than January

[1] The Report to Congress can be found in its entirety at *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf*.

[2] For the purposes of the surveys, ''vulnerable patient populations'' were defined as beneficiaries who were either eligible for the Part D low-income subsidy (LIS) 27 or residing in a health professional shortage area (HPSA).

1, 2015. We did not determine that it was appropriate to conduct a demonstration project based on the findings from the Home Health Study. Rather, the findings from the Home Health Study suggested that follow-on work should be conducted to better align payments with costs under the authority of section 1895 of the Act.

In addition to 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'', concerns have also been raised about the use of therapy thresholds in the current payment system. 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 in section III.A of this rule. A study examining an option of using predicted, rather than actual, therapy visits in the HH found that in 2013, 58 percent of home health episodes included some therapy services, and these episodes accounted for 72 percent of all Medicare home health payments.[3] Figure 1 from that 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. According to the study, the presence of sharp increases in the percentage of episodes just above payment thresholds suggests a response to financial incentives in the home health payment system. 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.[4] 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 (see Table 2 in section III.A. of this proposed rule).

FIGURE 1: Percent of Episodes and Average Payment by Number of Therapy Visits

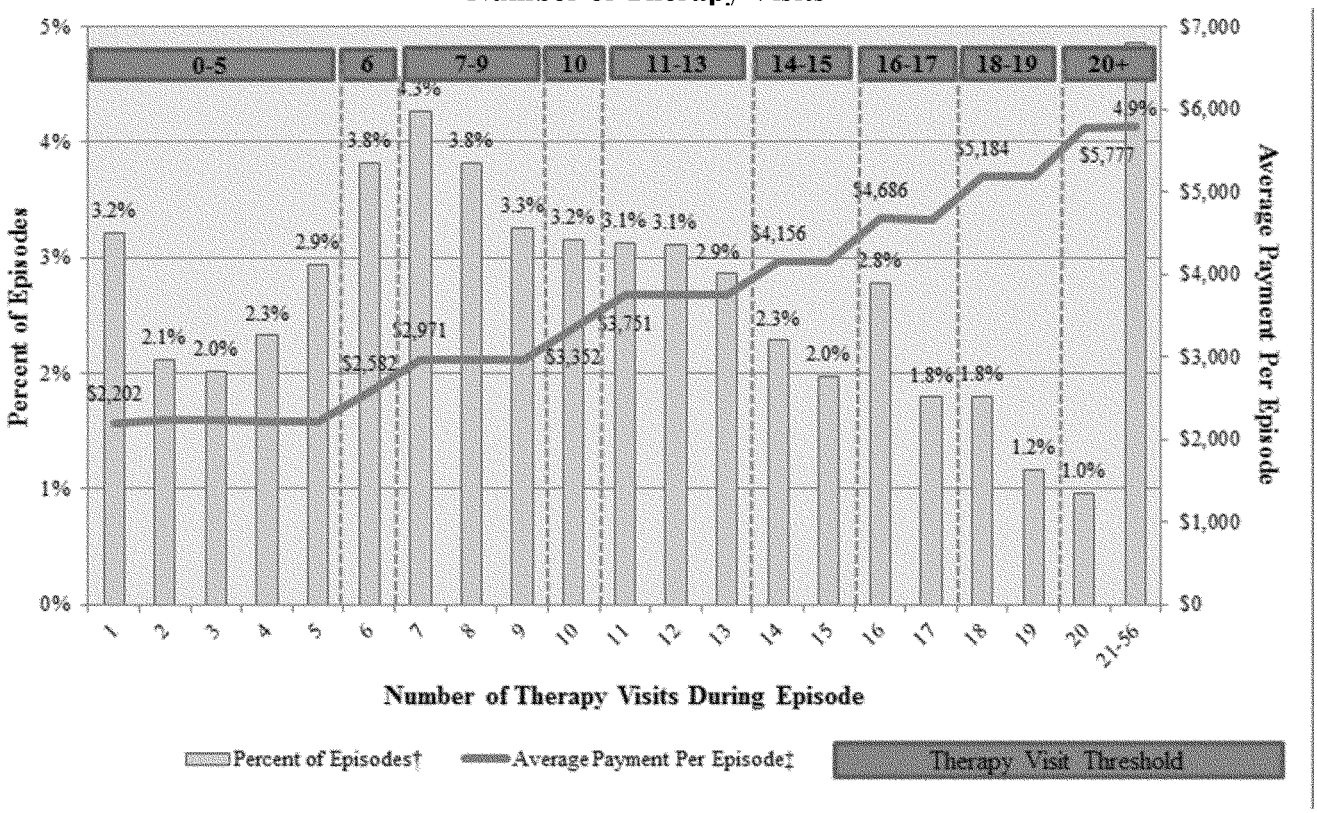


Figure 1 suggests that HHAs may be responding to financial incentives in the home health payment system when making care plan decisions. Additionally, an investigation into the therapy practices of the four largest publically-traded home health companies, conducted by the Senate Committee on Finance in 2010, found that 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''.[5] The Committee on Finance

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

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

[5] Committee on Finance, United States Senate. *Staff Report on Home Health and the Medicare*

investigation also highlighted the abrupt and dramatic responses the home health industry has taken to maximize reimbursement 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)). Under the HH PPS, the report noted that HHAs have broad discretion over the number of therapy visits to provide patients 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 well-being and health characteristics, rather than the numerical utilization measures.

MedPAC also continues to recommend the removal of the therapy thresholds used for determining payment from the HH PPS, as it believes that such thresholds run counter to the goals of a prospective payment system, create financial incentives that detract from a focus on patient characteristics and care needs when agencies are setting plans of care for their patients, and incentivize unnecessary therapy utilization. For the average HHA, according to MedPAC, the increase in payment for therapy visits rises faster than costs resulting in financial incentives for HHAs to overprovide therapy services.[6] HHAs that provide more therapy episodes tend to be more profitable and this higher profitability and rapid growth in the number of therapy episodes suggest that financial incentives are causing agencies to favor therapy services when possible.[7] Eliminating therapy as a payment factor would base home health payment solely on patient characteristics, which is a more patient-focused approach to payment, as recommended by both MedPAC and previously by the Senate Committee on Finance.

After considering the findings from the Report to Congress and recommendations from MedPAC and the Senate Committee on Finance, CMS, along with our contractor, conducted additional research on ways to improve the payment accuracy under the current payment system. Exploring all options and different models ultimately led us to further develop the Home Health Groupings Model (HHGM) proposal. The HHGM proposal uses 30-day periods, rather than 60-day episodes, and relies more heavily on clinical characteristics and other patient information (for example, principal diagnosis, functional level, comorbid conditions, admission source, and timing) to place patients into meaningful payment categories, rather than the current therapy driven system. We believe this patient-centered approach is consistent with how clinicians differentiate between home health patients and would improve payment accuracy and access for medically complex cases and not just cases receiving therapy. The HHGM proposal leverages many of the same aspects of the current system; however, the major differences between the current system and the HHGM proposal include a change from a 60-day to a 30-day billing cycle and the elimination of the therapy thresholds in the case-mix system.

We shared the analyses and development of the HHGM with both internal and external stakeholders via technical expert panels, clinical workgroups, special open door forums, and in the CY 2016 HH PPS proposed rule (80 FR 39840) and the CY 2017 HH PPS proposed rule (81 FR 43744). Most recently, we posted a detailed technical report on the CMS Web site in December of 2016.[8] After posting the technical report for the public to review, we also held additional technical expert panel and clinical workgroup webinars to garner feedback from the industry and conducted a National Provider call that occurred in January 2017 to solicit feedback from external stakeholders.[9] The feedback we received during the National Provider call on the HHGM was positive. We discuss the HHGM proposal further below, in section III.E, and seek public comment on this proposal and the underlying analyses.

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

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

1. Analysis of FY 2015 HHA Cost Report Data

As part of our efforts in monitoring the potential impacts of the rebasing adjustments finalized in the CY 2014 HH PPS final rule (78 FR 72293), we continue to update our analysis of home health cost report and claims data. Previous years' cost report and claims data analyses and results can be found in the CY 2017 HH PPS proposed rule (81 FR 43719 through 43720). For this proposed rule, we analyzed 2015 HHA cost report data and 2015 HHA claims data. To determine the 2015 average cost per visit per discipline, we applied the same trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) and weighted the costs per visit from the 2015 cost reports by size, facility type, and urban/rural location so the costs per visit were nationally representative according to 2015 claims data. The 2015 average number of visits was taken from 2015 claims data. We estimated the cost of a 60-day episode in CY 2015 to be $2,449.01 using 2015 cost report data as shown in Table 2. However, the national, standardized 60-day episode payment amount in CY 2015 was $2,961.38. For CY 2015, on average, payments were 21 percent higher than costs (($2,961.38—$2,449.01)/$2,449.01).

TABLE 2—2015 ESTIMATED COST PER EPISODE

Discipline	2015 Average costs per visit	2015 Average number of visits	2015 60-day episode costs
Skilled Nursing	$132.48	8.93	$1,183.05
Physical Therapy	156.32	5.39	842.56

Therapy Threshold. Washington, DC, 2011. Accessed on March 28, 2017 at *https://www.finance.senate.gov/imo/media/doc/Home_Health_Report_Final4.pdf.*

[6] Medicare Payment Advisory Commission (MedPAC). ''Home Health Services.'' *Report to Congress: Medicare Payment Policy.* Washington, DC, March 2011. P. 182–183. Accessed on March 28, 2017 at *http://www.medpac.gov/docs/default-source/reports/Mar11_Ch08.pdf?sfvrsn=0.*

[7] Medicare Payment Advisory Commission (MedPAC). ''Home Health Care Services.'' *Report to Congress: Medicare Payment Policy.* Washington, DC, March 2017. P. 243–244. Accessed on March 28, 2017 at *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch9.pdf?sfvrsn=0.*

[8] Ab Associates. *Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements. Overview of the Home Health Groupings Model.* Cambridge, MA, November 18, 2016. Accessed on April 27, 2017 at: *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

[9] Centers for Medicare & Medicaid Services (CMS). ''Home Health Groupings Model Technical Report Call.'' Baltimore, MD, January 18, 2017. Accessed on April 27, 2017 at: *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-01-18-Home-Health.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=descending.*

TABLE 2—2015 ESTIMATED COST PER EPISODE—Continued

Discipline	2015 Average costs per visit	2015 Average number of visits	2015 60-day episode costs
Occupational Therapy	154.64	1.41	218.04
Speech Pathology	170.96	0.29	49.58
Medical Social Services	220.07	0.14	30.81
Home Health Aides	62.80	1.99	124.97
Total	.....	18.15	2,449.01

Source: Medicare cost reports pulled in February 2017 and Medicare claims data from 2014 and 2015 for episodes (excluding low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes), linked to OASIS assessments for episodes ending in CY 2015.

2. Analysis of CY 2016 HHA Claims Data

In the CY 2014 HH PPS final rule (78 FR 72283), some commenters expressed concern that the rebasing of the HH PPS payment rates would result in HHA closures and would therefore diminish access to home health services. In addition to examining more recent cost report data, for this proposed rule we examined home health claims data from the first 3 years of the 4-year phase-in of the rebasing adjustments (CY 2014, CY 2015, and CY 2016), the first calendar year of the HH PPS (CY 2001), and claims data for 2 years before implementation of the rebasing adjustments (CY 2012 and CY2013). Analysis of CY 2016 home health claims data indicates that the number of episodes and the number of home health users that received at least one episode of care remained virtually the same (change of less than 1 percent) from 2015 to 2016, while the number of FFS beneficiaries increased 2 percent from 2015 to 2016. Between 2013 and 2014 there appears to be a net decrease in the number of HHAs billing Medicare for home health services of 1.6 percent, a continued decrease of 1.7 percent from 2014 to 2015, and a decrease of 2.5 percent from 2015 to 2016. The number of home health users, as a percentage of FFS beneficiaries, appears to have slightly decreased from 9.0 percent in 2012 to 8.7 percent in 2016, but remains higher than the 6.9 percent in 2001. In CY 2016, there were 2.9 HHAs per 10,000 FFS beneficiaries, which is still markedly higher than the 1.9 HHAs per 10,000 FFS beneficiaries observed close to the implementation of the HH PPS in 2001 (see Table 3). Therefore, the rebasing adjustments made to the HH PPS payment rates in CYs 2014 through 2016 do not appear to have resulted in significant HHA closures or otherwise diminished access to home health services.

TABLE 3—HOME HEALTH STATISTICS, CY 2001 AND CY 2012 THROUGH CY 2016 [10]

	2001	2012	2013	2014	2015	2016
Number of episodes	3,896,502	6,727,875	6,708,923	6,451,283	6,340,932	6,294,234
Beneficiaries receiving at least 1 episode (Home Health Users)	2,412,318	3,446,122	3,484,579	3,381,635	3,365,512	3,350,174
Part A and/or B FFS beneficiaries	34,899,167	38,224,640	38,505,609	38,506,534	38,506,534	38,555,150
Episodes per Part A and/or B FFS beneficiaries	0.11	0.18	0.17	0.17	0.17	0.16
Home health users as a percentage of Part A and/or B FFS beneficiaries	6.9%	9.0%	9.0%	8.8%	8.8%	8.7%
HHAs providing at least 1 episode	6,511	11,746	11,889	11,693	11,381	11,102
HHAs per 10,000 Part A and/or B FFS beneficiaries	1.9	3.1	3.1	3.0	3.0	2.9

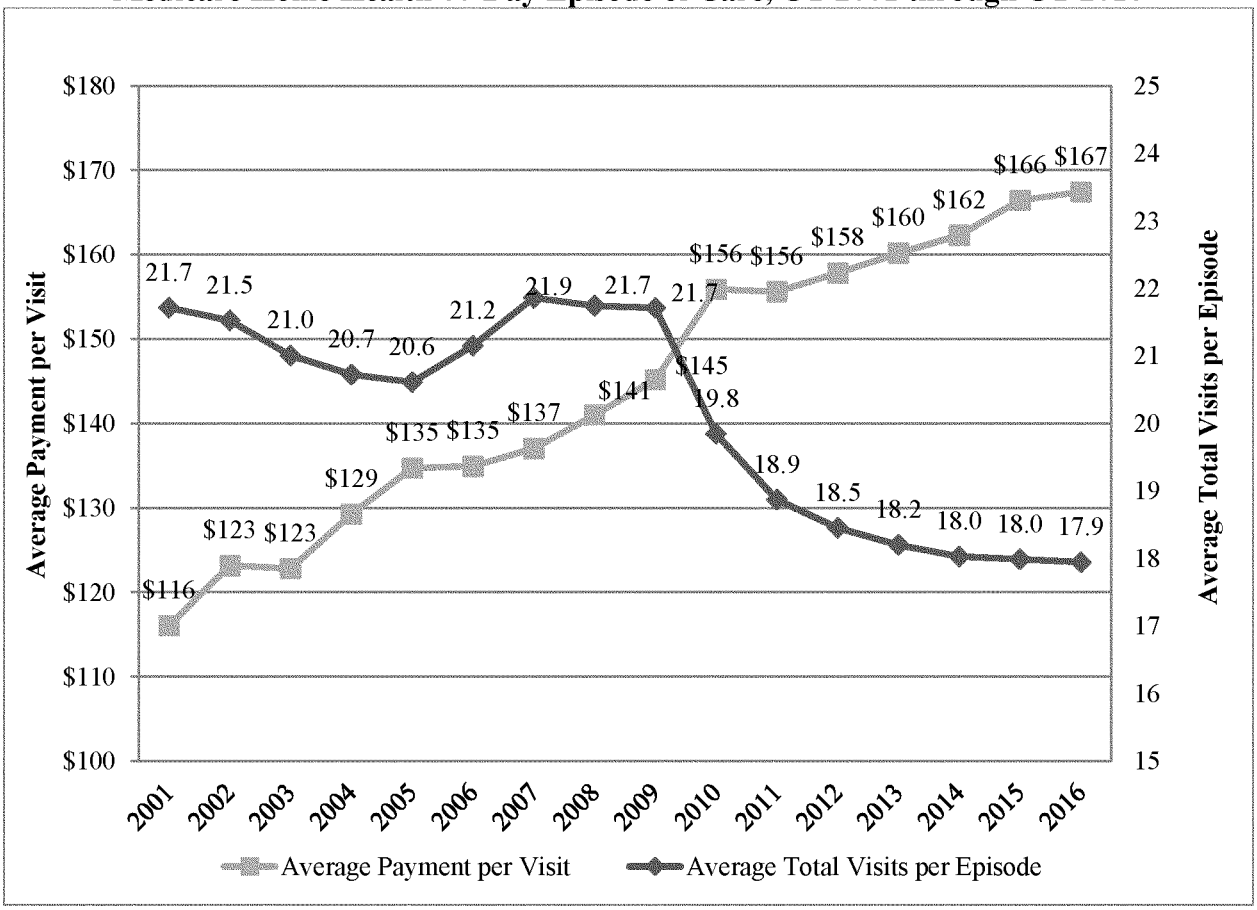
Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on May 14, 2014 and August 19, 2014 for CY 2011, CY 2012, and CY 2013 data; accessed on May 7, 2015 for CY 2001 and CY 2014 data; accessed on April 7, 2016 for CY 2015 data; and accessed on March 20, 2017 for CY 2016 data and Medicare enrollment information obtained from the CCW Master Beneficiary Summary File. Beneficiaries are the total number of beneficiaries in a given year with at least 1 month of Part A and/or Part B Fee-for-Service coverage without having any months of Medicare Advantage coverage.

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

In addition to examining home health claims data from the first three years of the implementation of rebasing adjustments required by the Affordable Care Act, we examined trends in home health utilization for all years starting in CY 2001 and up through CY 2016. Figure 2, displays the average number of visits per 60-day episode of care and the average payment per visit. While the average payment per visit has steadily increased from approximately $116 in CY 2001 to $167 for CY 2016, the average total number of visits per 60-day episode of care has declined, most notably between CY 2009 (21.7 visits per episode) and CY 2010 (19.8 visits per episode), which was the first year that the 10 percent agency-level cap on HHA outlier payments was implemented. The average of total visits per episode has steadily decreased from 21.7 in 2009 to 17.9 in 2016.

[10] The data used for this table is not publicly available. Providers and researchers have access to similar data via the home health public use files at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/HHA.html* and through the CMS program statistics Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/index.html.*

FIGURE 2: Average Total Number of Visits and Average Payment per Visit for a Medicare Home Health 60-Day Episode of Care, CY 2001 through CY 2016

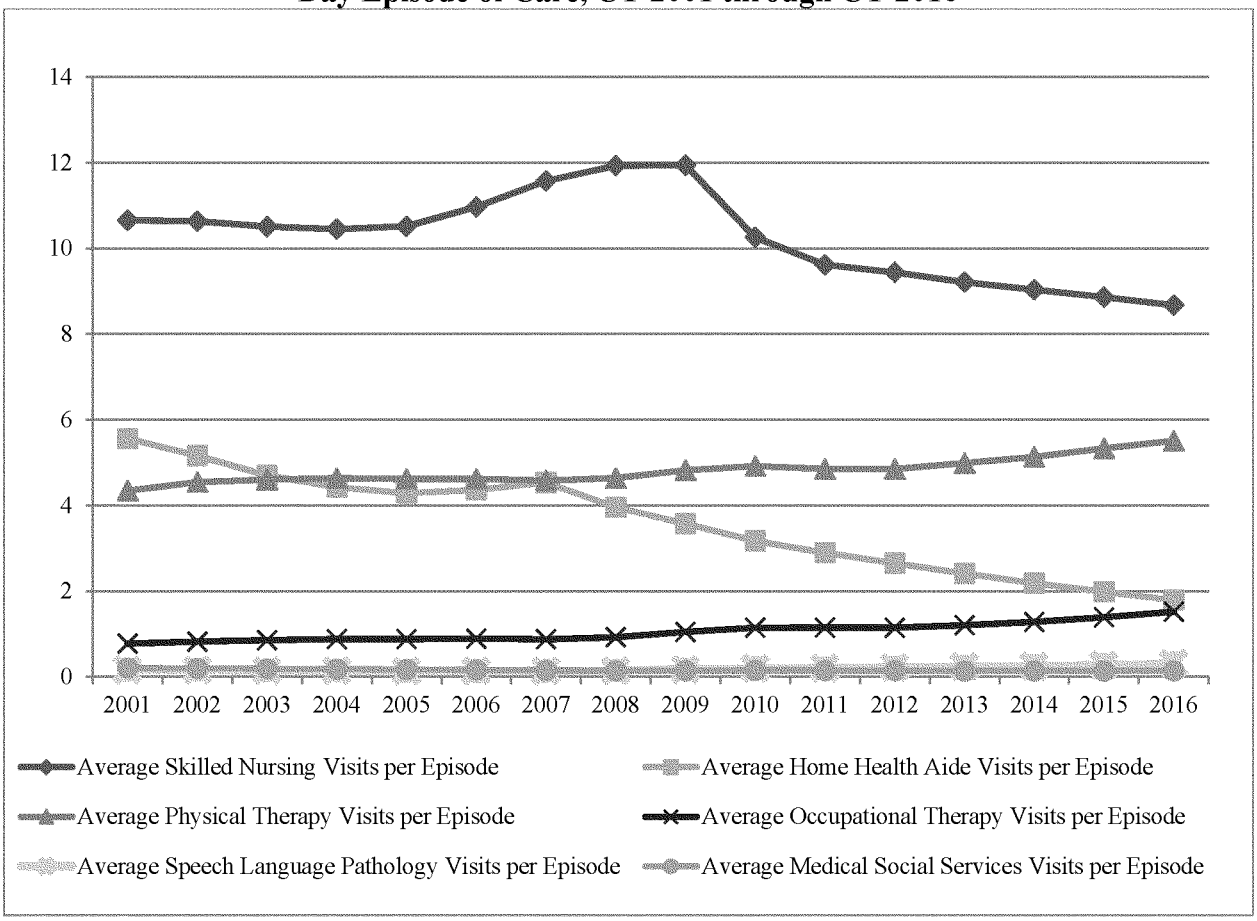


Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) – 2001 to 2014 data accessed on May 21, 2014, CY2015 data accessed on April 25, 2016, and CY2016 data accessed on March 16, 2017.
Note(s): These results exclude LUPA episodes, but include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

Figure 3 displays the average number of visits by discipline type for a 60-day episode of care and shows that the number of therapy visits per 60-day episode of care has increased steadily. However, the number of skilled nursing visits has decreased from 10.7 in 2009 to 8.7 in 2016. The number of home health aide visits has decreased from 5.6 average visits in 2009 to 1.5 visits in 2016. The results of the home health study required by section 3131(d) of the Affordable Care Act suggest that the current home health payment system may discourage HHAs from serving patients with clinically complex and/or poorly controlled chronic conditions who do not qualify for therapy but require a large number of skilled nursing visits.[11] The home health study results seem to be consistent with the recent trend in the decreased number of visits per episode of care driven by decreases in skilled nursing and home health aide services evident in Figures 2 and 3.

[11] The Report to Congress on the Home Health Study required by Section 3131(d) is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf.*

FIGURE 3: Average Number of Visits by Discipline Type for a Medicare Home Health 60-Day Episode of Care, CY 2001 through CY 2016



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - – 2001 to 2014 data accessed on May 21, 2014, CY2015 data accessed on April 25, 2016, CY2016 data accessed on March 16, 2017.

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

As part of our monitoring efforts, we also examined the trends in episode timing and service use over time. The first and second episodes are considered ''early'' episodes, while third and later episodes are considered ''late'' episodes. Specifically, we examined the percentage of early episodes with 0 to 19 therapy visits, late episodes with 0 to 19 therapy visits, and episodes with 20+ therapy visits from CY 2008 to CY 2016. In CY 2008, we implemented refinements to the HH PPS case-mix system. As part of those refinements, we added additional therapy thresholds and differentiated between early and late episodes for those episodes with less than 20+ therapy visits. When the case-mix system first differentiated payments between early and late episodes of care, late episodes of care tended to have higher case-mix weights compared to early episodes of care. Table 4 shows that while there was a substantial increase in the number of late episodes between 2008 and 2009 (8 percentage points), since 2011 the number of late episodes as a percentage of total episodes has decreased over time. In 2015, the case-mix weights for the third and later episodes of care with 0 to 19 therapy visits decreased as a result of the CY 2015 recalibration of the case-mix weights. The recalibration of the HH PPS case-mix weights, beginning in CY 2015, does not seem to have substantially impacted the percentage of early versus late episodes of care.

The case-mix weights for episodes with 20+ therapy visits are not determined based on the timing of the episode of care. The percentage of episodes with 20+ therapy visits increased from 4.6 percent in CY 2008 to 7.0 percent in CY 2016. The increase in the percentage of episodes with 20+ therapy visits is consistent with the overall observed increase in therapy visits provided during a 60-day episode of care (see Figure 3).

TABLE 4—HOME HEALTH EPISODES BY EPISODE TIMING, CY 2008 THROUGH CY 2016

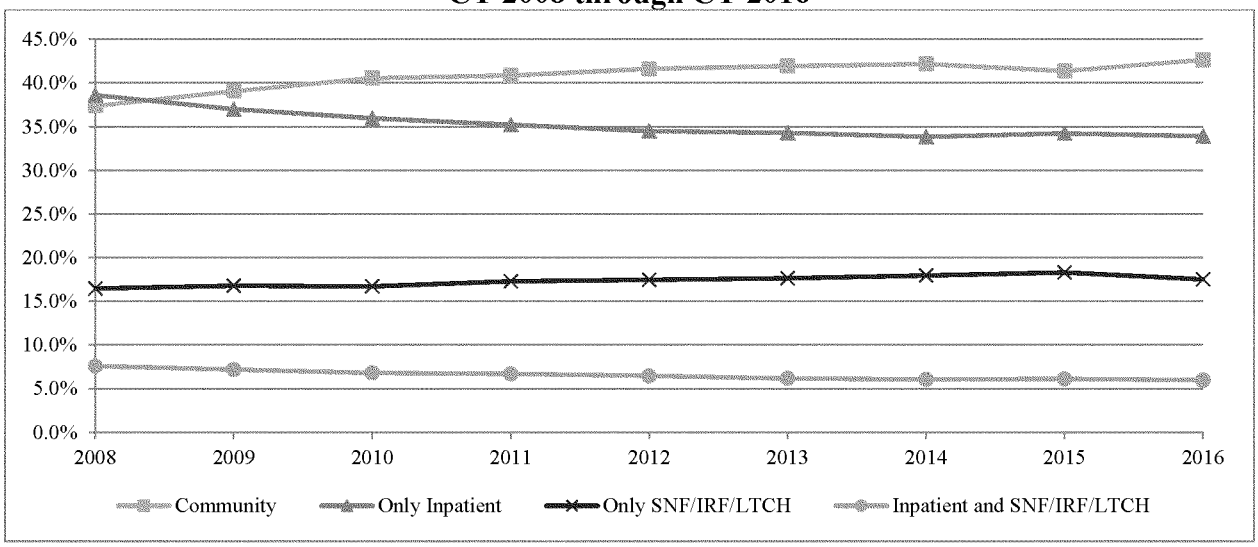
Year	All episodes	Number of early episodes (excluding episodes with 20+ therapy visits)	% of early episodes (excluding episodes with 20+ therapy visits)	Number of late episodes (excluding episodes with 20+ therapy visits)	% of late episodes (excluding episodes with 20+ therapy visits)	Number of episodes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

SOURCE: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on March 21, 2017.
NOTE(S): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to ''0'' (''Non-payment/zero claims'') and ''2'' (''Interim—first claim'') are excluded.

We also examined trends in admission source for home health episodes over time. Specifically, we examined the admission source for the ''first or only'' episodes of care (first episodes in a sequence of adjacent episodes of care or the only episode of care) from CY 2008 through CY 2016 (Figure 4). The percentage of first or only episodes with an acute admission source, defined as episodes with an inpatient hospital stay within the 14 days prior to a home health episode, has decreased from 38.6 percent in CY 2008 to 33.9 percent in CY 2016. The percentage of first or only episodes with a post-acute admission source, defined as episodes which had a stay at a skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long term care hospital (LTCH) within 14 days prior to the home health episode, slightly increased from 16.5 percent in CY 2008 to 17.5 percent in CY 2016. The percentage of first or only episodes with a community admission source, defined as episodes which did not have an acute or post-acute stay in the 14 days prior to the home health episode, increased from 37.4 percent in CY 2008 to 42.6 percent in CY 2016. Our findings on the trends in admission source are consistent with MedPAC's as outlined in their 2015 Report to the Congress.[12] MedPAC examined admission source trends from 2002 up through 2013 and concluded that ''there has been tremendous growth in the use of home health for patients residing in the community, episodes not preceded by a prior hospitalization. The high rates of volume growth for these types of episodes, which have more than doubled since 2001, suggest there is significant potential for overuse, particularly since Medicare does not currently require any cost sharing for home health care.''

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

FIGURE 4: Home Health Episode Trends by Admission Source (First or Only Episodes), CY 2008 through CY 2016



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - Accessed on February 21, 2017.
Note(s): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded.

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

B. Proposed CY 2018 HH PPS Case-Mix Weights

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

To generate the proposed CY 2018 HH PPS case-mix weights, we used CY 2016 home health claims data (as of March 17, 2017) with linked OASIS data. These data are the most current and complete data available at this time. We will use CY 2016 home health claims data (as of June 30, 2017 or later) with linked OASIS data to generate the CY 2018 HH PPS case-mix weights in the CY 2018 HH PPS final rule. The process we used to calculate the HH PPS case-mix weights are outlined below.

Step 1: Re-estimate the four-equation model to determine the clinical and functional points for an episode using wage-weighted minutes of care as our dependent variable for resource use. The wage-weighted minutes of care are determined using the CY 2015 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 2016 home health claims data, are shown in Table 5. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

TABLE 5.—CASE-MIX ADJUSTMENT VARIABLES AND SCORES

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0–13	14+	0–13	14+
	EQUATION:	*1*	*2*	*3*	*4*
	CLINICAL DIMENSION				
1	Primary or Other Diagnosis = Blindness/Low Vision				
2	Primary or Other Diagnosis = Blood disorders		1		
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms.		4		4
4	Primary Diagnosis = Diabetes		3		1
5	Other Diagnosis = Diabetes	1			
6	Primary or Other Diagnosis = Dysphagia *AND* Primary or Other Diagnosis = Neuro 3—Stroke.	2	16	1	10

TABLE 5.—CASE-MIX ADJUSTMENT VARIABLES AND SCORES—Continued

7	Primary or Other Diagnosis = Dysphagia *AND* M1030 (Therapy at home) = 3 (Enteral).	1	6	.....	6
8	Primary or Other Diagnosis = Gastrointestinal disorders	.....	.....	.....	2
9	Primary or Other Diagnosis = Gastrointestinal disorders *AND* M1630 (ostomy)= 1 or 2.	.....	7	.....	.....
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.	1	3	.....	2
12	Primary Diagnosis = Neuro 1—Brain disorders and paralysis.	2	9	6	9
13	Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis *AND* M1840 (Toilet transfer) = 2 or more.	.....	4	.....	4
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.	2	4	1	4
15	Primary or Other Diagnosis = Neuro 3—Stroke	3	9	2	4
16	Primary or Other Diagnosis = Neuro 3—Stroke *AND* M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3.	.....	2	.....	.....
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.	3	7	5	10
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	1	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).	3	.....	3	7
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	.....	2	.....	1
24	Primary or Other Diagnosis = Pulmonary disorders *AND* M1860 (Ambulation) = 1 or more.	.....	.....	.....	.....
25	Primary Diagnosis = Skin 1–Traumatic wounds, burns, and post-operative complications.	3	17	6	17
26	Other Diagnosis = Skin 1—Traumatic wounds, burns, post-operative complications.	6	13	8	13
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).	2	.....	.....	.....
28	Primary or Other Diagnosis = Skin 2—Ulcers and other skin conditions.	2	16	8	17
29	Primary or Other Diagnosis = Tracheostomy	2	17	.....	17
30	Primary or Other Diagnosis = Urostomy/Cystostomy	.....	17	.....	12
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral).	.....	15	5	15
32	M1030 (Therapy at home) = 3 (Enteral)	.....	15	.....	8
33	M1200 (Vision) = 1 or more	.....	.....	.....	.....
34	M1242 (Pain)= 3 or 4	3	.....	2	.....
35	M1311 = Two or more pressure ulcers at stage 3 or 4	4	6	4	6
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	4	19	7	16
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	8	31	10	25
38	M1334 (Stasis ulcer status)= 2	4	13	7	13
39	M1334 (Stasis ulcer status)= 3	7	17	9	17
40	M1342 (Surgical wound status)= 2	2	7	6	13
41	M1342 (Surgical wound status)= 3	.....	6	5	10
42	M1400 (Dyspnea) = 2, 3, or 4	1	1	.....	.....
43	M1620 (Bowel Incontinence) = 2 to 5	.....	3	.....	2
44	M1630 (Ostomy)= 1 or 2	4	11	2	8
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3	.....	.....	.....	.....

TABLE 5—CASE-MIX ADJUSTMENT VARIABLES AND SCORES—Continued

FUNCTIONAL DIMENSION					
46	M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3.	1			
47	M1830 (Bathing) = 2 or more	6	5	5	2
48	M1840 (Toilet transferring) = 2 or more		1		
49	M1850 (Transferring) = 2 or more	3	1	2	
50	M1860 (Ambulation) = 1, 2 or 3	7		4	
51	M1860 (Ambulation) = 4 or more	8	9	6	7

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 (as of December 31, 2016) 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.

In updating the four-equation model for CY 2018, using 2016 home health claims data (the last update to the four-equation model for CY 2017 used CY 2015 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 2015 and CY 2016. The CY 2018 four-equation model resulted in 120 point-giving variables being used in the model (as compared to the 124 variables for the CY 2017 recalibration). There were 8 variables that were added to the model and 12 variables that were dropped from the model due to the absence of additional resources associated with the variable. Of the variables that were in both the four-equation model for CY 2017 and the four-equation model for CY 2018, the points for 14 variables increased in the CY 2018 four-equation model and the points for 48 variables decreased in the CY 2018 4-equation model. There were 50 variables with the same point values.

Step 2: Re-defining the clinical and functional thresholds so they are reflective of the new points associated with the CY 2018 four-equation model. After estimating the points for each of the variables and summing the clinical and functional points for each episode, we look at the distribution of the clinical score and functional score, breaking the episodes into different steps. The categorizations for the steps are as follows:

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

We then divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.[13] Also, we looked at the average resource use associated with each clinical and functional score and used that as a guide for setting our thresholds. We grouped scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off the CY 2018 four-equation model points are shown in Table 6.

TABLE 6—CY 2018 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 B1)		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 13	0 to 7	0 to 6	0 to 2	0 to 2
	F2	14	8 to 15	7 to 10	3 to 7	3 to 6
	F3	15+	16+	11+	8+	7+

[13] For Step 1, 45.4% of episodes were in the medium functional level (All with score 14).

For Step 2.1, 87.3% of episodes were in the low functional level (Most with scores 5 to 7).

For Step 2.2, 81.9% of episodes were in the low functional level (Most with score 1).

For Step 3, 46.4% of episodes were in the medium functional level (Most with score 9).

For Step 4, 48.6% of episodes were in the medium functional level (Most with score 5 or 6).

Step 3: Once the clinical and functional thresholds are determined and each episode is assigned a clinical and functional level, the payment regression is estimated with an episode's wage-weighted minutes of care as the dependent variable. Independent variables in the model are indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 7 shows the regression coefficients for the variables in the payment regression model updated with CY 2016 home health claims data. The R-squared value for the payment regression model is 0.5073 (an increase from 0.4919 for the CY 2017 recalibration).

TABLE 7—PAYMENT REGRESSION MODEL

	Payment regression from 4-equation model for CY2018
Step 1, Clinical Score Medium	$24.35
Step 1, Clinical Score High	54.10
Step 1, Functional Score Medium	71.10
Step 1, Functional Score High	104.74
Step 2.1, Clinical Score Medium	47.79
Step 2.1, Clinical Score High	133.50
Step 2.1, Functional Score Medium	30.46
Step 2.1, Functional Score High	55.93
Step 2.2, Clinical Score Medium	39.93
Step 2.2, Clinical Score High	192.15
Step 2.2, Functional Score Medium	17.99
Step 2.2, Functional Score High	53.34
Step 3, Clinical Score Medium	14.03
Step 3, Clinical Score High	92.83
Step 3, Functional Score Medium	56.27
Step 3, Functional Score High	86.76
Step 4, Clinical Score Medium	78.75
Step 4, Clinical Score High	260.68
Step 4, Functional Score Medium	25.95
Step 4, Functional Score High	58.66
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	497.79
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	508.40
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	–67.30
Step 4, All Episodes, 20+ Therapy Visits	883.46
Intercept	382.25

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 (as of March 17, 2017) for which we had a linked OASIS assessment.

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

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

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

Step 7: The interpolated weights are then adjusted so that the average case-

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

[15] 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.

mix for the weights is equal to 1.0000.[15] This last step creates the proposed CY 2018 case-mix weights shown in Table 8.

TABLE 8—PROPOSED CY 2018 CASE-MIX PAYMENT WEIGHTS

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2018 weight
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5617
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.6925
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8232
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9539
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0846
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.6662
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.7845
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9027
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0209
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1392
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7157
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8311
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9464
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.0618
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1772
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.5975
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7343
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8711
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0078
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1446
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.7020
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8263
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9506
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0749
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1991
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.7514
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.8729
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9943
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1157
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2372
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6412
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.7929
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9446
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.0963
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2480
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7457
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.8850
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0242
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.1634
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3026
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7952
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9315
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0679
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.2043
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.3406
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2154
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3780
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5406
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2574
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4176
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5779
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2926
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4558
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6189
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2814
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4573
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6332
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3234
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4970
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6705
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3586
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5351

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

TABLE 8—PROPOSED CY 2018 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2018 weight
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7116
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.3997
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6178
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8359
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4418
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6575
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8732
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.4770
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.6956
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	1.9142
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2300
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3877
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5455
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2549
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4159
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5770
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3037
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4632
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6226
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2852
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4598
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6345
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3100
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4880
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6660
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3588
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5352
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7117
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4954
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6816
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8678
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5202
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7098
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8993
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5690
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.7570
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	1.9449
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4628
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6163
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7697
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9232
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0766
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5455
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.6874
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8293
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9711
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1130
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.5903
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7330
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.8757
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0183
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1610
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4835
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6438
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8041
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	0.9645
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1248
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5662
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7149
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8637
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0125
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1612
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6110
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7605
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9101
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.0597
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2093
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.5993

TABLE 8—PROPOSED CY 2018 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2018 weight
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.7785
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9577
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1369
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3162
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.6820
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8496
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0173
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.1849
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3526
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7268
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.8952
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0637
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.2321
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4006
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.7032
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.7381
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.7821
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.8091
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.8440
40231	All Episodes, 20+ Therapy Visits	C2F3S1	1.8881
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.0539
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.0889
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.1329

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the proposed CY 2018 national, standardized 60-day episode payment rate (see section III.C.3. of this proposed rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when the CY 2018 HH PPS case-mix weights (developed using CY 2016 home health claims data) are applied to CY 2016 utilization (claims) data to total payments when CY 2017 HH PPS case-mix weights (developed using CY 2015 home health claims data) are applied to CY 2016 utilization data. This produces a case-mix budget neutrality factor for CY 2018 of 1.0159.

C. Proposed CY 2018 Home Health Payment Rate Update

1. Proposed CY 2018 Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2018 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. The home health market basket was rebased and revised in CY 2013. A detailed description of how we derive the HHA market basket is available in the CY 2013 HH PPS final rule (77 FR 67080 through 67090).

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.

Prior to the enactment of the MACRA, which amended section 1895(b)(3)(B) of the Act, the proposed home health update percentage for CY 2018 would have been based on the estimated home health market basket update of 2.7 percent (based on IHS Global Insight Inc.'s first-quarter 2017 forecast with historical data through fourth-quarter 2016). Due to the requirements specified at section 1895(b)(3)(B)(vi) of the Act prior to the enactment of MACRA, the estimated CY 2018 home health market basket update of 2.7 percent would have been reduced by a MFP adjustment as mandated by the Affordable Care Act (currently estimated to be 0.5 percentage point for CY 2018). In effect, the proposed home health payment update percentage for CY 2018 would have been 2.2 percent. However, section 411(c) of the MACRA amended section 1895(b)(3)(B) of the Act, such that for home health payments for CY 2018, the market basket percentage increase is required to be 1 percent.

Section 1895(b)(3)(B) 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 2018, the home health payment update would be -1 percent (1 percent minus 2 percentage points).

2. Proposed CY 2018 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment

factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We propose to continue this practice for CY 2018, as we continue to believe that, in the absence of HH-specific wage data, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. Specifically, we propose to continue to use the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2018, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2013, and before October 1, 2014 (FY 2014 cost report data). We would 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 2018 HH PPS wage index, we propose to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we would 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 would 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 would continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we would 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 2018, 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. The most recent bulletin (No. 15–01) concerning the revised delineations was published by the OMB on July 15, 2015.

The proposed CY 2018 wage index is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html*.

3. Proposed CY 2018 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 rate would continue to be 78.535 percent and the non-labor-related share would continue to be 21.465 percent as set out in the CY 2013 HH PPS final rule (77 FR 67068). The CY 2018 HH PPS rates would use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and would be adjusted as described in section III.B of this rule. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode rate:

(1) Multiply the national 60-day episode rate by the patient's applicable case-mix weight.

(2) Divide the case-mix adjusted amount into a labor (78.535 percent) and a non-labor portion (21.465 percent).

(3) Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.

(4) 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, this document proposes 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 would 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. Proposed CY 2018 National, Standardized 60-Day Episode Payment Rate

Section 1895(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 2018 national, standardized 60-day episode payment rate, we would apply a wage

index budget neutrality factor; a case-mix budget neutrality factor described in section III.B. of this proposed rule; a reduction of 0.97 percent to account for nominal case-mix growth from 2012 to 2014, as finalized in the CY 2016 HH PPS final rule (80 FR 68646); and the home health payment update percentage discussed in section III.C.1 of this proposed rule.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the proposed CY 2018 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2017 wage index. By dividing the total payments for non-LUPA episodes using the proposed CY 2018 wage index by the total payments for non-LUPA episodes using the CY 2017 wage index, we obtain a wage index budget neutrality factor of 1.0001. We would apply the wage index budget neutrality factor of 1.0001 to the calculation of the proposed CY 2018 national, standardized 60-day episode rate.

As discussed in section III.B. of this proposed rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we would apply a case-mix weight budget neutrality factor to the CY 2018 national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2018 case-mix weights are applied to CY 2016 utilization (claims) data to total payments when CY 2017 case-mix weights are applied to CY 2016 utilization data. The case-mix budget neutrality factor for CY 2018 would be 1.0159 as described in section III.B of this proposed rule.

Next, we would apply a reduction of 0.97 percent to the national, standardized 60-day payment rate for CY 2018 to account for nominal case-mix growth between CY 2012 and CY 2014. Lastly, we would update the proposed payment rates by the proposed CY 2018 home health payment update percentage of 1 percent as mandated by section 1895(b)(3)(B)(iii) of the Act. The proposed CY 2018 national, standardized 60-day episode payment rate is calculated in Table 9.

TABLE 9—PROPOSED CY 2018 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2017 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	Proposed CY 2018 HH payment update	Proposed CY 2018 national, standardized 60-day episode payment
$2,989.97	× 1.0001	× 1.0159	× 0.9903	× 1.01	$3,038.43

The proposed CY 2018 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the proposed CY 2018 home health payment update of 1 percent minus 2 percentage points and is shown in Table 10.

TABLE 10—PROPOSED CY 2018 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2017 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	Proposed CY 2018 HH payment update minus 2 percentage points	Proposed CY 2018 national, standardized 60-day episode payment
$2,989.97	× 1.0001	× 1.0159	× 0.9903	× 0.99	$2,978.26

c. Proposed CY 2018 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); and
- Speech-language pathology (SLP).

To calculate the proposed CY 2018 national per-visit rates, we start with the CY 2017 national per-visit rates. We then apply a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculate the wage index budget neutrality factor by simulating total payments for LUPA episodes using the proposed CY 2018 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2017 wage index. By dividing the total payments for LUPA episodes using the proposed CY 2018 wage index by the total payments for LUPA episodes using the CY 2017 wage index, we obtain a wage index budget neutrality factor of 1.0005. We would apply the wage index budget neutrality factor of 1.0005 in order to calculate the CY 2018 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, there is no case-mix weights budget neutrality factor needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the proposed CY 2018 home health payment update percentage of 1 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The proposed CY 2018 national per-visit rates are shown in Tables 11 and 12.

TABLE 11—PROPOSED CY 2018 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH discipline type	CY 2017 per-visit payment	Wage index budget neutrality factor	Proposed CY 2018 HH payment update	Proposed CY 2018 per-visit payment
Home Health Aide	$64.23	× 1.0005	× 1.01	$64.90
Medical Social Services	227.36	× 1.0005	× 1.01	229.75
Occupational Therapy	156.11	× 1.0005	× 1.01	157.75
Physical Therapy	155.05	× 1.0005	× 1.01	156.68
Skilled Nursing	141.84	× 1.0005	× 1.01	143.33
Speech- Language Pathology	168.52	× 1.0005	× 1.01	170.29

The proposed CY 2018 per-visit payment rates for HHAs that do not submit the required quality data are updated by the proposed CY 2018 HH payment update percentage of 1 percent minus 2 percentage points and are shown in Table 12.

TABLE 12—PROPOSED CY 2018 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH discipline type	CY 2017 per-visit rates	Wage index budget neutrality factor	Proposed CY 2018 HH payment update minus 2 percentage points	Proposed CY 2018 per-visit rates
Home Health Aide	$64.23	× 1.0005	× 0.99	$63.62
Medical Social Services	227.36	× 1.0005	× 0.99	225.20
Occupational Therapy	156.11	× 1.0005	× 0.99	154.63
Physical Therapy	155.05	× 1.0005	× 0.99	153.58
Skilled Nursing	141.84	× 1.0005	× 0.99	140.49
Speech- Language Pathology	168.52	× 1.0005	× 0.99	166.92

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, 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 (78 FR 72306). 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 would be $264.46 (1.8451 multiplied by $143.33), subject to area wage adjustment.

e. Proposed CY 2018 Non-Routine Medical Supply (NRS) Payment Rates

Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the proposed CY 2018 NRS conversion factor, we update the CY 2017 NRS conversion factor ($52.50) by the proposed CY 2018 home health payment update percentage of 1 percent. We do not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The proposed NRS conversion factor for CY 2018 is shown in Table 13.

TABLE 13—PROPOSED CY 2018 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2017 NRS conversion factor	Proposed CY 2018 HH payment update	Proposed CY 2018 NRS conversion factor
$52.50	× 1.01	$53.03

Using the CY 2018 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 14.

TABLE 14—PROPOSED CY 2018 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed CY 2017 NRS payment amounts
1	0	0.2698	$ 14.31
2	1 to 14	0.9742	51.66
3	15 to 27	2.6712	141.65
4	28 to 48	3.9686	210.45

TABLE 14—PROPOSED CY 2018 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA—Continued

Severity level	Points (scoring)	Relative weight	Proposed CY 2017 NRS payment amounts
5	49 to 98	6.1198	324.53
6	99+	10.5254	558.16

For HHAs that do not submit the required quality data, we update the CY 2017 NRS conversion factor ($52.50) by the proposed CY 2018 home health payment update percentage of 1 percent minus 2 percentage points. The proposed CY 2018 NRS conversion factor for HHAs that do not submit quality data is shown in Table 15.

TABLE 15—PROPOSED CY 2018 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2017 NRS conversion factor	Proposed CY 2018 HH payment update percentage minus 2 percentage points	Proposed CY 2018 NRS conversion factor
$52.50	× 0.99	$51.98

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 16.

TABLE 16—PROPOSED CY 2018 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed CY 2018 NRS payment amounts
1	0	0.2698	$ 14.02
2	1 to 14	0.9742	50.64
3	15 to 27	2.6712	138.85
4	28 to 48	3.9686	206.29
5	49 to 98	6.1198	318.11
6	99+	10.5254	547.11

f. Rural Add-On

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

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

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

Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018. Therefore, for episodes and visits that end on or after January 1, 2018, a rural add-on payment will not apply.

D. 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 in the case of outliers because of unusual variations in the type or amount of medically necessary care. Prior to the enactment of the Affordable Care Act, section 1895(b)(5) of the Act stipulated that projected total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. In the July 3, 2000 Medicare Program; Prospective Payment System for Home Health Agencies final rule (65 FR 41188 through 41190), we described the method for determining outlier payments. Under this system, 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. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost

beyond the wage-adjusted threshold. The threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

In the CY 2010 HH PPS proposed rule (74 FR 40948, 40957), we stated that outlier payments increased as a percentage of total payments from 4.1 percent in CY 2005, to 5.0 percent in CY 2006, to 6.4 percent in CY 2007 and that this excessive growth in outlier payments was primarily the result of unusually high outlier payments in a few areas of the country. In that discussion, we noted that despite program integrity efforts associated with excessive outlier payments in targeted areas of the country, we discovered that outlier expenditures still exceeded the 5 percent target in CY 2007 and, in the absence of corrective measures, would continue do to so. Consequently, we assessed the appropriateness of taking action to curb outlier abuse. As described in the CY 2010 HH PPS final rule (74 FR 58080 through 58087), to mitigate possible billing vulnerabilities associated with excessive outlier payments and adhere to our statutory limit on outlier payments, we finalized an outlier policy that included a 10 percent agency-level cap on outlier payments. This cap was implemented in concert with a reduced FDL ratio of 0.67. These policies resulted in a projected target outlier pool of approximately 2.5 percent. (The previous outlier pool was 5 percent of total home health expenditures). For CY 2010, we first returned the 5 percent held for the previous target 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. Then, we reduced the CY 2010 rates by 2.5 percent to account for the new outlier pool of 2.5 percent. This outlier policy was adopted for CY 2010 only.

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 may 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, our HH PPS outlier policy is that 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 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.

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.

For this proposed rule, using preliminary CY 2016 claims data (as of March 17, 2017) and the proposed CY 2018 payment rates presented in section III.C of this proposed rule, we estimate that outlier payments would constitute

approximately 2.47 percent of total HH PPS payments in CY 2018 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 are not proposing a change to the FDL ratio for CY 2018 as we believe that maintaining an FDL ratio of 0.55 with a loss-sharing ratio of 0.80 is still appropriate given the percentage of outlier payments projected for CY 2018. Likewise, we are not proposing a change to the loss-sharing ratio (0.80) for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.). While we are not proposing to change the FDL ratio of 0.55 for CY 2018, we note that in the final rule, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete year of HH PPS data (CY 2016 claims data as of June 30, 2017 or later). This may result in changes to the FDL ratio in the final rule.

E. Proposed Implementation of the Home Health Groupings Model (HHGM) for CY 2019

1. Overview, Data, and File Construction

Under the home health prospective payment system (HH PPS), Medicare pays for home health services provided during a 60-day episode of care. Episodes are case-mix adjusted based on the timing of the episode within a sequence of episodes, the patient's clinical status and functional status as determined using information from the Outcome and Assessment Information Set (OASIS), and the amount of therapy service provided during the 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): 0–5; 6; 7–9; 10; 11–13; 14–15; 16–17; 18–19; and 20 or more visits. The combinations of episode timing, clinical and functional levels, and therapy service use categories result in 153 home health resource groups (HHRGs) into which home health episodes are categorized. Each HHRG is assigned a relative weight reflecting the average resource use of patients in that group compared with average resource use across all Medicare home health patients; this weight is then used to case mix adjust the episode's payment (with an additional adjustment for geographic variation in wages). Additional payment adjustments are made for very resource intensive (outlier) episodes, episodes with very few visits, transfers to other HHAs or to hospitals with a return to home health during the episode, and the expected use of non-routine medical supplies (NRS).

As discussed in section II.D of this proposed rule, the Report to Congress, required by section 3131(d) of the Affordable Care Act, found that payment accuracy could be improved under the current payment system, particularly for patients with certain clinical characteristics.[16] Findings from the report suggest that the current home health payment system may discourage HHAs from serving patients with clinically complex and/or poorly controlled chronic conditions who do not need therapy services, but require skilled nursing care. In addition, MedPAC believes that the Medicare home health benefit is ill-defined and the current reliance on therapy service thresholds for determining payment is counter to the goals of a prospective payment system. Under the current payment system, HHAs receive higher payments for providing more therapy visits, which may incentivize unnecessary utilization. MedPAC reitereated their recommendation in the March 2017 Report to Congress that CMS eliminate the use of the number of therapy vists as a payment factor in the home health PPS beginning in 2019.[17]

To better align payment with patient care needs and better ensure that clinically complex and ill beneficiaries have adequate access to home health care, we are proposing for CY 2019 case-mix methodology refinements through the implementation of the Home Health Groupings Model (HHGM). We propose to implement the HHGM for home health periods of care beginning on or after January 1, 2019. The implementation of the HHGM will require provider education and training, updating and revising relevant manuals, and changing claims processing systems. Implementation starting in CY 2019 would provide an opportunity for CMS, its contractors, and the agencies themselves to prepare. This patient-centered model groups periods of care in a manner consistent with how clinicians differentiate between patients and the primary reason for needing home health care. The HHGM uses 30-day periods rather than the 60-day episode used in the current payment system, eliminates the use of the number of therapy visits provided to determine payment, 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. In total, there are 144 different payment groups in the HHGM.

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 HHGM, we propose shifting to a Cost-Per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from the Medicare Cost Report. The CPM + NRS approach incorporates a wider variety of costs (such as transportation) compared to the BLS estimates and the costs are available for individual HHA providers while the BLS costs are aggregated for the Home Health Care Service industry. The proposed methodology used to calculate the cost of an episode/period of care is discussed in detail in section III.E.2. of this proposed rule.

We propose using the 30-day periods rather than the 60-day episodes in the current payment system. Episodes have more visits, on average, during the first 30 days compared to the last 30 days.[18] Costs are much higher earlier in the episode and lesser later on, therefore we believe that dividing a single 60-day episode into two 30-day periods more accurately apportions payments. Overall, we found that the average length of an episode of care was 47 days, but roughly a quarter of all 60 days episodes lasted 30 days or less. The proposed change from 60-day billing to 30-day billing under the HHGM is discussed in detail in section III.E.3. of this proposed rule.

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

[17] Medicare Payment Advisory Commission (MedPAC). ''Home Health Care Services.'' *Report to Congress: Medicare Payment Policy.* Washington, DC, March 2015. P. 233. Accessed on March 28, 2017 at *http://www.medpac.gov/docs/default-source/reports/mar2015_entirereport_revised.pdf?sfvrsn=0.*

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

Similar to the current payment system, 30-day periods under the HHGM 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 HHGM, the first 30-day period is classified as early. All subsequent 30-day periods in the sequence (second or later) are classified as late. We propose to adopt this episode timing classification for 30-day periods with the implementation of the HHGM. Similar to the current payment system, we propose that a 30-day period could not be considered early unless there was a gap of more than 60 days between the end of one period and the start of another. The comprehensive assessment would still be completed within 5 days of the start of care date and completed no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, Condition of participation: Comprehensive assessment of patients. The proposed episode timing classification is discussed in detail in section III.E.4. of this proposed rule.

Under the HHGM, each period would be classified into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to home health. The 30-day period would be categorized as institutional if an acute or post-acute care stay occurred in the 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 propose to adopt this categorization by admission source with the implementation of the HHGM. The proposed admission classification source is discussed in detail in section III.E.5. of this proposed rule.

The HHGM would group 30-day periods into categories based on a variety of patient characteristics. Within the HHGM, one of the steps in case-mix adjusting the 30-day payment amount would include grouping periods into one of six clinical groups based on the principal diagnosis listed on the home health claim. We propose grouping periods into one of six clinical groups based on the principal diagnosis with the implementation of the HHGM. The principal diagnosis reported would provide information to describe the primary reason for which patients are receiving home health services under the Medicare home health benefit. The proposed six clinical groups, which are discussed in detail in section III.E.6. of this proposed rule, are as follows:

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

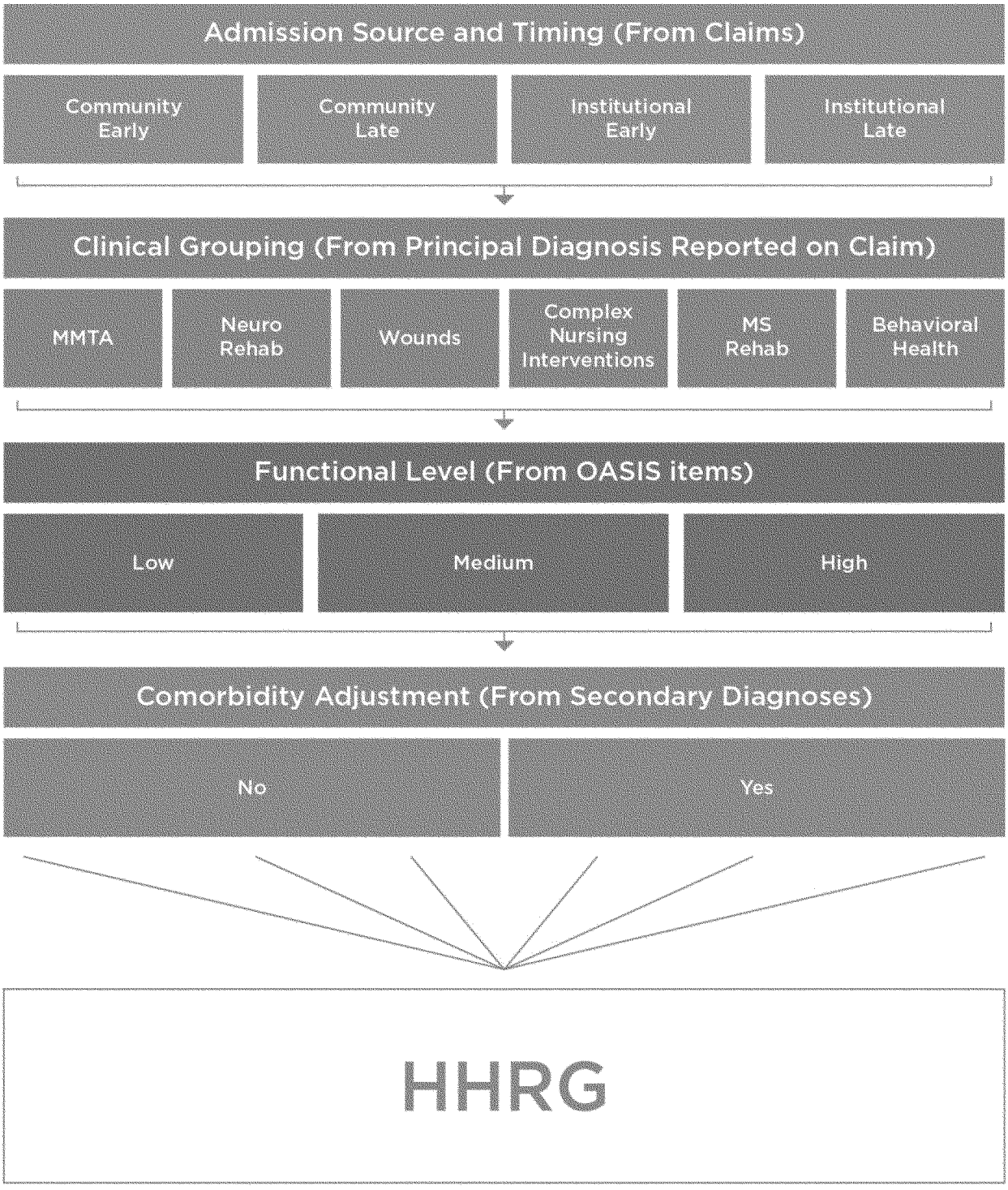
Under the HHGM, each 30-day period would be placed into one of three functional levels. The level would indicate if, on average, given its responses on certain functional OASIS items, a 30-day period is predicted to have higher costs or lower costs. We propose classifying 30-day periods according to functional level. For each of the six clinical groups, we propose that periods would be further classified into one of three functional levels with roughly 33 percent of periods in each level. The creation of this functional level is very similar to how the functional level is created in the current payment system. The proposed functional levels and corresponding OASIS items are discussed in detail in section III.E.7. of this proposed rule.

Exploratory analyses determined that comorbidities—that is, secondary diagnoses—provide additional information that can further explain resource use differences across 30-day periods of care even after controlling for the primary diagnosis. Comorbidities are tied to poorer health outcomes, more complex medical need and management, and higher costs. The HHGM would include a comorbidity adjustment category based on the presence of secondary diagnoses. We propose that 30-day periods would receive a comorbidity adjustment if any diagnosis codes listed on the home health claim are included on a list of comorbidities that occurred in at least 0.1 percent of 30-day periods and associated with increased average resource use. The proposed comorbidity adjustment is discussed in detail in section III.E.8. of this proposed rule.

Currently, if an HHA provides four visits or less in an episode, they will be paid a standardized per visit payment instead of an episode payment for a 60-day episode of care. These payment adjustments are called Low-Utilization Payment Adjustments (LUPAs). While the HHGM would still include LUPAs, the approach to calculating the LUPA thresholds would need to change in the HHGM because of the switch to 30-day periods from 60-day episodes. Whereas there is a single LUPA threshold of 4 visits for all episodes under the current payment system, we propose the LUPA threshold would vary for a 30-day period under the HHGM depending on the HHGM payment group to which it was assigned. To create LUPA thresholds, 30-day periods (including those that were LUPAs in the current payment system) were grouped into the 144 different HHGM payment groups. For each payment group, we propose to use the 10th percentile value of visits to create a payment group specific LUPA threshold with a minimum threshold of at least 2 for each group. The proposed LUPA thresholds are discussed in more detail in section III.E.9. of this proposed rule.

Figure 5 represents how each 30-day period of care would be placed into one of 144 home health resource groups (HHRGs) under the proposed HHGM.

FIGURE 5: Structure of the Proposed HHGM



Under the Home Health Groupings Model, an episode is grouped into one (and only one) subcategory under each larger colored category. An episode's combination of subcategories groups the episode into one of 144 different payment groups.

While the proposed HHGM would reflect a change in the case-mix adjustment methodology, the conditions for payment would remain the same for Medicare home health services, meaning all requirements would still

need to be met in accordance with § 424.22. This includes physician certification that: (1) The individual is in need or needed intermittent skilled nursing care, or physical therapy or speech-language pathology services, and is confined to the home; (2) a plan of care has been established and will be periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine; (3) the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine; and, (4) a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner. Likewise, under the HHGM, the Medicare beneficiary would retain all rights that currently exist under the current HH PPS, including those related to beneficiary liability for services or any reduction or termination of services. These would include the issuance of the Advanced Beneficiary Notice (ABN) and the Home Health Change of Care Notice (HHCCN), when appropriate. Medicare home health agencies are required to issue an ABN when a HHA believes Medicare will not pay for some or all of the patient's Medicare home health care. In these circumstances, if the beneficiary chooses to receive the items/services in question and Medicare does not cover the home health care, HHAs may use the ABN to shift liability for the non-covered home health care to the beneficiary. The HHCCN is a written notice that the HHA provides a beneficiary when his/her home health plan of care is changing because the home health agency makes a business decision to reduce or stop providing the patient some or all of the home health services or supplies OR the beneficiary's physician changed orders which may reduce or stop certain Medicare covered home health services or supplies.

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

The core file for most of the analyses for this proposed rule includes 100 percent of home health episode claims with Through Dates in Calendar Year (CY) 2016, processed by March 17, 2017, accessed via the Chronic Conditions Data Warehouse (CCW). Original or adjustment claims processed after March 17, 2017, would not be reflected in the core file. The claims-based file was supplemented with additional variables that were obtained from the CCW, such as information regarding other Part A and Part B utilization.

The data were cleaned by processing any remaining adjustments and by excluding duplicates and claims that were Requests for Anticipated Payment (RAP). In addition, visit-level variables needed for the analysis were extracted from the revenue center trailers (that is, the line items that describe the visits) and downloaded as a separate visit-level file, with selected episode-level variables merged onto the records for visits during those episodes. To account for potential data entry errors, the visit-level variables for visit length were top-censored at eight hours.[19]

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

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

The analysis file also includes data on patient characteristics obtained from the OASIS assessments conducted by HHA staff at the start of each episode. The assessment data are electronically submitted by home health agencies (HHAs) to a central CMS repository. In constructing the core data file, 100 percent of the OASIS assessments submitted October 2015, through December 2016 from the CMS repository were uploaded by CMS to the CCW. A CCW-derived linking key (Bene_ID) was used to match the OASIS data with CY 2016 episodes of care. Episodes that could not be linked with an OASIS assessment were excluded from the analysis file, as they included insufficient patient-level data to create the HHGM.

To construct measures of resource use, a variety of data sources were used (see section III.E.2 of this proposed rule for the proposed methodology used to calculate the cost of care under the HHGM). First, BLS data on average wages and fringe benefits were used to produce one version of the wage-weighted cost per minute for each home health discipline. The wage data are for North American Industry Classification System (NAICS) 621600—Home Health Care Services. The wage data are broken down by the following occupations:

TABLE 17—BLS STANDARD OCCUPATION CLASSIFICATION (SOC) CODES FOR HOME HEALTH PROVIDERS

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

For visits where the service provided—as indicated by the Healthcare Common Procedure Coding System (HCPCS) code—can be provided by only a single standard occupation classification code; for example, establishment or review of a plan of care by a registered nurse (RN; HCPCS = G0162), the wage (and fringe) rate for that standard occupation classification is used to calculate the cost of the minutes for the visit. For visits where the service provided can potentially be provided by different standard occupation classification, such as observation and assessment by an RN or a Licensed Practical Nurse (LPN; HCPCS = G0163), a blended rate is applied, with the rate for each standard occupation classification code weighted by the total home health employment for that standard occupation classification code. The employment data are available from the same BLS table as the wage data.

Home Health Agency Medicare Cost Report (MCR) data were also used to construct a measure of resource use after trimming out HHAs whose costs were outliers. These data are used to provide a representation of the average costs of visits provided by HHAs in the six Medicare home health disciplines: Skilled nursing; physical therapy; occupational therapy; speech-language pathology; medical social services; and home health aide services. Cost report

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

data are publicly available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/*.

The 2016 analytic file included 6,293,442 episodes. Of these, 469,346 (7.5 percent) were excluded because they could not be linked to OASIS assessments or because of the reasons listed above. This yielded an analysis file including 5,824,096 episodes. Those episodes are 60-day episodes under the current payment system, but for the HHGM those 60-day episodes were converted into two 30-day periods. This yielded a final HHGM analytic file that included 10,231,507, 30-day periods. Certain 30-day periods were excluded for the following reasons:

- Periods missing a diagnosis code or where the diagnosis code did not link to a clinical group to case-mix adjust the period's payment (after exclusions, n = 10,177,949).
- Inability to merge to certain OASIS items to create the episode's functional level that is used for risk adjustment. For all the periods in the analytic file, there was a look-back through CY 2015 for a Start of Care or Resumption of Care assessment that preceded the period being analyzed and was in the same sequence of periods. If such an assessment was found, it was used to impute responses for OASIS items that were not included in the follow-up assessment. Periods which did not link to a Start of Care or Resumption of Care assessment were dropped (after exclusions, n = 9,477,856).
- No nursing visits or therapy visits (after exclusions, n = 9,290,340).
- LUPAs were excluded from the analysis. Periods that are identified as LUPAs in the current payment system are excluded in the creation of the functional score. Following the creation of the score (and the corresponding levels), case-mix group specific LUPA thresholds were created and episodes/periods were excluded that were below the new LUPA threshold when computing the case-mix weights.[20] Therefore, the final analytic sample included 8,642,107 30-day periods that were used for the analyses in the HHGM.

As noted in section II.D of this proposed rule, the analyses and the ultimate development of Home Health Groupings Model (HHGM) have been shared with both internal and external stakeholders via technical expert panels, clinical workgroups, special open door forums, and in the CY 2017 HH PPS final rule (81 FR 76702). Technical expert panel and clinical workgroup webinars on the technical report were held in December 2016 and a detailed technical report was posted on the CMS home health agency Web page in December, providing opportunity for stakeholder feedback.[21] We also held a National Provider call in January 2017, to further solicit feedback from the public.[22]

2. Methodology Used To Calculate the Cost of Care

To construct the case-mix weights for the HHGM proposal, the costs of providing care needed to be determined. A Wage-Weighted Minutes of Care (WWMC) approach is used in the current payment system based on data from the BLS. However, we are proposing to adopt a Cost-per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from Medicare Cost Reports (MCR). We used the following data sources and methodology for calculating these measures of resource use:

- *BLS Wage Estimates:* For the WWMC method of calculating home health resource use, wage and fringe data was obtained from the BLS by industry code from the NAICS and occupation code from the Standard Operation Classification. These data provide nationwide average wage rates and the average value of fringe benefits per hour of work for specific occupations.
- *Home Health Medicare Cost Report Data:* All Medicare-certified HHAs must report their own costs through publicly-available home health cost reports maintained by the Healthcare Cost Report Information System (HCRIS). Freestanding HHAs report HHA-specific cost reports while HHAs that are hospital-based report on the HHA component of the hospital cost reports. These cost reports enable estimation of the cost per visit by provider and the estimated NRS cost to charge ratios. To obtain a more robust estimate of cost, a trimming process was applied to remove cost reports with missing or questionable data and extreme values.[23]
- *Home Health Claims Data:* Medicare home health claims data are used in both the WWMC and CPM+NRS methods to obtain minutes of care by discipline of care.
- *Wage-Weighted Minutes of Care (WWMC) Approach:* Used in the current payment system, this approach determines resource use for each episode by multiplying utilization (in terms of the number of minutes of direct patient care provided by each discipline) by the corresponding opportunity cost of that care (represented by wage and fringe benefit rates from the BLS).[24] Table 18 shows the occupational titles and corresponding mean hourly wage rates from the BLS. The employer cost per hour worked shown in the fifth column is calculated by adding together the mean hourly wage rates and the fringe benefit rates from the BLS (generally around 37 percent of wages). For home health disciplines that include multiple occupations (such as skilled nursing), the opportunity cost is generated by weighting the employer cost by the proportions of the labor mix.[25] Otherwise, the opportunity cost is the same as the employer cost per hour.

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

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

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

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

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

[25] Labor mix represents the percentage of employees with a particular occupational title (as obtained from the BLS) within a home health discipline.

TABLE 18—OCCUPATIONAL EMPLOYMENT AND WAGES PROVIDED BY THE FEDERAL BUREAU OF LABOR STATISTICS

Occupation title	National employment counts	Mean hourly wage	Estimate of benefits as a % of wages	Estimated employer cost per hour worked	Labor mix	Home health discipline	Opportunity cost
Registered Nurses.	173,590	$32.94	43.76	$47.36	0.68	Skilled Nursing	$42.21
Licensed Practical and Licensed Vocational Nurses.	82,860	21.86	43.76	31.43	0.32		
Physical Therapists.	25,700	46.42	39.91	64.95	0.76	Physical Therapy	59.18
Physical Therapist Assistants.	7,460	30.81	35.75	41.83	0.22		
Physical Therapist Aides.	500	15.85	35.75	21.52	0.01		
Occupational Therapists.	10,780	44.17	39.91	61.80	0.82	Occupational Therapy	58.46
Occupational Therapist Assistants.	2,220	32.03	35.75	43.48	0.17		
Occupational Therapist Aides.	110	25.20	35.75	34.21	0.01		
Speech-Language Pathologists.	5,340	46.83	39.91	65.52	.....	Speech Therapy	65.52
Medical and Public Health Social Workers.	17,270	28.16	39.91	39.40	0.97	Medical Social Service	39.35
Mental Health and Substance Abuse Social Workers.	450	26.87	39.91	37.59	0.03		
Home Health Aides.	385,440	10.93	35.75	14.84	.....	Home Health Aide	14.84

Source: May 2015 National Industry-Specific Occupational Employment and Wage Estimates NAICS 621600—Home Health Care Services.

For each home health period of care, the number of minutes of care provided (obtained from the home health claims) is weighted by the corresponding opportunity cost for each discipline providing the minutes. The resulting wage-weighted minutes of care are summed for the 30-day period to obtain total costs. Table 19 shows these costs overall for 30-day periods in CY 2016 (n = 8,642,107). On average, total period costs were $374.52. The distribution ranged from a 5th percentile value of $73.87 to a 95th percentile value of $912.10.

TABLE 19—DISTRIBUTION OF AVERAGE RESOURCE USE USING WWMC APPROACH

[30 day periods]

Statistics	Mean	N	5th Percentile	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile	95th Percentile
Average Resource Use (WWMC)	$374.52	8,642,107	$73.87	$94.97	$158.29	$303.19	$517.063	$749.22	$912.10

In the current HH PPS, all episodes without a LUPA payment receive payment for NRS, regardless of whether or not the HHA provided NRS during that episode. NRS payment amounts are determined through a payment model separately from the one used to construct the episode's case-mix weight. The current payment system determines NRS payment using the presence of clinical factors associated with NRS provision from the OASIS. Two-thirds of episodes do not include provision of NRS, yet those episodes still receive an NRS payment.

We are proposing to calculate resource use under the HHGM using a Cost-per-Minute plus Non-Routine Supplies (CPM + NRS) approach. It determines resource use using information from Medicare cost reports. Under the proposed HHGM, we would group episodes 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. 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 drives the case-mix weights. CMS would return $53.03 to the base rate (that is, the NRS conversion factor). If there is a high amount of NRS cost for all episodes in a particular group (holding all else equal), the resource use will be higher relative to the average and the case-mix weight will correspondingly be higher. Similar to the current system, NRS would still be paid prospectively under the HHGM, but the HHGM eliminates the separate case-mix adjustment model for NRS. Incorporating the NRS cost into the measure of overall resource use (that is, the dependent variable of the payment model) requires adjusting the NRS charges submitted on claims based on the NRS cost-to-charge ratio from cost report data.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Resource use is then obtained by:

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

Table 20 shows these costs overall for 30-day periods in CY 2015 (n = 8,642,107). On average, total 30-day period costs are $1,585.48. The distribution ranges from a 5th percentile value of $300.03 to a 95th percentile value of $3,908.93.

TABLE 20—DISTRIBUTION OF AVERAGE RESOURCE USE USING CPM + NRS APPROACH

[30 day periods]

Statistics	Mean	N	5th Percentile	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile	95th Percentile
Average Resource Use (CPM + NRS)	$1,585.48	8,642,107	$300.03	$396.82	$671.96	$1262.65	$2,119.49	$3,135.38	$3,908.93

The distributions and magnitude of the estimates of costs for the two methods are very different. The differences arise because the CPM + NRS method incorporates HHA-specific costs that represent the total costs incurred during a 30-day period (including overhead costs), while the WWMC method provides an estimate of only the labor costs (wage + fringe) related to direct patient care from patient visits that are incurred during a 30-day period. Those costs are not HHA-specific and do not account for any non-labor costs (such as transportation costs) or the non-direct patient care labor costs (such as, administration and general labor costs). Because the costs estimated using the two approaches are measuring different items, they cannot be directly compared. However, if the true cost of a 30-day period is correlated with the labor that is provided during visits, the two approaches should be highly correlated. The correlation coefficient between the two approaches to calculating resource use is equal to 0.8016 (n = 8,642,107). Therefore, the relationship in relative costs is similar between the two methods.

Using cost report data to develop case-mix weights more evenly weights skilled nursing services and therapy services than the BLS data. Table 21 shows the ratios between the estimated costs per hour for each of the home health disciplines compared with skilled nursing resulting from the CPM +NRS versus WWMC methods. Under the CPM+NRS methodology, the ratio for physical therapy costs per hour to skilled nursing is 1.14 compared with 1.40 using the WWMC method.

TABLE 21—RELATIVE VALUES IN COSTS PER HOUR BY DISCIPLINE

[Skilled nursing is base]

Estimated cost per hour	Skilled nursing	Physical therapy	Occupational therapy	Speech therapy	Medical social service	Home health aide
CPM+NRS	1.00	1.14	1.16	1.24	1.36	0.41
WWMC	1.00	1.40	1.39	1.50	0.95	0.36

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

3. Change From 60-Day Billing to 30-Day Billing Under the HHGM

a. 30-Day Unit of Payment

Currently, HHAs are paid for each 60-day episode of home health care provided. We are proposing 30-day periods of payment for the HHGM. Through examination of 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 (see Tables 22 and 23). 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. This difference in resource use between the first and second 30-day period within a 60-day episode is one of the main reasons we are proposing 30-day periods of payment for the HHGM. Another reason for proposing to change the unit of payment from 60-days to 30-days is the removal of the therapy visit thresholds from the case-mix adjustment methodology under the HHGM (the current system accounts for therapy visit variation through the use of these thresholds). Without thresholds being used to account for resource use variation, a shorter period of care is needed to reduce the variation and improve the accuracy of the case-mix weights generated under the HHGM. The HHGM's goodness of fit statistics (for example, R-squared) improve due to reduced resource use variation when a shorter, more constrained time period is examined. Therefore, the case-mix weights and proposed move to a 30-day period under the HHGM better approximate relative resource use. Furthermore, by switching to a 30-day period, the billing cycle for Medicare home health services would be the same as for other Medicare health care settings, such as hospices and SNFs, which currently bill on a monthly basis.

Using two segments of the current 60-day episodes, 30-day periods were constructed as follows for the development of the HHGM:

- A 30-day period comprising days 1–30 of a current 60-day episode where ''day 1'' is the current 60-day episode's From Date.
- A second period comprising days 31 and above of a current 60-day episode. This period would be 30-days in length if the current episode was 60-days (from the From Date of the episode to the Through Date of the episode) and some lesser length if the current episode were fewer than 60-days.

A typical 60-day episode was broken down into two portions: A first 30-day period; and a second 30-day period consisting of the remaining days. For example, if the current episode was 58 days, then the first period was 30-days, and the second period was comprised of the remaining 28 days. Resource utilization was calculated for each 30-day period based on the discipline visits that occur within each respective 30-day time span. The OASIS information that is applied to the two 30-day periods (for example, OASIS information) is established by the same OASIS that is linked to the current 60-day episode.

Table 22 shows the average number of visits by discipline and resource use estimates during 15-day periods in a 60-day episode, and shows that visit patterns differ over the course of a 60-day episode. Across all labor categories there is a decline in visits as the episode proceeds; in total there are 6.8 visits on average in days 1–15 and 2.6 visits on average in days 46–60 which is a 61.8 percent decline from the first 15 days of care in a 60-day episode to the last 15 days of care in a 60-day episode.

Table 23 shows the average number of visits and resource use estimates by discipline during 15-day periods in a 60-day episode, but for only those episodes that are first in a sequence of episodes and last a full 60-days. A sequence of episodes contains episodes where no more than 60-days elapse from the end of one episode to the start of the next. Therefore, first episodes are those where the beneficiary has not had home health in the 60-days prior to the start of the first episode. Even among this subset of episodes, there is a decline in average visits by quarter as the episode proceeds.

These results show that there is variation in average resource use across 60-day episodes. By moving to two 30-day periods within a 60-day episode (or a single 30-day period if the 60-day episode contains 30 or fewer days), the HH PPS case mix weights better align with the resource use patterns across the current 60-day episode. Though the analyses are based on two 30-day periods in a 60-day episode, we are not proposing a change in the requirements for completing the comprehensive assessment. Under the HHGM, the comprehensive assessment would still be required, as outlined in § 484.55 roughly every 60-days as is required under the current HH PPS. While we examined resource use in 15-day periods in a 60-day episode of care, as outlined in Tables 22 and 23, in order to strike an appropriate balance between increasing payment accuracy and being cognizant of increasing burden for the home health industry, we are not proposing to adjust payments every 15 days. We expect that billing on a 30-day basis should not be completely unfamiliar to HHAs as HHAs billed as such prior to the implementation of the HH PPS.

TABLE 22—AVERAGE VISITS PER 15 DAYS DURING A 60-DAY EPISODE

	Days 1–15	Days 16–30	Days 31–45	Days 46–60
Average Daily Resource Use	$261.97	$162.44	$107.49	$88.67
Average Skilled Nursing Visits	3.3	2.1	1.6	1.4
Average PT Visits	2.2	1.7	1.0	0.6
Average OT Visits	0.6	0.5	0.3	0.2
Average SLP Visits	0.1	0.1	0.1	0.0
Average Aide Visits	0.5	0.5	0.4	0.3
Average MSS Visits	0.1	0.0	0.0	0.0
Average Total Visits	6.8	4.9	3.3	2.6

TABLE 23—AVERAGE VISITS PER 15 DAYS DURING A 60-DAY EPISODE

[Only First Episodes in a Sequence of Episodes That Last a Full 60-Days]

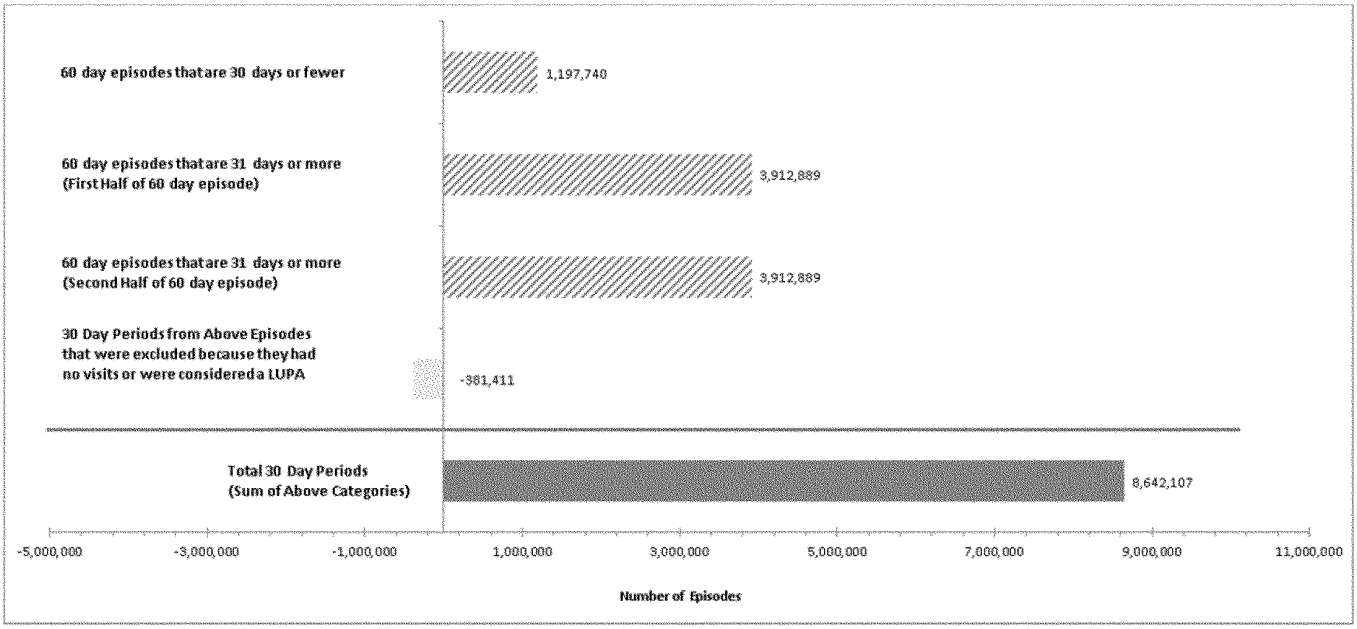
	Days 1–15	Days 16–30	Days 31–45	Days 46–60
Average Daily Resource Use	$326.78	$217.75	$174.82	$167.69
Average Skilled Nursing Visits	3.9	2.5	2.2	2.3
Average PT Visits	2.6	2.4	1.7	1.4
Average OT Visits	0.8	0.8	0.5	0.4
Average SLP Visits	0.1	0.2	0.1	0.1
Average Aide Visits	0.5	0.5	0.5	0.4
Average MSS Visits	0.1	0.1	0.0	0.0
Average Total Visits	8.1	6.4	5.1	4.6

Overall, approximately 25 percent of episodes are 30 days or less in length, and therefore, would produce no second 30-day period under the HHGM. These episodes (with 30 days or fewer) would convert to only one 30-day period each; any 60-day episode that is 31 days or more would produce two 30-day periods: A first period comprising 30 days in length and then a second period with the remaining days in the 60-day episode.

Overall, after conversion from the 5,110,629 60-day episodes, there were 8,642,107 30-day periods:

- There were 1,197,740 30-day periods that could potentially be one-to-one conversions from 60-day episodes that were 30-days or fewer in length.
- Additionally, there were 3,912,889 60-day episodes that were between 31 and 60-days in length in which two 30-day periods could be produced. That is, those 60-day episodes could produce up to 7,825,778 30-day periods.
- However, from the above episodes (which were used to create the 30-day periods), there were 381,411 periods that had no visits included or were considered a LUPA under the HHGM and therefore were excluded. This is shown in Table 24.

TABLE 24: Total Numbers of 60-day Episodes and 30-day Simulated Home Health Periods



Tables 25 and 26 show the frequency of episode length in days and estimates of resource use among the original, 60-day episodes and the corresponding distribution of episode length and resource use estimates among the simulated 30-day periods. Again, these results show differences by the length of care. By shortening the unit of time that CMS pays for within the HH PPS (from 60-day episodes to 30-day periods), payment would more accurately relate to the variation in costs seen across episodes and periods of care.

TABLE 25—FREQUENCY OF LENGTH OF 60-DAY EPISODES AND AVERAGE RESOURCE USE FOR EPISODES OF A CERTAIN LENGTH

Length of episode in days	Number of episodes	Percent of episodes	Average resource use	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
1	189	0.0	$390.10	$200.87	$348.85	$249.99	$495.03
2	1,204	0.0	542.52	348.55	453.72	318.34	673.97
3	3,796	0.1	673.54	418.19	596.78	403.37	846.78
4	6,051	0.1	751.09	474.35	667.26	447.37	940.19
5	9,385	0.2	829.89	521.12	730.17	506.40	1,021.84
6	11,793	0.2	873.31	505.81	785.61	542.35	1,083.79
7	16,587	0.3	941.17	560.28	838.68	588.23	1,152.63
8	19,887	0.4	972.38	556.43	875.29	613.68	1,200.88
9	21,026	0.4	1,024.75	592.64	920.13	641.04	1,272.40
10	25,724	0.5	1,078.33	623.90	965.80	671.36	1,345.45
11	29,757	0.6	1,130.59	645.67	1,021.82	708.30	1,418.14
12	34,725	0.7	1,210.00	661.38	1,094.30	769.13	1,515.79
13	40,923	0.8	1,264.30	704.44	1,138.39	791.18	1,585.99
14	49,796	1.0	1,328.34	737.07	1,194.49	829.00	1,667.27
15	55,035	1.1	1,348.52	744.31	1,210.83	840.75	1,697.71
16	47,921	0.9	1,386.45	780.24	1,245.80	850.81	1,754.75
17	48,442	0.9	1,417.42	818.41	1,265.56	865.41	1,796.48
18	48,802	1.0	1,467.76	851.49	1,311.49	883.41	1,864.69
19	48,998	1.0	1,538.06	887.62	1,377.47	926.88	1,955.85
20	53,699	1.1	1,583.97	897.61	1,427.87	954.98	2,014.18
21	59,071	1.2	1,649.78	939.64	1,482.19	995.89	2,097.03
22	66,055	1.3	1,678.50	958.48	1,501.48	1,012.61	2,129.05
23	58,291	1.1	1,743.90	995.17	1,565.59	1,047.09	2,225.60
24	59,211	1.2	1,797.28	1,026.42	1,605.71	1,085.07	2,292.14
25	58,481	1.1	1,847.21	1,059.00	1,656.07	1,103.81	2,363.45
26	58,245	1.1	1,919.71	1,098.44	1,734.72	1,145.08	2,456.08
27	63,077	1.2	1,976.10	1,115.08	1,799.37	1,188.51	2,534.66
28	67,228	1.3	2,038.34	1,156.00	1,845.61	1,229.39	2,608.78
29	73,202	1.4	2,056.06	1,176.25	1,850.93	1,227.68	2,630.45
30	61,139	1.2	2,131.43	1,219.42	1,925.44	1,266.69	2,748.63
31	54,481	1.1	2,054.35	1,239.89	1,844.53	1,175.90	2,664.68
32	48,964	1.0	2,106.57	1,320.10	1,876.72	1,183.96	2,745.18
33	45,330	0.9	2,162.62	1,347.74	1,940.78	1,206.50	2,828.61
34	47,568	0.9	2,249.85	1,433.54	2,011.03	1,250.25	2,928.78
35	50,567	1.0	2,323.60	1,436.69	2,094.77	1,331.92	3,004.86
36	54,810	1.1	2,355.59	1,436.60	2,133.82	1,372.34	3,017.30
37	44,844	0.9	2,429.51	1,534.67	2,185.85	1,389.64	3,114.63
38	43,262	0.8	2,474.67	1,561.76	2,208.94	1,423.02	3,166.09
39	40,322	0.8	2,521.79	1,611.74	2,258.31	1,429.43	3,244.51
40	39,193	0.8	2,611.98	1,669.37	2,348.75	1,487.83	3,344.28
41	42,316	0.8	2,676.84	1,652.00	2,433.86	1,570.54	3,392.77
42	43,428	0.8	2,717.91	1,713.02	2,433.05	1,570.70	3,486.36
43	44,866	0.9	2,723.30	1,692.49	2,429.86	1,594.39	3,475.35
44	36,714	0.7	2,784.62	1,751.30	2,489.70	1,608.51	3,560.94
45	34,973	0.7	2,825.00	1,800.40	2,498.55	1,617.88	3,621.28
46	32,604	0.6	2,843.98	1,881.88	2,516.21	1,592.33	3,649.60
47	31,457	0.6	2,901.93	1,914.85	2,568.74	1,637.72	3,722.24
48	33,588	0.7	2,967.28	1,890.38	2,637.52	1,692.59	3,802.17
49	35,758	0.7	2,985.66	1,881.80	2,661.29	1,728.52	3,810.65
50	38,505	0.8	3,006.91	1,948.18	2,656.75	1,714.03	3,846.70
51	34,081	0.7	3,069.10	1,987.99	2,711.23	1,754.01	3,911.27
52	35,200	0.7	3,044.64	1,968.48	2,699.22	1,730.90	3,902.26
53	37,353	0.7	3,041.44	2,031.19	2,656.68	1,663.20	3,911.30
54	42,039	0.8	3,050.40	1,995.63	2,691.98	1,681.25	3,935.63
55	57,053	1.1	3,031.82	1,993.77	2,686.03	1,655.26	3,929.67
56	133,103	2.6	2,739.54	1,902.85	2,402.36	1,337.71	3,653.27
57	134,831	2.6	2,910.43	1,957.02	2,568.83	1,506.89	3,835.12
58	124,027	2.4	2,979.59	2,032.32	2,616.53	1,506.76	3,934.52
59	131,881	2.6	3,056.59	2,106.81	2,671.40	1,531.18	4,042.43
60	2,339,771	45.8	3,167.25	2,582.35	2,584.60	1,381.40	4,146.38
Total	5,110,629	100.0	2,668.61	2,167.89	2,126.24	1,223.35	3,471.50

TABLE 26A—FREQUENCY OF LENGTH OF 30-DAY PERIODS AND AVERAGE RESOURCE USE FOR EPISODES OF A CERTAIN LENGTH

Length of period in days	Number of periods	Percent of periods	Average resource use	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
1	3,524	0.0	$324.24	$263.35	$280.90	$211.49	$370.04
2	8,369	0.1	388.82	369.29	315.71	239.78	433.16
3	15,906	0.2	457.10	366.59	362.89	264.75	533.87
4	23,219	0.3	505.38	421.31	389.49	278.90	600.01
5	32,751	0.4	548.40	454.32	422.29	293.29	661.01
6	41,608	0.5	574.07	450.58	448.54	304.63	704.08
7	43,863	0.5	659.05	534.21	512.49	332.18	825.53
8	51,527	0.6	701.40	524.40	566.85	362.61	892.13
9	52,384	0.6	750.57	575.81	606.90	383.81	957.98
10	57,437	0.7	821.25	612.49	679.85	416.34	1,056.92
11	64,917	0.8	871.27	626.24	738.18	452.60	1,118.16
12	71,310	0.8	937.62	667.37	791.38	482.71	1,220.16
13	79,309	0.9	990.00	697.39	832.05	514.47	1,288.99
14	81,603	0.9	1,097.23	740.41	943.52	584.53	1,432.03
15	86,340	1.0	1,154.17	754.00	999.52	634.63	1,495.77
16	77,411	0.9	1,180.96	793.23	1,017.08	634.79	1,538.93
17	77,257	0.9	1,217.06	828.31	1,044.18	656.03	1,579.78
18	79,981	0.9	1,251.95	846.54	1,070.55	665.44	1,632.13
19	82,356	1.0	1,296.30	881.05	1,109.47	687.23	1,690.54
20	89,669	1.0	1,336.50	899.78	1,144.26	709.84	1,748.36
21	91,247	1.1	1,426.72	942.61	1,230.61	773.65	1,859.45
22	99,530	1.2	1,472.50	956.21	1,274.66	809.29	1,910.76
23	94,124	1.1	1,494.61	993.71	1,285.28	793.44	1,959.20
24	99,779	1.2	1,513.58	1,018.60	1,302.00	791.75	1,989.40
25	113,978	1.3	1,486.39	1,035.65	1,260.53	749.62	1,964.15
26	188,106	2.2	1,282.22	1,006.44	1,027.40	550.41	1,727.53
27	195,398	2.3	1,372.37	1,038.05	1,126.05	617.79	1,844.29
28	189,012	2.2	1,465.50	1,086.75	1,219.26	668.85	1,967.27
29	202,819	2.3	1,541.39	1,118.11	1,295.04	727.83	2,060.18
30	6,247,373	72.3	1,719.92	1,375.02	1,396.74	728.43	2,305.59
Total	8,642,107	100.0	1,585.48	1,289.23	1,262.65	671.96	2,119.49

The 60-day episode unit of payment was originally implemented on October 1, 2000, because most episodes in the HHA per-episode PPS demonstration, which was used to inform the development of the HH PPS, ended in 60 days or less, the OASIS data would be captured on a 60-day cycle, and Medicare plan of care/certification requirements continue to be bimonthly (64 FR 58143). In the FY 2001 HH PPS proposed rule, we noted that about 60 percent of episodes paid under the HH PPS were completed within one 60-day episode and 73 percent within two 60-day episodes. In the FY 2001 HH PPS final rule, we noted that we would continue to monitor the appropriateness of the 60-day unit of payment, and would consider modifying our approach to the episode definition in subsequent years of PPS, if warranted (65 FR 41136).

In CY 2016, 73 percent of episodes were completed within one 60-day episode and 86 percent within two 60-day episodes. We currently observe wide variation in the length of care in the current HH PPS. Overall, the average length of home health care was approximately 46 days, but roughly a quarter of all 60-day episodes lasted 30 days or less. For example, those episodes that had a hospital stay in the seven days prior to the start of the episode where the Diagnosis Related Group (DRG) was either 469 or 470 (major joint replacement or reattachment of lower extremity) had an average length equal to 23.7 days. As noted above, there is a decline in visits as the episode proceeds with a 61.8 percent decline from the first 15 days of care in a 60-day episode to the last 15 days of care in a 60-day episode.

The wide variation in resource use and trends toward shorter episodes of care, the difference in resources between the first and second 30-day period within a 60-day episode, and the removal of the therapy visit thresholds from the case-mix adjustment methodology (which currently account for variation in resource use, but create adverse incentives as outlined in section II.D of this proposed rule) result in less accurate case-mix weights. When a shorter, more constrained time period is used for payment, the HHGM's goodness of fit statistics (for example, R-squared) improve due to reduced resource use variation. Accordingly, the case-mix weights under the HHGM better approximate relative resource use. Therefore, we are proposing to change the unit of payment under section 1895(b)(2) of the Act from a 60-day episode of care to 30-day periods of care. Section 1895(b)(2) of the Act requires the Secretary to consider potential changes in the mix of services provided within that unit and their cost. Our analysis shows evidence of a change in the mix of services under a 60-day episode of care, as outlined above and in section II.D of this proposed rule. Therefore, to better account for changes in the mix of services over time; to ensure that the unit of payment reflects an appropriate number, type, and duration of visits provided within a unit of payment; and to provide continued access to quality services, we are proposing to change the unit of payment from a 60-day episode of care to a 30-day period of care and to implement case-mix adjustment methodology refinements, outlined in sections III.E.1 through III.E.12 of this proposed rule.

b. National, Standardized 30-Day Payment Amount

We note that we propose to implement the HHGM for 30-day periods of care beginning on or after January 1, 2019.[26] As a result, we would calculate a proposed national, standardized 30-day payment amount in the CY 2019 HH PPS proposed rule. In calculating a national, standardized 30-day payment amount for CY 2019, we propose to start with the CY 2019 national, standardized 60-day episode payment amount reflecting the HHA market basket update as specified in section 1895(b)(3)(B) of the Act, add back in the CY 2019 non-routine medical supply (NRS) conversion factor amount reflecting the HHA market basket update as specified in section 1895(b)(3)(B) of the Act, and then divide the sum by two.

If we had proposed to implement the HHGM in CY 2018, we would have calculated a proposed 30-day payment amount for CY 2018 by starting with the CY 2018 proposed national, standardized 60-day episode payment amount of $3,038.43, adding back in the CY 2018 proposed NRS conversion factor amount of $53.03, and dividing the sum by two to produce a 30-day payment amount of $1,545.73. However, we reiterate that we propose to implement the HHGM for 30-day periods of care beginning on or after January 1, 2019; so we propose to calculate a national, standardized 30-day payment amount for CY 2019 using the CY 2019 60-day episode payment amount, adding back in the CY 2019 NRS conversion factor and dividing the sum by two to produce a 30-day payment amount. Finally, we note that the calculation proposed above would only be used to calculate a national, standardized 30-day payment amount for CY 2019. To calculate a national, standardized 30-day payment amount for CY 2020 and subsequent years, we would update the national, standardized 30-day payment amount from the immediate preceding year by the home health payment update percentage required by the statute, as described in section III.C.1 of this rule.

In determining the 30-day payment amount, we evaluated whether starting with the national, standardized 60-day episode payment amount, adding back in the NRS conversion factor amount and dividing the sum by two was an appropriate estimate of the cost of a 30-day period of care. Section 1895(b)(3) of the Act provides a methodology for determining an initial payment amount for the PPS and for calculating annual increases. As noted in this proposed rule, the Act at section 1895(b)(2) gives the Secretary the discretion to determine the ''unit of payment'' (also referred to in the statute as a ''unit of service'') on which a standard prospective payment amount would be based. Since we are proposing to change the unit of payment, we believe it is necessary to calculate a 30-day payment amount that would accurately reflect what a 30-day payment would be had we chosen to use a 30-day rather than a 60-day unit of payment when we first implemented the PPS.

To do this, we calculated an estimated 30-day payment amount by taking the average number of visits per discipline per 30-day period of care in CY 2016 multiplied by the FY 2001 per-visit amounts (including average NRS costs per visit) initially established under the HH PPS based on the most recent audited cost report data available to the Secretary in accordance with section 1895(b)(3)(A)(I) of the Act, as adjusted for inflation and productivity. The FY 2001 per-visit amounts were adjusted for inflation by the actual HHA market basket updates (reflecting historical data from FY 2002 to CY 2016), the regulatory HHA market basket updates for CY 2017 (which is based on the CY 2017 forecasted data at the time of CY 2017 rulemaking (81 FR 76714)) and CY 2018 (which is based on the CY 2018 forecasted data in this CY 2018 proposed rule), and for productivity (using Economy-wide Multifactor Productivity as specified in section 1895(b)(3)(B)(vi) to the Act and described in section 1886(b)(3)(B)(xi)(II) of the Act) beginning in 2015, as reflected in Table 26B.

TABLE 26B—HHA MARKET BASKET UPDATES AND PRODUCTIVITY ADJUSTMENTS, FY 2002 THROUGH CY 2018

	FY 02	FY 03	FY/CY 04*	CY 05	CY 06	CY 07	CY 08	CY 09	CY 10
Market Basket Update (Historical Data FY02 to CY16, forecast CY17 and CY18)	3.4	3.2	4.0	3.1	3.1	3.5	3.2	1.7	1.7
	CY 11	CY 12	CY 13	CY 14	CY 15	CY 16	CY 17	CY18	
Market Basket Update (Historical FY02 to CY16, forecast CY 17 and CY 18)	2.0	1.7	1.6	1.6	1.6	2.0	2.8	2.7	
Multi-Factor Productivity Adjustment (historical CY15, preliminary historical CY16, forecast CY17 and CY18)					0.4	0.6	0.3	0.5	

As shown in Table 28, using the FY 2001 per-visit amounts initially established under the HH PPS results in an estimated 30-day payment amount of $1,494.64. This value is less than, but similar to half the sum of the proposed CY 2018 national, standardized 60-day episode payment amount and proposed CY 2018 NRS conversion factor amount ($1,545.73).

We also calculated an estimated 30-day payment amount by taking the average number of visits per discipline per 30-day period of care in CY 2016 multiplied by the FY 2015 costs-per-visit, per discipline, based on the most recent cost report data available at the time of CY 2018 HH PPS rulemaking (as outlined in Table 2 in section III.A of this proposed rule) and further adjusted to include average NRS costs per visit, for outliers in accordance with section 1895(b)(3)(C) of the Act, and for inflation and productivity. As shown in Table 29, using 2015 costs-per-visit, per discipline, based on the most recent cost report data available at the time of CY 2018 HH PPS rulemaking, results in an estimated 30-day payment amount of $1,485.11. This value is also less than, but similar to half the sum of the proposed CY 2018 national, standardized 60-day episode payment amount and proposed CY 2018 NRS conversion factor amount ($1,545.73).

[26] 60-day episodes of care that begin on or before December 31, 2018 and end on or after January 1, 2019, will be paid using the current case-mix adjustment methodology (153-group system) and a CY 2019 national, standardized 60-day episode payment amount and/or CY 2019 national per-visit amounts.

TABLE 27—AVERAGE VISITS PER DISCIPLINE FOR 30-DAY PERIODS OF CARE, CY 2016

Discipline	CY 2016 Average number of visits in 30-day period
Skilled Nursing	5.0
Physical Therapy	3.3
Occupational Therapy	0.9
Speech-Language Pathology	0.2
Medical Social Services	0.1
Home Health Aides	1.0
Total	10.5

Source: CY 2016 claims data (as of March 17, 2017), excluding 30-day periods of care with no visits and those classified as LUPAs as outlined in section III.E.9 of this proposed rule.

TABLE 28—ESTIMATED 30-DAY PAYMENT AMOUNT IN CY 2018 (USING FY 2001 HH PPS PER-VISIT AMOUNTS, PER DISCIPLINE, ADJUSTED FOR INFLATION AND FOR PRODUCTIVITY BEGINNING IN 2015)

Discipline	FY 2001 per-visit amounts [1]	FY 2001 per-visit amounts trended forward to 2018	CY 2016 average number of visits in 30-day period	CY 2018 30-day period costs
Skilled Nursing	$95.34	$143.03	5.0	$715.15
Physical Therapy	104.27	156.43	3.3	516.22
Occupational Therapy	104.97	157.48	0.9	141.73
Speech-Language Pathology	113.32	170.01	0.2	34.00
Medical Social Services	152.95	229.47	0.1	22.95
Home Health Aides	43.05	64.59	1.0	64.59
Total	.....	.....	10.5	1,494.64

[1] The FY 2001 per-visit amounts can be found in 65 FR 41187 through 41188 (Table 6).

Note(s): When the HH PPS was established on October 1, 2000, the original per-visit payment amounts for each discipline included a one-time adjustment of $0.21 to reflect the costs associated with OASIS assessment schedule refinements (65 FR 41187). In addition, the resulting per-visit rates were then divided by 1.05 to account for the estimated percentage of outlier payments, a calculation further refined in the CY 2008 HH PPS final rule (72 FR 49868) by multiplying by 1.05 and 0.95. The FY 2001 per-visit amounts in the text reflect removing the $0.21 from the FY 2001 per-visit amounts and include the effects of the CY 2008 outlier calculation refinement.

TABLE 29—ESTIMATED 30-DAY PAYMENT AMOUNT IN CY 2018 (USING FY 2015 AVERAGE COSTS-PER-VISIT, PER DISCIPLINE, ADJUSTED FOR INFLATION AND FOR PRODUCTIVITY BEGINNING IN 2015)

Discipline	FY 2015 average costs-per-visit	FY 2015 average NRS costs-per-visit [1]	FY 2015 average NRS costs-per-visit plus NRS	FY 2015 average costs-per-visit plus NRS trended forward to 2018	Outlier adjustment factor	CY 2016 average number of visits in 30-day period	CY 2018 30-day period costs
Skilled Nursing	$132.48	+$3.36	$135.84	$144.29	× 0.95	5.0	$685.38
Physical Therapy	156.32	3.36	159.68	169.61	× 0.95	3.3	531.73
Occupational Therapy	154.64	3.36	158.00	167.83	× 0.95	0.9	143.50
Speech-Language Pathology	170.96	3.36	174.32	185.17	× 0.95	0.2	35.18
Medical Social Services	220.07	3.36	223.43	237.33	× 0.95	0.1	22.55
Home Health Aides	62.80	3.36	66.16	70.28	× 0.95	1.0	66.77
Total	.....	.....	.....	.....	.....	10.5	1,485.11

[1] Of the 8,032 FY 2015 HHA cost reports used for the analysis presented in Table 2 in section III.A of this proposed rule, NRS costs totaled $301,207,702. For those same 8,032 HHAs, visits (all visits, all episode types) where the claim through date fell on or between the FY start end date of the agency's cost report totaled 89,726,272. $301,207,702 divided by 89,726,272 = $3.36 per visit.

We believe our proposal to start with the national, standardized 60-day episode payment amount, add back in NRS conversion factor amount, and then divide the sum by two is a reasonable estimate of the cost of a 30-day period of care. We propose to implement the change in the unit of payment from 60-day episodes of care to 30-day periods of care in a non-budget neutral manner. We note that in its March 2017 Report to Congress, MedPAC highlighted that home health payments have consistently and substantially exceeded costs because agencies are able to reduce the number of visits provided and cost growth is generally lower than the annual payment updates for home health care.[27] MedPAC recommended a 5 percent reduction in the base rate for 2018 and a 2-year rebasing beginning in 2019.[28] We invite comments on the proposed calculations for determining the 30-day payment amount, including our rationale for proposing to

[27] Medicare Payment Advisory Commission (MedPAC). ''Home Health Care Services.'' *Report to Congress: Medicare Payment Policy*. Washington, DC, March 2017. P. 232. Accessed on July 16, 2017 at: *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch9.pdf?sfvrsn=0.*

[28] Ibid.

implement the HHGM in a non-budget neutral manner.

We are further proposing to implement the HHGM in a fully non-budget neutral manner beginning in CY 2019 or alternatively to use a phased approach to implementation. We acknowledge that implementing the HHGM in a partially budget-neutral manner could lessen the economic impact for HHAs in transitioning to the HHGM. Therefore, we considered potential alternative implementation approaches for the HHGM, including, but not limited to, a partially budget-neutral approach with a phase-out period. Specifically, for the phased approach, we propose to apply a HHGM partial budget neutrality adjustment factor in CY 2019 that would reduce the estimated impact of the HHGM from an estimated −4.3 percent to −2.2 percent in the initial year of implementation with the removal of the HHGM partial budget neutrality adjustment factor in CY 2020. We invite comments on whether to implement the HHGM in a fully non-budget neutral manner beginning in CY 2019; whether to alternatively implement the HHGM in CY 2019 with a HHGM partial budget neutrality adjustment factor applied and then subsequently removed in CY 2020; or whether a HHGM partial budget neutrality adjustment factor should be applied and then phased-out over a longer period of time.

c. Split Percentage Payment Approach for 30-Day Periods of Care

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 episode. The second, final bill is submitted at the end of the 60-day episode of care. An initial percentage payment of 60 percent of the anticipated final claim payment amount is paid at the beginning of the episode and a final percent payment of 40 percent is paid at the end of the episode. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes are paid at a 50/50 percentage payment split. A new initial and final bill must be submitted for each 60-day episode period. HHAs are encouraged to submit the RAP as soon as possible after care begins 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 episode of care to enforce the consolidating billing edits required by law.

We are not proposing a change to the split percentage payment approach in conjunction with proposing to change the unit of payment from a 60-day episode to a 30-day period of care. Under the proposed HHGM, we propose that the initial payment for initial 30-day periods would be paid at 60 percent of the case-mix and wage-adjusted 30-day payment rate. The residual final payment for initial 30-day periods would be paid at 40 percent of the case-mix and wage-adjusted 30-day payment rate. We propose the initial payment for subsequent 30-day periods would be paid at 50 percent of the case-mix and wage-adjusted 30-day payment rate. The residual final payment for subsequent 30-day periods would be paid at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

However, we note the length of time HHAs currently take to submit the RAP indicates that the RAP payment might not be necessary for the majority of HHAs to maintain an adequate cash flow (see Table 30). Approximately 5 percent of RAPs (95th percentile) are not submitted until the end of an episode of care and the median length of days for RAP submission is 12 days from the start of the episode. In addition, eliminating RAP payments would address existing program integrity vulnerabilities. For example, $1.8 billion in RAP payments (July 1, 2015 through July 31, 2016) were auto-cancelled, and of that amount, a final claim was never submitted for $321 million worth of RAP payments.[29]

TABLE 30—NUMBER OF DAYS FROM THE START OF CARE TO INITIAL RAP SUBMISSION

Percentile	Number of days from the start of care to initial RAP submission
1	1
10	5
25	8
50	12
75	21
90	36
95	57
99	169

Source: Analysis of CWF data from July 1, 2015 through July 31, 2016 and HIGLAS payments and recoupments.

We are soliciting 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 are soliciting comments on ways to phase-out the split percentage payment approach in the future if the proposed HHGM is finalized with the split percentage payment approach being initially maintained. Specifically, we are soliciting comments on reducing the percentage of the upfront payment over a period of time. We believe that payment based on 30-day periods would reduce, if not eliminate, the need for these partial, up-front payments that occur in the current payment system. Home health agencies would bill on a monthly basis, similar to hospices and SNFs, and thus receive final payment sooner.

If in the future the split percentage approach was eliminated, we are also soliciting comments on the need for HHAs to submit a notice of admission within 5 days of the start of care to assure being established as the primary HHA for the beneficiary and so that the claims processing system is alerted that a beneficiary is under a HH period of care to enforce the consolidating billing edits required by law.

We invite comments on the proposed change in the unit of payment from a 60-day episode of care to a 30-day period of care under the HHGM; the calculation of the national, standardized 30-day payment amount, initially maintaining the split percentage payment approach and applying such policy to 30-day periods of care; and the associated regulations text changes outlined in section III.E.13. of this proposed rule. We are also soliciting comments on ways the split percentage payment approach could be phased-out and whether to implement a notice of admission process if the split percentage payment approach is eliminated in the future.

4. Episode Timing Categories

To advance the goals of better aligning payment with patient needs, as well as addressing payment incentives and vulnerabilities within the current system, we investigated the impact of episode timing on home health resource use. In the current payment system, 60-day episodes are classified as ''early'' if they are the first or second in a sequence of episodes and ''late'' if they are the third or later in the sequence. Episodes are defined as being in the same sequence if there are no more than 60 days between the end of one episode and the start of the next. In the development of the proposed HHGM, we sought to evaluate whether payments to providers appropriately reflect the varying resource needs of

[29] A RAP is auto-cancelled and recouped on the next disbursement if the final claim is not received within 4 months of the start of care or within 2 months of when the RAP was paid (whichever is greater).

home health beneficiaries during various portions of the home health stay, accounting for contrasting patient characteristics.

We endeavored to evaluate whether beneficiaries in their first 30-day period of care have different needs and patterns of resource use than those in later 30-day periods, thus possibly resulting in the potential need for differentiated payment amounts. We reviewed related research, held technical and clinical expert panels, and performed our own investigative analyses. In particular, we were interested in whether home health patients utilize more resources at the beginning of home health than in later periods of the home health stay, and, if so, does the current payment structure sufficiently account for this elevated need. In a review of research related to episode timing, studies show that more frequent skilled visits in the first few weeks of a home health stay can prove beneficial for certain diagnoses by reducing the likelihood of readmission to an institutional setting and easing the transition from hospital to home, which can be challenging for patients.

The Visiting Nurse Associations of America defines ''frontloading'' as the practice of providing an increase in intensity of visits during the first two to three weeks of the home health care episode for patients that have been determined to be at high risk for hospitalization.[30] A 2014 literature review titled ''Frontloading and Intensity of Skilled Home Health Visits: A State of the Science'' found that Medicare patients benefited from an intensified level of care through a ''frontloading'' approach, which reduced the need for re-hospitalization among skilled home health patients, and especially for those with heart failure.[31] For the purposes of this particular study, frontloading was defined as providing 60 percent of planned visits within the first 2 weeks of the home health episode of care. Furthermore, frontloading was also found by the Briggs® National Quality Improvement/ Hospitalization Reduction Study,[32] to be one of 15 best practices routinely employed by 64 percent of the HHAs who were most successful at reducing hospitalizations. Similarly, in an article titled ''The Effect of Frontloading Visits on Patient Outcomes,'' [33] the authors assessed the impact of frontloading on patients with insulin-dependent diabetes and with heart failure. In their research, the authors found that frontloading was effective for patients with heart failure, decreasing re-hospitalization by more than half (39.4 percent vs. 16 percent), with fewer visits overall (15.5 vs. 9.5) and equal clinical outcomes and patient satisfaction. These improvements in overall outcomes were presumably due to the timing of the services, where more visits were provided in the beginning portion of the episode, even when fewer visits were provided overall. However, we note that there was no significant impact for those patients with diabetes. No specific effect for patients with mental health or behavioral health conditions was noted. Given the potential positive outcomes of the practice of frontloading, specifically for those beneficiaries with heart disease, we expect that HHAs would provide more frequent skilled services in the beginning portion of a home health stay to educate patients in medication management, coordinate the instruction of both the patient and family, and support patients in navigating their clinical situation, especially in cases of heart disease. The first and fourth reported top primary reasons for home health care in CY 2016 were hypertension and heart failure, respectively, and we therefore believe an opportunity exists for HHAs to improve the outcomes for these high-volume home health beneficiaries by providing more resources in the early period of a home health stay.

For many patients admitted to home health, the transition from hospital or other institutional settings back to the home environment can be very challenging and lead to adverse effects for the beneficiary, such as medication errors, harmful drug events, and additional complications. The provision of intensified home health services early in a home health stay can potentially help to mitigate any negative events that could result from this time of transition from the institutional setting to the home. As such, we would expect that beneficiaries would require more resources, particularly from skilled disciplines providing teaching and medication management, during the first 30 days of a home health admission.

As described in section III.E.3 of this proposed rule, analysis of home health data demonstrates that HHAs provide more services in the first 30-day period of home health than in later periods of care. The differences in the resource utilization during home health episodes are presented in Table 22, which shows the average resource use of home health episodes divided into 15-day segments. The first two 15-day periods in a home health episode have significantly higher average resource use at $261.97 and $162.44, respectively, as compared with the third and fourth 15-day segments in a 60-day period, at $107.49 and $88.67, respectively. Additionally, the average number of visits by the six disciplines is also significantly higher in the first two 15-day segments, at 6.8 and 4.9 visits per segment, respectively as compared to the third and fourth 15-day segments of a 60-day episode, at 3.3 and 2.6, respectively.

Further analysis of home health data demonstrates that under the current payment system, when analyzed by 30-day periods, HHAs provide more resources in the first 30-day period of home health (''early'') than in later periods of care. The differences in the average resource use during early and late home health episodes when divided into 30-day periods are presented in Table 28, and shows the first 30-day periods in a home health sequence have significantly higher average resource use at $2,102.29 as compared with subsequent 30-day periods. Specifically, the later 30-day periods showed an average resource use of $1,348.18, a difference of more than $700 or a 36 percent decrease. Table 31 also shows a significant difference between the early and late episode median values of resource use. The median for the first 30-day period is $1,848.12, while the median for subsequent 30-day periods is $987.54, a difference of more than $850 or an approximately 47 percent decrease.

[30] Care-Initiation-Frontloading. (n.d.). Retrieved March 20, 2017, from *http://vnaablueprint.org/Care-Initiation-Frontloading.html.*

[31] O'Connor, M., Bowles, K.H., Feldman, P. H., Pierre, M. S., Jarrín, O., Shah, S., & Murtaugh, C. M. (2014). Frontloading and Intensity of Skilled Home Health Visits: A State of the Science. Retrieved March 02, 2017, from *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4532304/.*

[32] Briggs National Quality Improvement/ Hospitalization * * * (n.d.). Retrieved March 2, 2017, from *http://www.briggscorp.com/ACHstrategies/BriggsStudy.pdf.*

[33] Rogers, J., Perlic, M., & Madigan, E. A. (2007). The Effect of Frontloading Visits on Patient Outcomes. Home Healthcare Nurse: The Journal for the Home Care and Hospice Professional, 25(2), 103–109. doi:10.1097/00004045–200702000–00011; *https://www.ncbi.nlm.nih.gov/pubmed/17285038.*

TABLE 31—AVERAGE RESOURCE USE BY TIMING (30 DAY PERIODS)

Timing	Average resource use ($)	Number of episodes	Percent of episodes (%)	Standard deviation of resource use ($)	25th percentile of resource use ($)	Median resource use ($)	75th percentile of resource use ($)
Early Episodes	2,102.29	2,719,495	31.47	1,265.68	1,213.51	1,848.12	2,681.90
Late Episodes	1,348.18	5,922,612	68.53	1,229.14	537.85	987.54	1,760.20
Total	1,585.48	8,642,107	100.00	1,289.23	671.96	1,262.65	2,119.49

There is significant difference in the resource utilization between early and late 30-day periods as demonstrated in Table 31. Moreover, the predictive power of the HHGM in terms of estimating resource utilization improved when separating episodes into 30-day periods rather than 60-day periods (that is, the first and second 30-day periods). We believe that an HHGM that accounts for the demonstrated increase in resource utilization in the first 30-day period better captures the variations in resource utilization and further promotes the goal of payment accuracy within the HH PPS. We are proposing to classify the 30-day periods under the proposed HHGM as ''early'' or ''late'' depending on when they occur within a sequence of 30-day periods. For the purposes of defining ''early'' and ''late'' periods for the proposed HHGM, we are proposing that only the first 30-day period in a sequence of periods be defined as ''early'' and all other subsequent 30-day periods would be considered ''late''. Additionally, we are proposing that the definition of a ''home health sequence'' (as currently described in § 484.230) will remain unchanged relative to the current system, that is, 30-day periods are considered to be in the same sequence as long as no more than 60 days pass between the end of one period and the start of the next, which is consistent with the definition of a ''home health spell of illness'' described at section 1861(tt)(2) of the Act. We note that because section 1861(tt)(2) of the Act is a definition related to eligibility for home health services as described at section 1812(a)(3) of the Act, it does not affect or restrict our ability to propose a 30-day prospective payment period.

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

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

5. Admission Source Category

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) implementing the HH PPS. In that final rule, we discussed and finalized the use of a methodology that included variables identifying pre-admission location (that is, whether certain inpatient and other stays occurred in the 14-day period immediately preceding the home health episode) as part of our case-mix adjustment methodology. We stated that not only were pre-admission inpatient stays a traditional indication of need in clinical practice, but also that such variables were useful correlates of resource cost in our evaluation of the home health case-mix data (65 FR 41146). This pre-admission information was submitted by HHAs via OASIS assessments.

In the CY 2008 HH PPS final rule, we removed elements from the case-mix adjustment methodology that were based upon the source of admission (72 FR 49766). In the CY 2008 HH PPS proposed and final rules, we assessed variables for policy and payment appropriateness and ultimately decided to remove the variable that had been used to identify the patient's pre-admission location from the case-mix adjustment methodology (72 FR 25361 and 72 FR 49766, respectively). This decision was based, in part, upon concerns that some agencies were encountering challenges in obtaining concrete information regarding the patient's preadmission location while performing the initial home health assessment and thus the OASIS item used to indicate the preadmission location of the patient was not always reliable. Moreover, the pre-admission information did not perform well in terms of the four-equation model used for payment estimation and also had a small impact in terms of payment accuracy within the model. In the CY 2008 HH PPS final rule, we further noted that the item's results across the four equation model created difficulties in terms of interpretation and the explanatory power (for example, its contribution to the R-squared value) was minimal (72 FR 49766).

For the purposes of constructing the HHGM, which would not use a 4-equation model or otherwise adjust payments based on therapy visit thresholds; we reexamined the impact of beneficiary admission source, either from the community or from an institutional setting, on home health resource use. In our review of related scholarly research, we found that beneficiaries admitted directly or recently from an institutional setting (acute or post-acute care (PAC)) tend to have different care needs and higher resource use than those admitted from the community, thus indicating the need for differentiated payment amounts. For instance, a literature review of 25 research studies published between 2002 and 2011, titled ''Hospitalization Among Medicare-Reimbursed Skilled Home Health Recipients,'' found that Medicare beneficiaries discharged from PAC and acute facilities differ significantly in resource need when compared to community-admitted beneficiaries.[34] Patients discharged from acute and PAC settings tend to be sicker upon admission and are being discharged rapidly back to the community. Additionally, they are more likely to be

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

re-hospitalized after discharge due to the acute nature of their illness. One study discussed in this literature review determined that patients being discharged from an inpatient hospitalization typically present with multiple comorbidities, suggesting that initially-hospitalized patients subsequently transferred to home care were more likely to have four or more secondary diagnoses, as well as a pressure or stasis ulcer, urinary incontinence, a urinary catheter, depression, or dyspnea.[35] They generally had more than five medications than their non-hospitalized counterparts and required assistance with medication management.[36] As such, patients referred to home health after an institutional stay tend to be more infirm, requiring significant resources upon admission to home health. Additionally, the same literature review also highlighted a study titled ''Unplanned hospital readmissions: A home care perspective'' that demonstrated that patients referred from acute and PAC settings are at a high risk of hospitalization within 14 to 21 days of admission to home health.[37] Given that the first few weeks after an institutional stay represent a critical window in terms of providing beneficiaries with appropriately intensive supports and services, as well as preventing re-hospitalization, we would expect that providing care for those beneficiaries admitted from institutional settings would require more resource use compared to patients admitted to home health from the community. Comprehensive and deliberate interventions in this timeframe could also potentially reduce re-hospitalization rates.

Research studies also demonstrate that patients admitted to home health from institutional settings are more vulnerable to adverse effects and injury because of the functional decline that occurs as a result of their institutional stay, indicating that this patient population requires more concentrated resources and supports to account for and mitigate this functional decline. In the article titled ''The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital,'' [38] Alan J. Forster, MD noted that beneficiaries are susceptible to harm post-hospitalization: ''Patients may be especially vulnerable to injuries during this [post-discharge] period because they may still have functional impairments and because discontinuities may occur at the interface of acute and ambulatory care.'' The author also notes that the current health care environment encourages potentially expedited discharges from hospital stays, ''in which patients are leaving the hospital 'quicker and sicker.' '' Patients may be leaving the hospital environment in a tenuous and fragile state, leaving them vulnerable to further harm once returned to the home environment. Additionally, the change from constant monitoring in the inpatient facility to less frequent monitoring in the home environment can potentially cause gaps in care and consequently increased risk for adverse events for the newly-admitted home health beneficiary. The article notes that many of the negative impacts of the transition can be reduced by an appropriate increase in care for the beneficiary in the home setting, notably with more frequent assessment of their condition and ongoing monitoring. Therefore, we believe that an opportunity may exist for the HHGM to account for this increased need and accordingly provide a differentiated payment to facilitate the provision of more frequent assessments and monitoring for beneficiaries admitted to home health from acute and PAC settings, which could in turn help prevent re-hospitalizations and adverse events. We expect that HHAs would provide more resource-intensive services after discharge from an institutional setting to educate patients in new medication management, facilitate discharge education for the patient and family, and provide support in the recovery from the illness that caused the originating hospitalization or institutional stay.

In the guidebook ''Patient Safety and Quality: An Evidence-based Handbook for Nurses,'' authors Ruth M. Kleinpell, Kathy Fletcher, of and Bonnie M. Jennings note in chapter 11 that deconditioning, a status characterized by a ''decrease in muscle mass and the other physiologic changes related to bed rest, contributes to overall weakness,'' has become commonplace in the post-institutional beneficiary population.[39] This physiological weakening of the institutionalized beneficiary can then, in turn, lead to significant functional decline, resulting in reduction in ability to perform Activities of Daily Living (ADLs), and ultimately in increased home health resource utilization. The article notes that hospitalization of the elderly is usually marked by decreased levels of mobility and increased levels of bed rest, with deterioration from their baseline levels as soon as day two of the hospitalization. Hence, a hospitalization itself leads to declines in mobility, which consequently yields reduced functionality in patients relative to their status before their inpatient stay. This decline in functional ability likewise merits appropriate skilled services to support the patient's increased needs after a hospital stay.

In the article ''Determinants of health after hospital discharge: Rationale and design of the Vanderbilt Inpatient Cohort Study (VICS),'' the authors describe the period after a hospitalization as a ''vulnerable time'' for patients.[40] This vulnerability is due to a number of factors, including the need to manage new health care issues, major modifications to medication interventions, and the coordination of follow-up appointments, all while a beneficiary strives to recuperate after a hospital stay for an acute medical event. Of particular concern are the risks for adverse drug events, for errors in a beneficiary's medication regimen, and for the need to readmit to the hospital due to deterioration of the patient's condition. Given the risks during this intense, challenging, and potentially costly period after discharge, we would expect that beneficiaries would require more visits from skilled disciplines, particularly for the purpose of teaching and medication management. This increased utilization of resources would, in turn, warrant a differentiated, potentially higher payment for such services, and the proposed HHGM payment system refinement could account for this difference with varying

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

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

[37] Anderson, M. A., Helms, L. B., Hanson, K. S., & Devilder, N. W. (1999). Unplanned Hospital Readmissions: A Home Care Perspective. Nursing Research, 48(6), 299–307. doi:10.1097/00006199–199911000–00005.

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

[39] Hughes, R. (2008). Patient safety and quality: An evidence-based handbook for nurses. Rockville, MD: Agency for Healthcare Research and Quality, U.S. Dept. of Health and Human Services. *https://archive.ahrq.gov/professionals/clinicians-providers/resources/nursing/resources/nurseshdbk/nurseshdbk.pdf,* 259–274.

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

payment amounts based upon admission source. We note that we do not expect the source of the patient's admission would lead to an HHA furnishing home health services that would replace any orders made by the referring physician regarding the type or frequency of services the patient might need during the home health stay. The admission source variable in the proposed HHGM is meant to serve as a meaningful indicator of resource utilization, which determines Medicare payment. The HHA, in consultation with the physician and ordered by the physician, will continue to articulate, in the plan of care, what services are required to meet the needs of the patient, as well as the frequency of such services.

With regard to beneficiaries admitted to home health from the community, research related to home health admission source demonstrates that community-admitted beneficiaries tend to receive care from the less-costly disciplines. In its 2016 Report to Congress, MedPAC noted that, in their analysis of CY 2013 HH claims, beneficiaries admitted from the community tend to receive more visits from home health aides than their non-community counterparts, stating that ''aide services were the majority of services provided in 14 percent of the episodes for community-admitted users compared with 5 percent for PAC users.'' [41] However, these same community entrants averaged 2.6, 60-day episodes, while the institutional admits averaged only 1.4, 60-day episodes, demonstrating longer lengths of stay for the community-admitted beneficiaries than those entering from institutional settings. These findings suggest that beneficiaries admitted to home health from the community typically require less resources but for longer periods of time when compared to the beneficiaries admitted from an institutional stay. Additionally, a 2001 Department of Health and Human Services Office of Inspector General study found Medicare home health referrals coming from the community (in this case defined as a referral for a beneficiary who had not been admitted to an overnight stay in a hospital or skilled nursing facility for 15 days prior to beginning a home health care episode) were more likely to have chronic conditions than those referred from hospitals, and therefore, were more likely to require ongoing but less resource-intensive care.[42]

In addition to our review of related research, we also evaluated home health utilization and patient assessment data as described in section III.E.1 of this proposed rule, and our findings demonstrate that those beneficiaries admitted from PAC, as well as acute care settings demonstrate higher resource utilization than their community-admitted counterparts.

The differences in care needs during home health based on admission source are illustrated in the resource utilization figures presented in Table 32, which shows the distribution of admission sources as well as average resource use for 30-day periods by admission source. Institutional admissions have significantly higher average resource use at $2,165.06 compared with community admissions at $1,393.10, a difference of $771.96. Median values of resource use also show a significant difference between sources of admission, with institutional resource use at $1,899.41 while community resource use is at $1,060.51, a difference of nearly $840. The pattern of higher resource use for institutional admissions as compared to community admissions continues for the 25th and 75th percentiles, with a difference of approximately $700 and $900, respectively.

TABLE 32—AVERAGE RESOURCE USE BY ADMISSION SOURCE (14 DAY LOOK-BACK) ADMISSION SOURCE

	Average resource use	Number of 30-day periods	Percent of 30-day periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Institutional	$2,165.06	$2,153,712	24.92	$1,350.43	$1,224.83	$1,899.41	$2,772.04
Community	1,393.10	6,488,395	75.08	1,208.29	571.97	1,060.51	1,838.39
Total	1,585.48	8,642,107	100.00	1,289.23	671.96	1,262.65	2,119.49

Source: CY 2016 Medicare Home Health Claims Data (as of March 17, 2017).

For all of these reasons, we are proposing to establish two admission source categories for grouping 30-day periods of care under the HHGM—institutional and community—as determined by the healthcare setting utilized in the 14 days prior to home health admission. We are proposing the institutional category would include 30-day periods of care for patients admitted from either acute care or PAC settings. Thirty-day periods for beneficiaries with any inpatient acute care hospitalizations, skilled nursing facility stays, inpatient rehabilitation facility stays, or long term care hospital stays within the 14 days prior to a home health admission would be designated as institutional admissions. Similarly, we are proposing that the institutional admission source category would also include patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted (that is, the admission date and from date for the subsequent 30-day period of care do not match) as we acknowledge that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital discharge. However, we would not categorize post-acute care 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 requires post-acute care in a different setting (for example, a SNF or IRF) and then readmit the patient, if necessary, after discharge from such setting. If the patient is discharged and then readmitted to home health, the admission date and from date on the 30-day claim will match and the claims

[41] Medicare Payment Advisory Commission (MedPAC). ''Home Health Care Services.'' *Report to Congress: Medicare Payment Policy.* Washington, DC, March 2016. P. XX. Accessed on March 28, 2017 at *http://www.medpac.gov/docs/default-source/reports/chapter-8-home-health-care-services-march-2016-report-.pdf?sfvrsn=0.*

[42] *https://oig.hhs.gov/oei/reports/oei-02-01-00070.pdf;* ''Medicare Home Health Care Community Beneficiaries 2001''; HHSM–500–2010–00072C 12.

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 any other payer. All other 30-day periods would be designated as community admissions.

We initially investigated maintaining two separate institutional categories, one for PAC and another for acute care settings, to identify any meaningful differences in resource use. However, we observed similar resource use in those cases where the patient was admitted from both PAC and acute care settings. Furthermore, in our analysis of the data from CY 2013, we found that the volume of home health cases with an admission from PAC settings across all 30-day periods of care was a low value at 736,112 cases (approximately 8 percent) out of a total of 8,539,996 cases as compared with cases admitted from acute settings at 1,376,567 cases (approximately 16 percent). The number of cases admitted from acute settings was approximately double the number of cases admitted from PAC settings. Moreover, in the creation of case-mix groups that differentiated between community, acute, and PAC admission sources, there were some case-mix groups with a very low number of 30-day periods of care, which in turn can result in substantial variability in the average resource use from year- to- year. We were concerned that this variability could introduce unnecessary instability in the case-mix weights under the proposed HHGM. As such, we are proposing to group 30-day periods of care for patients admitted from acute care and PAC settings together as ''institutional'' admissions.

We also considered the employment of a ''look-back'' period for determining the admission source that was longer than 14 days and thus examined data for a longer 30-day ''look-back'' period to assess the resource utilization for patients admitted to home health from institutional and community settings; however, our findings indicated that there is only a slight difference in resource use, as well as volume of beneficiaries utilizing PAC or acute services before home health between the two timeframes. Table 33 shows the distribution of 30-day periods and average resource utilization with admission source categories now defined by service use for beneficiaries in the 30 days prior instead of 14 days prior. In general, results are similar to those for the 14-day look-back period when compared to the 30-day ''look-back'' window. Average resource use under a 14-day ''look-back'' period for institutional entrants is at $2,165.06 while the 30-day entrants show an average resource use of $2,140.40. The same similarity holds true for community entrants, who show an average resource use of $1,393.10 for the 14-day ''look-back'' period versus $1,382.38 under the 30-day window. We note that the 30-day ''look-back'' period only produces a slightly higher proportion of institutional periods of care, at 2,315,557 periods as compared with the 14-day period value of 2,153,712, a difference of approximately 10 percent.

TABLE 33—AVERAGE RESOURCE USE BY ADMISSION SOURCE

[30 Day look-back]

Admission source	Average resource use	Number of 30-day periods	Percent of 30-day periods	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
Institutional	$2,140.40	2,315,557	26.79%	$1,354.34	$1,197.39	$1,873.71	$2,748.79
Community	1,382.38	6,326,550	73.21	1,202.14	567.05	1,049.66	1,823.04
Total	1,585.48	8,642,107	100.00	1,289.23	671.96	1,262.65	2,119.49

Source: CY2016 Medicare Home Health Claims Data (as of March 17, 2017).

We believe that a 14-day ''look-back'' period is more likely to be directly related to the patients' need for home health care than a 30-day ''look-back'' period. This would also be more intuitive for HHAs, as the OASIS item M1000 specifically assesses whether a beneficiary was discharged from an institutional setting within the past 14 days. Thus, we ultimately are proposing to use the 14-day ''look-back'' period as we believe it will better categorize those beneficiaries with a relatively short transition between institutional care and home health care. Given that beneficiary admission source has previously been utilized for the purposes of Medicare home health payment, HHAs will be familiar with this concept. Moreover, the proposed 14-day ''look-back'' period simplifies the structure of the proposed model and limits burden on claims systems and related processing. Additionally, a ''look-back'' period of 14 days is consistent with section 1861(tt)(1) of the Act, which defines the term ''post-institutional home health services''.

To differentiate between an institutional and community admission source, we would establish an evaluation process whereby the Medicare claims processing system would check for the presence of an acute/post-acute Medicare claim occurring within 14 days of the home health admission on an ongoing basis. In the past, HHAs stated that they had encountered challenges in terms of identifying the source of admission for home health beneficiaries, and we believe that an automated systems approach where Medicare systems evaluate for the presence of an institutional claim within the 14-day ''look-back'' window will serve to overcome this earlier challenge. Under this approach, the Medicare systems would only evaluate for whether an acute/post-acute Medicare claim occurring within 14 days of the home health admission was processed by Medicare, not whether it was paid.

Moreover, we propose that newly-created occurrence codes would also be established that would allow HHAs to manually indicate on Medicare home health claims an institutional admission source prior to an acute/post-acute Medicare claim, if any, being processed by Medicare systems. We note 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. Although 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 as discussed below. We expect

home health agencies would utilize discharge summaries from institutional providers to inform the usage of these occurrence codes. We note that 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).

If an occurrence code is submitted on the home health claim, the home health claim would be categorized as an institutional admission. However, if a home health claim is submitted without an institutional admission occurrence code, thereby categorizing it with a community admission source, and later an acute/post-acute Medicare 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 home health claim would be automatically adjusted and re-categorized as an institutional admission and appropriate payment modifications would be made. Our systems would adjust community-admitted home health claims on a claim-by-claim, flow basis if an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission is received. Given that our systems can only evaluate for the presence of a Medicare acute/post-acute claim, 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 the institutional stay, the HHA would be able to resubmit a home health claim that included an occurrence code, subject to the timely filing deadline, and payment adjustments would be made accordingly.

Conversely, if an occurrence code is submitted on the home health claim along with dates of the institutional stay, and an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission is not subsequently submitted within the timely filing deadline and processed by the Medicare systems, or an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission was submitted but later denied for payment, we may conduct post-payment medical review of the home health claim to determine whether the admission was in fact preceded by an institutional stay occurring within 14 days of the home health admission. If upon medical review a determination is made that the admission was not from an institutional setting, we would take appropriate administrative action, including correcting any improper payments and potentially referring the provider to another CMS review contractor for further review or investigation. In summary, we believe that allowing HHAs to submit a claim with an institutional admission occurrence code for a beneficiary with either a Medicare or non-Medicare institutional admission source would enable HHAs to receive appropriate payment for the home health services, while also allowing us the opportunity and flexibility to verify the source of the admission and correct any improper payments as deemed appropriate.

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/post-acute Medicare claim was submitted for that patient before the final home health claim was submitted, we would not adjust the RAP and would only adjust the final home health claim so that it reflected an institutional admission. Additionally, HHAs would only indicate admission source occurrence codes on the final claim and not on any RAPs submitted.

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

6. Proposed Clinical Groupings

a. Background

As discussed in section II.D of this proposed rule, the Home Health Study Report to Congress found that the current payment system may encourage HHAs to select certain types of patients over others, as some clinical sub-groups within the current case mix system are associated with lower margins.[43] These sub-groups include patients with a higher severity of illness, including those receiving a greater level of skilled nursing care; for example, patients with wounds, with ostomies, or who are receiving total parenteral nutrition or mechanical ventilation. Additionally, the Medicare Payment Advisory Commission (MedPAC) has expressed concerns that the HH PPS disincentivizes care for patients needing skilled nursing visits, thereby limiting access of care to the most clinically vulnerable patient populations.[44]

Although the clinical domain of the current case-mix system accounts for whether or not the patient has one or more certain clinical conditions, there could be improvements in clarity regarding patient needs to clearly explain resource use and cost. Given that payment should be predicated on resource use, providing additional clinical groups in the case-mix system and adjusting payment based on identified clinical characteristics and associated services, along with other patient variables, should better align payment with resource use. As such, under the HHGM, we propose grouping 30-day periods of care into six clinical groups designed to capture the most common types of care that HHAs provide. The proposed groups mirror how clinicians differentiate between patients as to what types of care they are receiving. To inform the development of the clinical groups, Abt Associates and CMS conducted an extensive review of diagnosis codes to identify the primary reasons for home health services under the Medicare home health benefit. The workgroup developed six clinical groups reflecting the reported principal diagnosis, clinical relevance, and coding guidelines and conventions, see Table 34.

TABLE 34—CLINICAL GROUPS USED IN THE HOME HEALTH GROUPINGS MODEL

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.

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

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

TABLE 34—CLINICAL GROUPS USED IN THE HOME HEALTH GROUPINGS MODEL—Continued

Clinical groups	The primary reason for the home health encounter is to provide:
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).	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the above listed groups.

The 30-day periods of care were assigned to one of the six clinical groups based on the reported principal diagnosis. However, roughly 19 percent of 30-day periods could not be assigned to a clinical group based on principal diagnosis alone. Reasons for the inability to group 30-day periods based on primary diagnoses included codes that were too vague, meaning the code did not provide adequate information to support the need for home health services (for example, T14.90 Injury, unspecified); codes that would not be Medicare covered services in other settings (for example, dental codes); codes that would be unlikely to require skilled home health services (for example, R68.89 Other general symptoms and signs); codes that indicate death as the outcome (for example, G93.82, Brain death); manifestation codes, where coding guidelines require an etiology code to be reported as a principal diagnosis (for example, I39 Endocarditis and heart valve disorders in diseases classified elsewhere); or code first, meaning the diagnosis is subject to sequencing conventions under ICD–10–CM, where the underlying condition must be sequenced first (for example, dementia in Parkinson's disease, in which Parkinson's disease must be sequenced first). In these instances, 30-day periods were considered ''questionable encounters'' and secondary diagnosis codes were examined to group the 30-day period of care. An ICD–10–CM list with all of the codes that would assign 30-day periods into the six clinical groupings can be found on CMS's HHA Center Web page at *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 HHGM technical report, also available on the HHA Center Web page. Table 35 shows the distribution of episodes and associated resource use across the six clinical groups.

TABLE 35—FREQUENCY AND ASSOCIATED RESOURCE USE OF CLINICAL GROUPS

Clinical group	Average resource use	N	Percent	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
Musculoskeletal Rehabilitation	$1,713.10	1,430,813	16.56	$1,149.61	$1,495.09	$878.95	$2,276.98
Neuro/Stroke Rehabilitation	1,811.74	772,579	8.94	1,319.45	1,511.06	851.12	2,434.60
Wound	2,055.47	906,782	10.49	1,666.59	1,609.16	955.17	2,623.31
Behavioral Health	1,252.08	289,513	3.35	1,019.25	954.32	505.15	1,704.72
Complex Nursing Interventions	1,703.24	336,249	3.89	1,573.15	1,240.74	675.88	2,206.54
MMTA	1,437.37	4,906,171	56.77	1,200.35	1,105.63	589.92	1,936.81
Total	1,585.48	8,642,107	100.00	1,289.23	1,262.65	671.96	2,119.49

Table 35 illustrates the differences in average resource use between 30-day periods with similar care needs. Under the HHGM, we propose that each 30-day period would be assigned to a clinical group according to the primary reason the patient was receiving home health, which would be derived from the principal diagnosis code reported on the home health claims. If a 30-day period of care could not be grouped based on the home health reported principal diagnosis due to the reasons listed above, we propose that the claim for that 30-day period would remain a questionable encounter and be returned to the provider for more accurate or definitive coding. Upon publication of this proposed rule, we will post a complete list of ICD–10 codes and their assigned clinical groupings on the CMS HHA Center Web page (*https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html*) to allow ample time for HHAs to understand those codes which would be considered a ''questionable encounter.'' We believe this will help to minimize any returned claims for more definitive coding. Each code should be reported to the level of certainty and specificity known for the home health admission. Under our proposal, secondary diagnosis codes would not be used to assign the clinical group, as the intent of the HHGM is to increase clarity by classifying the 30-day period based on the primary reason for home health services. Although the principal diagnosis code is the basis for the home health period, secondary diagnosis codes would then be used to case-mix adjust the period further through additional elements of the model, such as the comorbidity adjustment. Using principal diagnoses as the core of the model would create a clinically intuitive payment system that more clearly identifies the types of patients that are treated in home health. Diagnosis codes would also provide clarity and transparency since they are clearly described and reported on claims and other care tools. Additionally, they would support medical necessity for services furnished, and provide information for establishing the home health plan of care. Ultimately, developing clinically similar groups based on the reported principal

diagnosis as part of the larger structure of the model would allow for more meaningful analysis of home health resource use, ensure that patients are receiving care commiserate with their level of need, and more accurately align payment with cost.

b. Musculoskeletal and Neuro/Stroke Rehabilitation

Rehabilitation is an integral part of recovery following an illness, injury, or surgical procedure, whether due to a neurological or a musculoskeletal condition. Given that different care goals and expected outcomes of neuro-rehabilitation and musculoskeletal rehabilitation affect resource use, the clinical groups in the HHGM would differentiate between the two. Patient characteristics between the two groups determine whether resources are directed towards preventing the loss of function or slowing the rate of loss of function; improvement or restoration of function; compensation for lost function; and maintenance of current function.[45] Musculoskeletal rehabilitation focuses on individuals with impairments or disabilities due to disease, disorders, or trauma to the muscles or bones, whereas neurological rehabilitation is designed for individuals with disease, trauma, or disorders of the nervous system.[46] Rehabilitation following a stroke, for instance, is primarily initiated early and intensively with the most recovery of function occurring within the first 3 months;[47] however, reacquiring the skills to perform ADLs may be an on-going process depending on the extent and area of injury. However, if improvement or recovery are not expected or achieved, the focus of therapy may shift to maintenance to prevent further decline. Therefore, the VA Clinical Practice Guidelines for Management of Stroke Rehabilitation ''strongly recommend that rehabilitation therapy should start as early as possible, once medical stability is reached'' and ''recommend that the patient receive as much therapy as needed and tolerated to adapt, recover, and/or reestablish the premorbid or optimal level of functional independence.'' [48] Neuro-rehabilitation resource use can encompass evaluation and treatment of impairments in cognitive and spatial functioning, swallowing, communication, and psychological or emotional deficit; whereas musculoskeletal rehabilitation generally focuses on evaluation and treatment of the impaired muscle, bone, or joint. Musculoskeletal rehabilitation is more targeted toward proprioception, strength, imbalances, orthopedic surgeries, and abnormal functional movement patterns, and generally streamlines resources following a surgery or injury. Because of these clinical differences and associated resource use differences based on variables in length and intensity of rehabilitation, the HHGM would adjust payment between musculoskeletal and neuro/stroke rehabilitation accordingly.

c. Wounds

Wound care is provided in a variety of settings, including in the home. Advances in wound care treatments have increasingly allowed for a wide range of wound therapies to be provided in the home.[49] According to the article ''Wound Care Outcomes and Associated Cost Among Patients Treated in US Outpatient Wound Centers: Data From the US Wound Registry,'' a ''rough population prevalence rate for chronic non-healing wounds in the United States is 2 percent of the general population,'' with an estimated cost of caring for these wounds exceeding $50 billion a year.[50] Non-healing, chronic wounds are often found in home health patients considering ''prolonged and non-healing connective tissue injuries are often associated with common diseases, such as metabolic disorders, obesity, hypertension, arteriosclerosis, neuropathy, and diabetes mellitus,'' [51] which are among the top home health diagnoses.

Surgical wound care is essential at preventing post-operative complications such as surgical site infections (SSIs) and dehiscence. Research has shown that post-discharge SSIs occur in 3 to 5 percent of all surgical patients, and up to 33 percent of patients undergoing abdominal surgery, and that ''more than half of patients who develop post-discharge SSIs are readmitted to the hospital, making SSIs the overall costliest healthcare-associated infection.'' [52] Home care management of burns requires a variety of resources as ''burn patients are unique, representing the most severe model of trauma.'' [53] The management of burn injury involves a multidisciplinary approach which may include nurses, occupational and physical therapists, dieticians, and psychosocial experts. Pressure ulcers are associated with an increased risk of morbidity and mortality and have a variety of intrinsic and external factors affecting their incidence and treatment. The incidence of pressure ulcers in home health is projected to rise due to the aging population, increasingly fragmented care, and nursing shortage.[54] Ultimately, wound care depends on a multitude of characteristics driving resource utilization. By highlighting them as a clinical group, the HHGM would recognize the variety of resources and skills that necessitate careful treatment and healing of different types of wounds, and more accurately ascribe resource use to payment.

d. Behavioral Health Care

The World Health Organization (WHO) defines health as ''a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.'' [55] As such, behavioral and mental home health is an important clinical group of the HHGM. If all eligibility and coverage criteria are met according to § 409.42, then a patient may receive skilled nursing services for the assessment, treatment, and evaluation of psychiatric conditions. The Home Health Benefit Policy Manual states that ''the evaluation, psychotherapy, and teaching needed by a patient suffering from a diagnosed psychiatric disorder that requires active treatment by a

[45] World Health Organization. (2011). Rehabilitation. World Report on Disability. Chapter 4. Retrieved from *http://www.who.int/disabilities/world_report/2011/chapter4.pdf*.

[46] Johns Hopkins Online Health Library. Neurological Rehabilitation. Retrieved from *http://www.hopkinsmedicine.org/healthlibrary/conditions/adult/physical_medicine_and_rehabilitation/neurological_rehabilitation_85,P01163/*.

[47] Stinear,C., Ackerley,S., Byblow, W. (2013) Rehabilitation is Initiated Early After Stroke, but Most Motor Rehabilitation Trials Are Not. Stroke. 2013; 44:2039–2045. *https://doi.org/10.1161/STROKEAHA.113.000968*.

[48] *http://www.healthquality.va.gov/guidelines/Rehab/stroke/Mgmt_of_Stroke_Rehab_03151.pdf*.

[49] Rhee, S., Valle, M., Wilson, L., Lazarus, G., Zenilman, J., Robinson, K. (2015). Negative pressure wound therapy technologies for chronic wound care in the home setting: A systematic review. Wound Repair and Regeneration. 23, 506–517.

[50] *http://www.woundsresearch.com/article/wound-care-outcomes-and-associated-cost-among-patients-treated-us-outpatient-wound-centers-d*.

[51] Ackermann, P., Hart, D. Influence of Comorbidities: Neuropathy, Vasculopathy, and Diabetes on Healing Response Quality. (2013) Adv Wound Care (New Rochelle), 2(8): 410–421. doi: 10.1089/wound.2012.0437.

[52] Sanger, P., Hartzler, A., Han,S., *et al.* (2014) Patient Perspectives on Post-Discharge Surgical Site Infections: Towards a Patient-Centered Mobile Health Solution. PLoS One. 2014; 9(12): e114016.Published online 2014 Dec 1. doi: 10.1371/journal.pone.0114016.

[53] Al-Mousawi, A. MD, Mecott-Rivera, G. MD, Jeschke, M. MD, Ph.D., *et al.* (2009). Burn Teams and Burn Centers: The Importance of a Comprehensive Team Approach to Burn Care: Clin Plast Surg. 2009 Oct; 36(4): 547–554: doi: 10.1016/j.cps.2009.05.015.

[54] Lyder, C., Ayello, Elizabeth. (2008). Pressure Ulcers: A Patient Safety Issue. Patient Safety and Quality: An Evidence-based Handbook for Nurses. Chapter 12.

[55] Constitution of WHO: principles: *http://www.who.int/about/mission/en/*.

psychiatrically trained nurse, and the costs of the psychiatric nurse's services may be covered as a skilled nursing service.'' [56] However, the psychiatric care must be furnished by an agency that does not primarily provide care and treatment of mental diseases. Older adults may be more susceptible to psychiatric and behavioral health issues due to limited mobility, bereavement, loss of ability to live independently, or drop in socioeconomic status due to retirement.[57] Although psychiatric and behavioral conditions have different signs, symptoms, and treatment options than physical illness, mental health can have major consequences on physical health. Behavioral health research suggests that ''a model of care including solely hospital based provision (usually inpatient and outpatient care) will be insufficient to provide access for people facing barriers to care.'' [58] Additionally, the length of stay among Medicare beneficiaries who have been hospitalized for mental illness has declined over the last decade, with patients being discharged to home health rather than extending a hospitalization.[59] For these reasons, behavioral home health remains a crucial aspect of keeping beneficiaries out of the hospital. Distinguishing it as a clinical group delineates the resources associated with the unique care needs of these patients and would more accurately assign payment based on patient characteristics.

e. Complex Nursing Interventions

Understandably, the growing trend toward providing more healthcare services in the community shifts an increasing number of complex nursing interventions to home health. Providing complex nursing interventions in the home reflects a patient population with ''more complex health care needs who require more intensive medical services coordinated across multiple providers, as well as a wide range of social supports to maintain health and functioning.'' [60] Because of the range and intensity of services needed, these patients tend to generate high resource utilization and associated costs due to the need for a higher level of knowledge and expertise.[61] Additionally, readmission rates can be high in this vulnerable population as patients adjust to their home with therapies generally administered in the hospital or post-acute environment.[62]

For instance, the introduction of home mechanical ventilation is a technological advancement that not only keeps healthcare costs down but also allows patients, whose condition would otherwise necessitate an institutional environment, a maximum quality of life. For example, the results from one study found that long-term mechanical ventilation on average costs $14,500 less per patient, per month when administered at home rather than in an acute or post-acute facility.[63] However, it does not come without challenges. Caregiver competency, evolving technology, changes in patient medical status, and safety of home environment can lead to higher home health resource utilization. Likewise, management of ostomies and vascular access devices (VADs) are associated with higher resource use in the home. The impact on patients living with VADs and ostomies is significant, with research identifying physical, psychological, and social effects.[64] Ostomy and VAD specific challenges or complications may occur initially and persist and change daily as patients learn to troubleshoot and manage life with an ostomy or VAD. Care often requires resources aimed at education and support in addition to physical care. This can be made more challenging by the social and psychological effects that many new patients experience. Under the HHGM, ICD–10–CM codes on the home health claim that identify complex nursing interventions as the principal reason for home health would generate higher payment to account for these inherent challenges requiring additional resource utilization.

f. Medication Management, Teaching, and Assessment (MMTA)

Based on our analysis, the majority of 30-day periods of care in the HHGM would likely be classified under the MMTA clinical group. These 30-day periods would be characterized by codes that identify direct services related to the management and evaluation of the care plan, observation and assessment of the patient's condition, and training and/or education of a patient or family member that are not classified into one of the other clinical groups. The numerous and diverse conditions found in home health, and their associated medications and interventions, influence the principal diagnosis that would classify a 30-day period as under the MMTA clinical group.

Research on home health patient characteristics, home health nursing interventions, and outcomes of care show that there are four broad categories of interventions most frequently provided in the home:

(1) Health teaching, guidance and counseling;

(2) Treatments and procedures;

(3) Case management; and,

(4) Surveillance [65]

Of these interventions, surveillance is the most frequently occurring intervention, closely followed by health teaching, guidance and counseling.[66] Specific patient problems most frequently identified in the home health setting are related to medication regimens, especially with polypharmacy, and health-related behaviors.[67] The majority of home health care patients routinely take more than five prescription drugs, and many likely deviate from their prescribed medication regimen.[68] This increases

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

[57] *World Health Organization: Mental Health and Older Adults. Retrieved from http://www.who.int/mediacentre/factsheets/fs381/en/.*

[58] Thornicroft, G., Deb, T., Henderson, C. (2016) Community mental health care worldwide: current status and further developments. World Psychiatry, 15(3): 276–286.Published online 2016 Sep 22. doi: 10.1002/wps.20349.

[59] Banta, J., Belk, I., Newton, K., Sherzai, A. (2010) Inpatient Charges and Mental Illness: Findings from the Inpatient Sample 1999–2007. Clinicoecon Outcomes Res2010; 2: 149–158.

Published online 2010 Oct 11. doi: 10.2147/CEOR.S7560.

[60] Rich, E., Lipson, D., Libersky, J., Parchman, M. (2012). Coordinating Care for Adults With Complex Care Needs in the Patient-Centered Medical Home: Challenges and Solutions WHITE PAPER, prepared by Mathematica Policy Research AHRQ Publication No. 12–0010 January 2012: *https://www.mathematica-mpr.com/our-publications-and-findings/publications/coordinating-care-for-adults-with-complex-care-needs-in-the-patientcentered-medical-home-challenges-and-solutions.*

[61] Huisman-de Waal G., van Achterberg, T., Jansen, J., Wanten, G., Schoonhoven, L. (2011) High-tech home care: overview of professional care in patients on home parenteral nutrition and implications for nursing care: J Clin Nurs. 2011 Aug;20(15–16):2125–34. doi: 10.1111/j.1365–2702.2010.03682.x. Epub 2011 May 25.

[62] Vallab, H., Konrad, D., DeChicco, R., et al (2016). Thirty-Day Readmission Rate Is High for Hospitalized Patients Discharged With Home Parenteral Nutrition or Intravenous Fluids, JPEN J Parenter Enteral Nutr. 2016 Aug 18. doi: 0148607116664785.

[63] King, A. Long-Term Home Mechanical Ventilation in the United States. (2012). Respiratory Care June 2012, 57 (6) 921–932; doi: *https://doi.org/10.4187/respcare.01741.*

[64] Grant, M. RN, DNS, FAAN, McCorkle, R. Ph.D., FAAN, Hornbrook, M. Ph.D., et al. (2013). Development of a Chronic Care Ostomy Self-Management Program. J Cancer Educ. 2013 Mar; 28(1): 70–78. doi: 10.1007/s13187–012–0433–1.

[65] Martin, K., Scheet, N., Stegman, M.R. (1993). Home Health Clients: Characteristics, Outcomes of Care, and Nursing Interventions. American Journal of Public Health. 83(12), 1730–1734.

[66] Ibid.

[67] Ibid.

[68] Ellenbecker, C., Samia, L., Cushman, M., Alster, K. (2008). Patient Safety and Quality in Home Health Care. Patient Safety and Quality: An Evidence-based Handbook for Nurses. Chapter 13.

the potential for medication errors or adverse effects in home health, highlighting the substantial need for education and medication management regardless of whether the patient needs wound care, rehabilitation, or complex nursing interventions.

Additionally, patients with comorbidities tend to be high users of home health,[69] making education and assessment of disease diagnosis, medication interactions, lifestyle changes, and avoidance of adverse events a considerable portion of home health care. In an elderly patient population, the number of chronic conditions increases with age. Medications used to treat or prevent blood clots (anticoagulants), diabetes (insulin), and pain (opioid analgesics) are some of the most commonly implicated drugs in emergency room visits and emergent hospitalizations for adverse drug events in older adults.[70] These adverse events can potentially be reduced by improving dosing and monitoring of these drugs in high risk populations and settings like older adults in home health programs.[71] Anticoagulants are challenging to manage in home health settings and have been identified as targets for improvements in monitoring and care coordination by HHS. Also, as the number of medications being taken increases, so does the risk of adverse drug reactions, and the risk of drug reaction related emergency room visits and hospital admissions, especially in patients who are in poor health.[72] Elderly patients are especially at risk for adverse drug reactions as the organs that metabolize drugs have reduced functional ability which can lead to increased toxicity.[73] Similarly, roughly 31 percent of younger Medicare beneficiaries with disabilities report having five or more chronic conditions.[74] Polypharmacy can lead to reduced compliance with medication regimens, thus putting the patient at risk for adverse events resulting from poorly managed conditions. In the home healthcare setting, management of polypharmacy is a primary focus of nursing interventions.[75] These interventions include assessment of the patient's chronic conditions and medications used to treat those conditions; assessment of the patient's understanding of and compliance with his or her medication regimen; and teaching and reinforcing treatment and medication regimens. The medication review by the home health nurse can help reduce duplicate medications, medications that are contraindicated for older adults, and provide ways to ensure patients are being appropriately monitored and understand why they are taking the medications as well as how to take them correctly.[76]

Other studies show that primary functions of home health care skilled nursing interventions include providing disease-specific and general health information; helping patients to practice and refine disease management skills; assessing efficacy of treatment; and, advocating for any needed changes to established treatment and drug regimens.[77] The interventions encompassed under the MMTA clinical group are shown extensively in research literature to be the most prevalent services provided by home health clinicians. Analysis of home health episodes for the HHGM suggests that the MMTA services would be the most frequent home health service being provided to Medicare home health beneficiaries.

We believe that the proposed clinical groupings add a needed level of clarity in identifying and meeting the needs of home health patients; particularly the patient populations addressed in the Home Health Study Report to Congress as outlined in section II.D. of this proposed rule. Recognizing that all 30-day periods of home health care cannot be defined by the principal diagnosis alone, the clinical groupings would only be one step in the case-mix adjustment under the HHGM. We invite comments on the proposed clinical groups, which are designed to capture the most common types of care that HHAs provide.

7. Functional Levels and Corresponding OASIS Items

Research has shown a relationship exists between functional status, rates of hospital readmission, and the overall costs of health care services.[78] 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.[79] The assessment of functional status is often called ''the sixth vital sign'', which reflects its clinical relevance in the plan of care. CMS requires the collection of data on functional status in home health through a standardized assessment instrument: The Outcome and Assessment Information Set (OASIS).[80] Under the current HH PPS, functional status is assessed through the following OASIS items:

- M1810: Dressing Upper Body.
- M1820: Dressing Lower Body.
- M1830: Bathing.
- M1840: Toileting.
- M1850: Transferring.
- M1860: Ambulation/Locomotion.

For each of these OASIS items, the clinician or therapist conducting the assessment selects a numbered checkbox that best describes the patient's functional status in terms of ability to perform certain tasks. These numbered checkboxes typically range from zero, meaning independent with the task or no functional deficits, to higher numbers, meaning decreasing independence and/or increasing deficits. Responses to these OASIS items result in ''points'' to calculate an overall functional score which conveys the functional status of the patient. This means that patients with a higher functional score (that is, reduced functional status) have, on average, higher resource use compared to patients with a lower functional score (that is, higher functional status). As such, the functional status of the patient is a useful case-mix adjuster. Including functional status in the case-mix adjustment methodology allows for higher payment for those patients with

[69] Center for Healthcare and Transformation. (2010). Health Care Cost drivers: Chronic Disease, Comorbidity and Health Risk Factors in the U.S. and Michigan. Center for Healthcare and Transformation.

[70] Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency hospitalizations for adverse drug events among older Americans. N Engl J Med 2011;365:2002–2012.

[71] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2014). National Action Plan for Adverse Drug Event Prevention. Washington, DC.

[72] Alpert, P., Gatlin, T. (2015). Polypharmacy in Older Adults. Homehealth Care Now. 33(10), 524–529.

[73] Ibid.

[74] Cubanski, J., Neuman, T., Damico, A. (2010, August) *Medicare's Role for People Under Age 65 with Disabilities.* Retrieved from *http://kff.org/medicare/issue-brief/medicares-role-for-people-under-age-65-with-disabilities/.*

[75] Ibid.

[76] Ibid.

[77] Liebel, D., Powers, B.A., Friedman, B., Watson, N. (2011). Barriers and Facilitators to Optimize Function and Prevent Disability Worsening: A Content Analysis of a Nurse Home Intervention. Journal of Advanced Nursing. 68(1), 80–93.

[78] 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.

[79] 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.

[80] Bierman, A. (2001). ''Functional Status: The Sixth Vital Sign''. Journal of Internal Medicine. 16(11), 785–786.

higher service needs. As functional status is commonly used for risk adjustment in various payment systems, including in the current HH PPS, the proposed HHGM would also adjust payments to account for differences in resource use associated with functional status.

During the development of the HHGM, each OASIS–C item was evaluated using clinical review and analytical methods. Because the current case-mix adjustment methodology already utilizes OASIS items associated with functional status to adjust the home health payment, utilizing these OASIS items for inclusion in the HHGM was a primary focus. All OASIS items, including items not used in the current case-mix adjustment methodology, were evaluated for potential inclusion in the HHGM. OASIS items were eliminated for inclusion based on statistical factors (for example, the relationship of the item with resource use), clinical factors (for example, clinical appropriateness of using the item for payment purposes) and incentive factors (for example, potential for unintended consequences such as overutilization solely for increased reimbursement).

We presented our analysis of the OASIS items to a clinical workgroup that included physicians, nurses, and therapists with substantial home health clinical expertise, to obtain input regarding which OASIS items to include in the HHGM. Based on the clinical workgroup feedback and additional analyses by the research team, the following decisions were made regarding the narrowed list of OASIS items being considered for a functional status payment adjustment under the HHGM: [81]

• *M066, M0110: Age, Episode timing*—Both age and episode timing were determined to be appropriate for the HHGM, but both items can be accurately obtained directly from the home health claims data, rather than the OASIS. As such, responses on these OASIS items would not be used for this functional status adjustment under the HHGM.

• *M1018, M1030: Selected prior conditions and types of therapies a patient receives*—These OASIS items would not be used for functional status adjustment in the HHGM because the clinical groups, specifically Complex Nursing Interventions, (described in section III.E.6. of this proposed rule) account for most of the conditions described in these OASIS items (for example, IV therapy, TPN) so using these OASIS items would be duplicative.

• *M1200: Vision*—The clinical workgroup believed this OASIS item to be clinically significant. However, while this item is used in the current HH PPS, there are no longer ''points'' associated with this item for the clinical domain because there is no additional resource use related to this item beyond the average across all periods of care. Additionally, analysis of this vision impairment OASIS item showed decreased resource use in the HHGM and; therefore, was determined to have a counterintuitive relationship. As a result, this OASIS item would not be used for functional status adjustment in the HHGM. Analysis of this item is found in the ''Overview of the Home Health Groupings Model'' technical report found on the HHA Center Web page.[82]

• *M1220, M1230: Understanding of verbal content, speech and oral*—These items were determined to be subjective in nature and may not provide information that is an accurate reflection of the patient's cognitive status. As with other OASIS items in this analysis, these items showed that there was decreased resource costs associated with worsening status. As a result, these OASIS items would not be used for functional status adjustment in the HHGM.

• *M1242: Pain*—While this item is used in the current HH PPS, this is shown to have only a minimal relationship with resource use in the current payment model. Although the clinical workgroup believed this item to be clinically significant, CMS clinicians agreed this one item alone may not be robust enough to fully capture the pain presentation of the patient and its impact on resource utilization. Therefore, this OASIS item would not be used for functional status adjustment in the HHGM.

• *M1302, M1308, M1320, M1322, M1324, M1332, M1334, and M1340: Ulcers and wounds*—These OASIS items would not be used for functional status adjustment in the HHGM because the Wound clinical group (described in section III.E.6.of this proposed rule) already adjusts the period payment for these conditions and using these OASIS items would be duplicative.

• *M1400: Shortness of breath*—Although the clinical workgroup believed this item to be clinically significant, this OASIS item would not be used for functional status adjustment in the HHGM because the analysis showed decreased resource costs with worsening dyspnea which appears to be clinically counterintuitive.[83]

• *M1700—M1750: Cognitive items*—These items were initially determined to be clinically appropriate for inclusion in the HHGM but were later removed due to analysis that showed a counterintuitive relationship, meaning costs decreased as cognitive status worsened. This negative relationship with resource use was consistent with most of the OASIS cognitive items. This analysis is discussed more in depth in this section below and the full analysis of all of the cognitive items is found in the technical report.

• *M1800—M1890: Functional items*—These OASIS items include both ADLs and Instrumental Activities of Daily Living (IADLs). ADLs are routine activities that people tend to do every day without needing assistance. There are six basic ADLs: Eating, bathing, dressing, toileting, transferring (walking) and continence. IADLs are activities related to independent living and include preparing meals, managing money, shopping for groceries or personal items, performing light or heavy housework, doing laundry, and using a telephone. While most of these items were determined to be clinically appropriate for inclusion in the HHGM, M1870–M1890 (IADLs) would not be used for functional status adjustment in the HHGM due to responses having a negative relationship with resource use (for example, worsening status in performing IADLs was associated with decreased resource use).

• *M2030: Management of injectable medications*—This OASIS item would not be used for functional status adjustment in the HHGM because most of the responses associated with this item reflected less resource use when the patient increasingly had issues with preparing and taking injectable medications. We believe that clinically counterintuitive relationships resulting from responses to OASIS items, where the expectation would be to see increased resource costs associated with decreased function or ability, should not be included in the case mix adjustment.

In addition to the OASIS items listed above, the clinical workgroup also discussed M2100 (types and sources of assistance-specifically non-HHA caregiver assistance). Workgroup members agreed that the availability of non-agency caregiver assistance can be an important determinant of home health care needs. Caregiver availability

[81] Version OASIS C items were used for this initial analysis.

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

[83] Ibid.

and assistance was a focus in the Report to Congress ''Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations''. Vulnerable patient populations examined in this study included those patients with minimal or no caregiver support. Results from this study revealed that HHAs and physicians stated that family or caregiver issues are an important contributing factor in the inability to admit or place patients in home health.[84] However, the survey results suggest that much of the variation in access to Medicare home health services is associated with social and personal conditions, and therefore, CMS' ability to improve access for certain vulnerable patient populations through payment policy alone may be limited.[85] OASIS–C item M2100 identifies the ability and willingness of the caregiver(s) (other than home health agency staff) to provide categories of assistance needed by the patient, including ADL/IADL assistance, medication administration, and management of equipment. This particular OASIS item is multi-faceted, meaning this items requires one of six responses for seven different types of caregiver assistance. Because the responses to this item generally are not based on direct observation by the clinician conducting the assessment, 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. Analysis of the resource use associated with this item showed ambiguous results where the same response (''assistance needed, but no caregiver(s) available'') would be associated with increased resource costs for certain types of assistance but decreased resource costs for other types of assistance. We believe this is clinically counterintuitive as it would be expected that if a need for caregiver assistance exists but there are no available caregivers, then the result would be an increased need for resources for all of the types of caregiver assistance listed on this OASIS item. Analysis of OASIS–C item M2110, frequency of ADL/IADL assistance, which identifies the frequency of assistance provided by non-agency caregiver(s), also showed a counterintuitive and contradicting relationship with M2100. Therefore, these OASIS items would not be included as part of the functional status payment adjustment under the HHGM.

During the analysis of functional case mix adjustment under the HHGM, a review of the literature revealed growing evidence suggesting that cognitive dysfunction is an important risk factor in the development of functional disability and loss of independence.[86] The research team analyzed the responses to the OASIS items associated with cognitive status, but found there was decreased resource use associated with worsening cognitive status. We decided to further evaluate OASIS cognitive items (M1700–1750) in addition to functional items (M1800–1860), as well as other possible OASIS items that may contribute to overall function status. The following OASIS items were determined to be indicators of cognitive and functional status that potentially could be used as case mix adjusters:

- M066: Age.
- M1032: Risk of Hospitalization.
- M1220: Understanding of Verbal Content.
- M1230: Speech and Oral (Verbal) Expression of Language.
- M1700: Cognitive functioning.
- M1710: Confusion indicator.
- M1720: Anxiety indicator.
- M1740: Cognitive, behavioral, and psychiatric symptoms.
- M1745: Frequency of disruptive behavior symptoms.
- M1750: Receipt of psychiatric nursing services.
- M1800: Grooming.
- M1810: Current ability to dress upper body safely.
- M1820: Current ability to dress lower body safely.
- M1830: Bathing.
- M1840: Toilet transferring.
- M1845: Toilet hygiene.
- M1850: Transferring.
- M1860: Ambulation/locomotion.

One difficulty in using certain OASIS items (for example, M1700) to examine relationships with resource use is that they are only questioned on the Start of Care and Resumption of Care assessments, and not on follow-up assessments. Therefore, for this analysis, as outlined in the technical report, we looked back for the most recent period in the same sequence of periods that was linked to a Start of Care or Resumption of Care assessment, and carried forward the information from that assessment to the subsequent periods of care linked to follow-up (recertification) assessments. Analysis of these items, including looking at interactions between certain items, continued to show decreased resource use associated with worsening severity. The research team believed that clinically counterintuitive relationships to resource use may have the unintended consequence of discouraging HHAs to provide the appropriate amount of care to the patients who are clinically complex and need home health services the most.

For several of the OASIS items listed above, particularly the functional items, worsening status is associated with higher resource use, indicating that these items may be useful as adjustors to construct case-mix weights for the HHGM. However, several responses within other individual OASIS items had very similar average resource use. Due to the lack of variation in resource use across certain responses and because certain responses were infrequently chosen, some responses were combined into larger response categories to better capture the relationship between worsening status and resource use. Responses on these OASIS items were combined using the following methodology:

- Responses that corresponded to a small number of periods were combined with responses that corresponded to a larger number of periods and;
- Responses that had similar average resource use were combined together.

The resulting combinations of responses for these OASIS items are found at Exhibit 7–2 in the HHGM technical report.[87]

After making these combinations, the newly combined OASIS items and resource use were analyzed again to determine if those OASIS items could be used to help case-mix adjust periods within the HHGM. Results showed that decreasing functional status, increasing age, and increasing risk of hospitalization tended to be associated with higher resource use, while worsening cognitive status tended to be associated with lower resource use. The relationship between worsening cognitive status but lower resource use is counterintuitive to existing research regarding cognitive status and health

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

[85] Ibid.

[86] Njegovan, V., Man-Song-Hing, M., Mitchell, S., Molnar, F.(2001). ''The Hierarchy of Functional Loss Associated with Cognitive Decline in Older Persons''. Journal of Gerontology. 56A(10), M638–643.

[87] *https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html?redirect=/center/hha.asp; https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

care costs.[88] To further explore the relationship between the functional and cognitive OASIS items and resource use, additional analyses were conducted where the coefficients (that is, resource costs) associated with the functional and cognitive items were converted into a table of points to calculate the functional score for home health periods of care. However, even after controlling for each OASIS variable (as well as other components of the HHGM), the general trends between the cognitive and functional items from the other analyses remained the same. That is, worsening cognitive status was generally associated with less resource use; worsening functional status was generally associated with increased resource use; increased risk of hospitalization was associated with increased resource use; and age was not associated with either increased or decreased resource use. The summary statistics of these analyses are found at Exhibit 7–3 of the technical report, ''Overview of the Home Health Groupings Model''.[89] Therefore, we decided not to include those OASIS items with these types of inverse relationships to resource costs as part of the adjustment to the HHGM period payment. However, given the research support and clinical input from home health clinicians, we will continue to analyze the inclusion of cognitive items into the HHGM case mix adjustment. The analyses of the complete list of all OASIS items analyzed can be found in the Appendix Exhibits A7–1 and A7–2 of the technical report mentioned above.

On the basis of input from the clinical workgroup and these analytic results, all cognitive items, functional items with a negative relationship with resource use, and age were removed and the model was re-estimated. Each OASIS item included in the final model has a positive relationship with resource use, meaning as functional status declines (as measured by a higher response category), periods have more resource use on average. Additionally, periods with a higher risk of hospitalization (meaning four or more items checked on M1033) are associated with higher resource use compared with periods with a lower risk of hospitalization. This indicates that these items could be used to help risk adjust a period's payment and help determine case-mix weights for the HHGM. As such, we are proposing that the following OASIS items be included as part of the functional payment adjustment under the proposed HHGM:

- 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.
- M1032 (M1033 in OASIS–C1): Risk of Hospitalization.[90]

While the original analyses of these OASIS functional items were conducted using CY 2013 data from the OASIS–C version (as presented in the technical report), the updated analyses for CY 2016 reported in Tables 36, 37, and 38 are based on data obtained from OASIS C–1. While the OASIS item number for ''Risk of Hospitalization'' changed from M1032 (in OASIS C) to M1033 (in OASIS C–1), the remaining OASIS items (and item numbers) used for this functional adjustment analysis are the same. As discussed earlier in this section, to facilitate the interpretation of this analysis of the functional items used to construct the case mix weights, the results of this analysis were converted into a table of points that can be used to calculate the functional score for a home health period. Table 36 shows the points for 2013 and 2016 for those items associated with increased resource use using a reduced set of OASIS C–1 items:

TABLE 36—OASIS POINTS TABLE FOR THOSE ITEMS ASSOCIATED WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS, CY 2013 AND CY 2016

Variable	Response category	Points (2013)	Points (2016)	Percent of periods in 2013 with this response category (%)	Percent of periods in 2016 with this response category (%)
M1800: Grooming	1	3	4	41.5	51.9
M1810: Current Ability to Dress Upper Body	1	4	6	46.6	55.6
M1820: Current Ability to Dress Lower Body	1	7	6	52.1	57.5
	2	10	12	16.4	19.6
M1830: Bathing	1	6	4	24.4	20.3
	2	17	14	46.1	51.6
	3	25	22	19.1	21.9
M1840: Toilet Transferring	1	4	5	20.3	28.2
M1850: Transferring	1	7	4	61.6	47.7
	2	13	9	29.2	48.0
M1860: Ambulation/Locomotion	1	13	12	37.7	29.0
	2	17	15	33.0	47.8
	3	27	27	12.7	14.2
M1032 (M1033 for OASIS C–1): Risk of Hospitalization	4 or more items checked	12	11	12.6	16.3

[88] P.P. Pandharipande, T.D. Girard, J.C. Jackson, A. Morandi, J.L. Thompson, B.T. Pun, N.E. Brummel, C.G. Hughes, E.E. Vasilevskis, A.K. Shintani, K.G. Moons, S.K. Geevarghese, A. Canonico, R.O. Hopkins, G.R. Bernard, R.S. Dittus, and E.W. Ely. (2013). ''Long-Term Cognitive Impairment after Critical Illness''. The New England Journal of Medicine. 369(14), 1306–14.

[89] Abt Associates. ''Overview of the Home Health Groupings Model.'' *Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements.* Cambridge, MA, November 18, 2016. Accessed on April 27, 2017 at *https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html?redirect=/center/hha.asp; https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

[90] In Version OASIS C–1, two responses were excluded: ''currently reports exhaustion'' and ''other risks not listed in 1–8''.

Similar to the current case-mix adjustment methodology, the points generated in Table 36 were then used to create a functional score for each home health period of care in the HHGM. That is, a home health period of care receives points based on each of the responses associated with the OASIS items listed above. The sum of all of these points results in a functional score which is used in the HHGM to group home health periods into a functional level. As part of the HHGM case-mix adjustment, we are proposing to assign points for each of the responses to the proposed OASIS functional items and to sum up the points to create a functional score for the period of care. Whereas the results presented in the technical report showed that the number of functional levels varied by clinical group, continued analysis ultimately established three functional levels for each of the clinical groups—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 level have responses for the above OASIS items that are associated with the lowest resource use on average. Home health periods in the high level have responses on the above OASIS items that are associated with the highest resource use on average. We are proposing to use the three functional levels of low, medium, and high, based on the CY 2016 data for each of the clinical groups. Table 37 shows the functional thresholds for each functional level by clinical group for CYs 2013 and 2016.

TABLE 37—THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, CY 2013 AND CY 2016

Clinical group	Level	Points (2013 data)	Points (2016 data)
MMTA	Low	0–36	0–36
	Medium	37–55	37–54
	High	56+	55+
Behavioral Health	Low	0–30	0–38
	Medium	31–55	39–57
	High	56+	58+
Complex Nursing Interventions	Low	0–33	0–36
	Medium	34–60	37–59
	High	61+	60+
Musculoskeletal Rehabilitation	Low	0–37	0–39
	Medium	38–55	40–55
	High	56+	56+
Neuro Rehabilitation	Low	0–48	0–49
	Medium	49–67	50–66
	High	68+	67+
Wound	Low	0–41	0–42
	Medium	42–65	43–65
	High	66+	66+

Table 38 shows the average resource use by clinical group and functional level for CY 2016:

TABLE 38—AVERAGE RESOURCE USE BY CLINICAL GROUP AND FUNCTIONAL LEVEL, CY 2016

	Mean resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
MMTA—Low	$1,216.76	1,683,279	19.48	$1,091.11	$880.56	$507.63	$1,589.76
MMTA—Medium	1,466.19	1,594,451	18.45	1,182.78	1,163.49	617.07	1,979.71
MMTA—High	1,637.21	1,628,441	18.84	1,284.34	1,334.00	695.10	2,216.12
Behavioral Health—Low	963.97	100,572	1.16	847.72	679.14	407.74	1,255.47
Behavioral Health—Medium	1,308.10	94,030	1.09	1,018.11	1,040.79	543.96	1,780.03
Behavioral Health—High	1,501.87	94,911	1.10	1,107.73	1,237.97	662.86	2,047.39
Complex—Low	1,425.30	120,528	1.39	1,356.53	1,019.77	582.12	1,795.04
Complex—Medium	1,797.33	106,056	1.23	1,593.76	1,354.89	739.39	2,340.46
Complex—High	1,917.72	109,665	1.27	1,723.31	1,430.70	756.59	2,536.16
MS Rehab—Low	1,519.02	478,059	5.53	1,048.29	1,298.20	753.88	2,025.52
MS Rehab—Medium	1,730.99	480,676	5.56	1,121.66	1,534.42	921.87	2,296.70
MS Rehab—High	1,891.42	472,078	5.46	1,241.57	1,671.24	1,004.59	2,501.81
Neuro—Low	1,594.59	283,573	3.28	1,169.30	1,327.08	739.60	2,137.34
Neuro—Medium	1,847.36	233,398	2.70	1,271.54	1,581.08	914.70	2,487.14
Neuro—High	2,020.14	255,608	2.96	1,473.75	1,682.68	947.61	2,715.74
Wound—Low	1,860.42	305,556	3.54	1,550.96	1,436.36	861.98	2,345.97
Wound—Medium	2,052.45	303,435	3.51	1,603.05	1,646.76	980.27	2,634.01
Wound—High	2,258.66	297,791	3.45	1,814.01	1,771.12	1,043.72	2,897.54
Total	1,585.48	8,642,107	100.00	1,289.23	1,262.65	671.96	2,119.49

Like the annual recalibration of the case-mix weights under the current HH PPS, we expect that annual recalibrations would also be made to the HHGM case-mix weights. If the HHGM is finalized, we will continue to analyze all of the components of the case-mix adjustment, including adjustment for functional status, and would make refinements as necessary to ensure that payment for home health periods are in alignment with costs. We invite comments on the proposed OASIS items and the associated points and thresholds used to group patients into three functional levels under the HHGM, as outlined above.

8. Comorbidity Adjustment

The HHGM groups home health periods based on the primary reason for home health care (principal diagnosis), functional level, admission source, and timing. To further account for differences in resource use based on patient characteristics in the development of the HHGM, we analyzed the presence of comorbidities as another factor that could impact resource utilization and costs. We conducted a comprehensive literature review examining published, peer-reviewed research regarding the relationship between comorbidity and resource use.[91] This review also included findings on those conditions that impact health care resource utilization. Based on this review and findings, we propose a comorbidity adjustment to account for higher costs associated with comorbidities.

A comorbidity is most often defined as two or more coexisting medical conditions or disease processes that are in addition to an initial diagnosis.[92] Typically, a comorbidity is a condition(s) in which there is no direct correlation in the treatment of the principal diagnosis, but the presence of that condition(s) may impact the home health plan of care in terms of resource utilization and costs. With aging, the presence of comorbidity increases markedly because the frequency of individual conditions arises with age. While the elderly are far more likely to have multiple comorbidities, comorbidities also are prevalent in Medicare beneficiaries under the age of 65 who have intellectual and physical disabilities.[93] Research has repeatedly shown that comorbidity is associated with high health care utilization and expenditures.[94] Additionally, comorbidity is tied to worse health outcomes and the need for more complex treatment and disease management, which in turn results in higher health care costs.[95] Patients with comorbidities tend to be high users of home health visits and overall Medicare spending increases with the number of chronic conditions.[96]

In the home health setting, information regarding the patient's health conditions for which home health services are provided are assessed and documented by skilled clinicians on the OASIS. These conditions would include secondary diagnoses in addition to the principal diagnosis supporting the need for home health services. As such, exploratory analyses for the HHGM determined that secondary diagnoses (that is, comorbidities) provide additional information that can predict resource use even after controlling for the period's clinical group. We examined multiple approaches for a comorbidity adjustment in the HHGM and the analyses on these approaches is found in the ''Overview of the Home Health Groupings Model'' technical report found on the HHA Center Web page. Based on the results of these analyses, we moved towards the development of a home health specific comorbidity list for the HHGM comorbidity adjustment.

For the analysis of a comorbidity adjustment in the HHGM, some diagnosis exclusions were made. Under the HHGM, certain reported principal diagnosis codes, including some ICD–10–CM ''R-codes'' (R00–R99) which identify symptoms and abnormal clinical findings, would be considered a ''questionable encounter'', meaning these codes may be too vague to group the home health period, subject to sequencing or other ICD–10–CM coding conventions, not a Medicare-covered diagnosis, or a condition unlikely to require home health services. For these ''questionable encounters'', more information was needed to assign the period to a clinical group. This meant, for analysis purposes only, we looked at the secondary diagnoses to assign the home health period to one of the six clinical groups. As such, those periods with a principal diagnosis that was determined to be a ''questionable encounter'' code were excluded from our comorbidity adjustment analysis. However, if the HHGM is finalized, we are proposing that claims submitted with principal reported diagnosis codes that are considered ''questionable encounters'' would be returned to the provider for more definitive coding. Once the claim is resubmitted without a principal diagnosis that is considered a ''questionable encounter'', the home health period would be grouped into one of the six clinical groups. The secondary diagnoses on those resubmitted claims would then be eligible for the comorbidity adjustment.

Another exclusion from this comorbidity analysis included those secondary diagnoses that had the same three character ICD–10–CM code as the diagnosis used to assign a case to a particular clinical group (that is, musculoskeletal rehab, neuro/stroke rehab, wounds, behavioral health, complex nursing interventions, and MMTA). An additional exclusion was added that applied to diagnoses that identify an unspecified site or side (meaning the code is defined by laterality or site specificity). There are ICD–10–CM codes that are specific to site, laterality, and proximal versus distal parts of the body. For example, L89.004, Pressure ulcer of unspecified elbow, stage 4, can be coded to identify whether the pressure ulcer is on the left or right elbow. ICD–10 CM coding guidelines state to report diagnoses to the greatest level of specificity. The home health clinician should be able to identify the specific side or body part involved through either direct assessment or of a query of the certifying physician.

Finally, an exclusion was added for some secondary diagnoses that would not be considered a comorbidity if reported with certain Z codes. For example, if Z96.651, presence of right artificial knee joint, is reported as secondary, it would not be considered a comorbidity if Z47.1, aftercare following joint replacement surgery, was reported as the principal diagnosis. The secondary diagnosis in this scenario is not a comorbidity because this secondary diagnosis explains the reason for the aftercare. We are utilizing this approach to minimize the unintended consequence of providers reporting comorbidities that are duplicative of the

[91] Appendix Exhibit A9–1, ''Overview of the Home Health Groupings Model'', 2016. 12–23–12–26. *https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html.*

[92] Mosby's Medical Dictionary, 9th edition. ©2009, Elsevier.

[93] Cooper, S., McLean, G., Guthrie, B., McConnachie, A., Mercer, S., Sullivan, F., Morrison, J. (2015). ''Multiple physical and mental health comorbidity in adults with intellectual disabilities''. BMC Family Practice. 16(110), 1–11. doi 10.1186/s12875–015–0329–3.

[94] Fried, L., Ferrucci, L., Darer, J., Williamson, J., Anderson, G. (2004). ''Untangling the Concepts of Disability, Frailty, and Comorbidity: Implications for Improved Targeting and Care''. Journal of Gerontology. 59(3), 255–263.

[95] Starfield, B., Lemke, K., Bernhardt, T., Foldes, S., Forrest, C., Weiner, J. (2003). ''Comorbidity: Implications for the Importance of Primary Care in Case Management''. Annals of Family Medicine. 1(1), 8–14.

[96] *http://www.cdc.gov/chronicdisease/about/multiple-chronic.html.*

principal diagnosis, or are a further description of the principal diagnosis, which could potentially overestimate the actual resources needed for a home health period and could result in inaccurate payment.

Using the research from the comprehensive literature review, we identified common chronic comorbid conditions frequently cited as drivers of increased health care resource utilization, including coronary artery disease, congestive heart failure, diabetes, COPD, asthma, chronic wounds, and depression.[97] In addition to chronic comorbid conditions, other acute comorbid conditions have been shown to affect overall resource utilization as well. These conditions include pneumonia, Clostridium difficile (c-diff), and Methicillin-resistant Staphylococcus aureus (MRSA).[98] After compiling a list of both acute and chronic comorbid diagnoses that could affect home health resource utilization, we conducted initial analyses looking at controlling for the presence of the individual diagnoses. However, these analyses showed some counterintuitive relationships with resource use, meaning the presence of certain comorbidities showed that there would be less resource use than if the comorbidity was not present.

Because the core of the HHGM is a clinical one, CMS clinicians utilized the principles of patient assessment by body systems and their associated diseases, conditions, and injuries as a way to examine potential clinically relevant relationships. Next, we combined those individual diagnoses into larger categories utilizing the body systems as a clinically intuitive way to consider what diagnoses potentially could impact the home health plan of care and resource utilization. When combining the individual diagnoses into larger comorbidity categories, the counterintuitive relationships decreased. These broad body system categories include conditions, diseases, and injuries that affect each of the individual body systems (for example, heart disease). Neoplasms and infectious diseases were given their own discrete categories because of their potential to affect more than one body system. The broad categories used to group comorbidities within the HHGM were further refined by grouping similar diagnoses within the broad categories into subcategories. The subcategories allowed for additional refinement of diagnoses to include as part of the home health specific list. Subcategories were distinguished primarily (but not exclusively) by the first three characters of the ICD–10–CM diagnosis code to represent related conditions within the same body system. For example, subcategory Heart 10 includes diagnoses associated with various cardiac arrhythmias. The home health specific comorbidity list includes 13 broad body system based categories and 116 total subcategories using ICD–10–CM diagnosis codes. The broad categories used to group comorbidities within the HHGM include the following:

- Heart Disease (11 subcategories).
- Respiratory Disease (9 subcategories).
- Circulatory Disease and Blood Disorders (12 subcategories).
- Cerebral Vascular Disease (4 subcategories).
- Gastrointestinal Disease (9 subcategories).
- Neurological Disease and Associated Conditions (11 subcategories).
- Endocrine Disease (6 subcategories).
- Neoplasm (24 subcategories).
- Genitourinary and Renal Disease (5 subcategories).
- Skin Disease (5 subcategories).
- Musculoskeletal Disease or Injury (5 subcategories).
- Behavioral Health (11 subcategories).
- Infectious Disease (4 subcategories).

The secondary diagnoses listed on the OASIS that are attributed to any one of the listed subcategories were used to identify whether a period fell into one or more comorbidity categories and subcategories.

For the purpose of evaluating these identified comorbidities for inclusion in the HHGM, we assigned the CY 2016 home health periods that reported a secondary diagnosis included on this home health specific list to a comorbidity subcategory and subsequently dropped any subcategories that were in less than 0.1 percent of periods. This was done because low volume leads to instability in our estimates of how resource use is related to the comorbidity. A regression model was used to determine the relationship between the remaining subcategories and resource use. After this analysis, we dropped comorbidity subcategories that were not statistically significant with regards to their relationship to resource use (a coefficient with a p-value greater than 0.05). After these exclusions, we kept the subcategories associated with increased resource use that was at least as high as the median resource use, as they indicated a direct relationship between the comorbidity subcategories and resource utilization. These remaining subcategories would receive a comorbidity adjustment. As such, there are 15 subcategories that meet the current criteria for the comorbidity adjustment in the HHGM. This is a decreased number of subcategories that were presented in the technical report where 29 subcategories met the criteria to qualify for the comorbidity adjustment. The comorbidity analysis presented in the technical report was based on CY 2013 data and used ICD–9–CM diagnosis codes. There are several potential reasons for this decrease including that the analysis exclusions for the 2016 analysis were slightly different than were used in the technical report. Another potential reason for the decrease in subcategories may be due to diagnosis exclusions based on changes from ICD–9–CM to ICD–10–CM with regards to specificity. Some of this decrease could be related to the changes in case-mix weights from 2013 to 2016 where secondary conditions that received clinical points in 2013 may not have had any associated points in 2016 and hence, there would be no incentive to report those conditions. The analysis on the CY 2013 and CY 2016 data, including all of the diagnoses and their assigned subcategories is posted on the HHA Center Web page.[99] The 15 subcategories included in the comorbidity adjustment in the HHGM are as follows:

- Heart Disease 1: Includes hypertensive heart disease.
- Cerebral Vascular Disease 4: Includes sequelae of cerebrovascular disease.
- Circulatory Disease and Blood Disorders 9: Includes venous embolisms and thrombosis.
- Circulatory Disease and Blood Disorders 10: Includes varicose veins of lower extremities with ulcers and inflammation, and esophageal varices.
- Circulatory Disease and Blood Disorders 11: Includes lymphedema.
- Endocrine Disease 2: Includes diabetes with complications due to an underlying condition.
- Neoplasm 18: Includes secondary malignant neoplasms.

[97] Center for Healthcare Research and Transformation. (2010) ''Healthcare Cost Drivers: Chronic Disease, Comorbidity, and Health Risk Factors in the U.S. and Michigan.'' *http://www.chrt.org/publication/health-care-cost-drivers-chronic-disease-comorbidity-health-risk-factors-u-s-michigan/*.

[98] Drikoningen, J., Rohde, G., (2010). ''Pneumococcal Infection in Adults: Burden of Disease''. Clinical Microbiology and Infection. 45–51. Kyne, L., Hamel, M.B., Polavaram, R., Kelly, C. (2002). ''Health Care Costs and Mortality Associated with Nosocomial Diarrhea due to Clostridium difficile''. Clinical Infectious Diseases. 346–353.

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

- Neurological Disease and Associated Conditions 5: Includes secondary parkinsonism.
- Neurological Disease and Associated Conditions 7: Includes encephalitis, myelitis, encephalomyelitis, and hemiplegia, paraplegia, and quadriplegia.
- Neurological Disease and Associated Conditions 10: Includes diabetes with neurological complications.
- Respiratory Disease 7: Includes pneumonia, pneumonitis, and pulmonary edema.
- Skin Disease 1: Includes cutaneous abscesses, and cellulitis.
- Skin Disease 2: Includes stage one pressure ulcers.
- Skin Disease 3: Includes atherosclerosis with gangrene.
- Skin Disease 4: Includes unstageable and stages two through four pressure ulcers.

We propose that if a period had at least one secondary diagnosis reported on the home health claim that fell into one of the 15 subcategories, that period would receive a comorbidity adjustment to account for higher costs associated with the comorbidity. The comorbidity adjustment amount would be the same across all of the subcategories. 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 15 subcategories. Table 39 shows information on resource use for periods with and without the comorbidity adjustment.

TABLE 39—FREQUENCY OF COMORBIDITY GROUPS AND DISTRIBUTION OF AVERAGE RESOURCE USE

Comorbidity group	Mean resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
No Comorbidity Adjustment	$1,534.17	7,365,806	85.23	$1,228.43	$1,227.35	$653.57	$2,061.88
Comorbidity Adjustment	1,881.60	1,276,301	14.77	1,562.89	1,484.39	803.15	2,475.20
Total	1,585.48	8,642,107	100.00	1,289.23	1,262.65	671.96	2,119.49

The HHGM payment adjustment for comorbidities is predicated on the presence of one of the identified diagnoses within the subcategories associated with increased resource use at or above the median. If there is no reported diagnosis that meets the comorbidity adjustment criteria, the period would not qualify for the payment adjustment. We consider this comorbidity adjustment component of the proposed HHGM to be fluid, where OASIS-reported secondary diagnoses may be removed from, or added to the home health specific comorbidity list dependent upon the relationship between the comorbidity and resource costs. If the HHGM is finalized and implemented, we anticipate there may be behavioral shifts in secondary diagnosis reporting and the proposed comorbidity list and its associated subcategories may change to capture resource utilization associated with these or other conditions. We invite comments on the proposed comorbidity diagnoses, including additions or subtractions to the proposed home health specific list, and this comorbidity adjustment approach under the HHGM.

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

An 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 episode amount. Such payment adjustments are called Low Utilization Payment Adjustments (LUPAs). While the proposed HHGM system would still include LUPA payments, we are proposing that the approach to calculating the LUPA thresholds would change in the HHGM because of the proposed change in the unit of payment to 30-day periods from 60-day episodes. Whereas LUPAS are paid for all episodes consisting of four or fewer visits under the current payment system, in order to receive full episode amount under the HHGM (rather than receive a LUPA where the episode would be paid the national per visit amount by discipline) we propose to vary the LUPA threshold for a 30-day period under the HHGM depending on the HHGM payment group to which it is assigned. The 30-day periods have substantially more instances of four or fewer visits than 60-day episodes. To create LUPA thresholds, 30-day periods (including those that were LUPAs in the current payment system) were grouped into the 144 different HHGM payment groups. For each payment group, we propose to set the LUPA threshold at the 10th percentile value of visits or 2 visits, whichever is higher. In the current payment system approximately 8 percent of episodes are LUPAs. Under the HHGM, we propose the 10th percentile value of visits or 2 visits, whichever is higher, to target approximately the same percentage of LUPAs (approximately 7 percent of 30-day periods would be LUPAs (assuming no behavior change)).

For example, for 30-day periods of care in the payment group corresponding to ''MMTA– Functional Level Medium—Early Timing—Institutional Admission—No Comorbidity Adjustment'', the threshold is four visits. If 30-day periods assigned to that particular payment group had three or fewer visits they would be paid using the national per-visit rates in section III.C.3 of this proposed rule instead of the case-mix adjusted 30-day payment amount. We propose that the LUPA thresholds for each HHGM payment group would be re-evaluated every year based on the most current, complete utilization data available. The LUPA thresholds, based on the most current utilization data available (CY 2016 data as of March 17, 2017), for each corresponding HIPPS code, are listed in Table 40. We would propose updated LUPA thresholds using the most current, complete utilization data available at the time of rulemaking.

TABLE 40—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED HHGM PAYMENT GROUPS BASED ON CY 2016 UTILIZATION DATA

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Threshold (10th percentile or 2—whichever is higher)
1AAN	MMTA—Low	Early—Community	No	4
1AAY	MMTA—Low	Early—Community	Yes	4
1ABN	MMTA—Medium	Early—Community	No	4
1ABY	MMTA—Medium	Early—Community	Yes	4
1ACN	MMTA—High	Early—Community	No	4
1ACY	MMTA—High	Early—Community	Yes	4
1BAN	Neuro—Low	Early—Community	No	4
1BAY	Neuro—Low	Early—Community	Yes	5
1BBN	Neuro—Medium	Early—Community	No	5
1BBY	Neuro—Medium	Early—Community	Yes	5
1BCN	Neuro—High	Early—Community	No	5
1BCY	Neuro—High	Early—Community	Yes	5
1CAN	Wound—Low	Early—Community	No	5
1CAY	Wound—Low	Early—Community	Yes	4
1CBN	Wound—Medium	Early—Community	No	5
1CBY	Wound—Medium	Early—Community	Yes	5
1CCN	Wound—High	Early—Community	No	5
1CCY	Wound—High	Early—Community	Yes	5
1DAN	Complex—Low	Early—Community	No	3
1DAY	Complex—Low	Early—Community	Yes	3
1DBN	Complex—Medium	Early—Community	No	3
1DBY	Complex—Medium	Early—Community	Yes	3
1DCN	Complex—High	Early—Community	No	3
1DCY	Complex—High	Early—Community	Yes	3
1EAN	MS Rehab—Low	Early—Community	No	5
1EAY	MS Rehab—Low	Early—Community	Yes	5
1EBN	MS Rehab—Medium	Early—Community	No	5
1EBY	MS Rehab—Medium	Early—Community	Yes	5
1ECN	MS Rehab—High	Early—Community	No	5
1ECY	MS Rehab—High	Early—Community	Yes	5
1FAN	Behavioral Health—Low	Early—Community	No	3
1FAY	Behavioral Health—Low	Early—Community	Yes	3
1FBN	Behavioral Health—Medium	Early—Community	No	4
1FBY	Behavioral Health—Medium	Early—Community	Yes	4
1FCN	Behavioral Health—High	Early—Community	No	4
1FCY	Behavioral Health—High	Early—Community	Yes	4
2AAN	MMTA—Low	Early—Institutional	No	3
2AAY	MMTA—Low	Early—Institutional	Yes	4
2ABN	MMTA—Medium	Early—Institutional	No	4
2ABY	MMTA—Medium	Early—Institutional	Yes	5
2ACN	MMTA—High	Early—Institutional	No	4
2ACY	MMTA—High	Early—Institutional	Yes	4
2BAN	Neuro—Low	Early—Institutional	No	5
2BAY	Neuro—Low	Early—Institutional	Yes	5
2BBN	Neuro—Medium	Early—Institutional	No	6
2BBY	Neuro—Medium	Early—Institutional	Yes	6
2BCN	Neuro—High	Early—Institutional	No	5
2BCY	Neuro—High	Early—Institutional	Yes	5
2CAN	Wound—Low	Early—Institutional	No	4
2CAY	Wound—Low	Early—Institutional	Yes	4
2CBN	Wound—Medium	Early—Institutional	No	5
2CBY	Wound—Medium	Early—Institutional	Yes	5
2CCN	Wound—High	Early—Institutional	No	4
2CCY	Wound—High	Early—Institutional	Yes	5
2DAN	Complex—Low	Early—Institutional	No	3
2DAY	Complex—Low	Early—Institutional	Yes	4
2DBN	Complex—Medium	Early—Institutional	No	4
2DBY	Complex—Medium	Early—Institutional	Yes	4
2DCN	Complex—High	Early—Institutional	No	4
2DCY	Complex—High	Early—Institutional	Yes	4
2EAN	MS Rehab—Low	Early—Institutional	No	5
2EAY	MS Rehab—Low	Early—Institutional	Yes	5
2EBN	MS Rehab—Medium	Early—Institutional	No	6
2EBY	MS Rehab—Medium	Early—Institutional	Yes	6
2ECN	MS Rehab—High	Early—Institutional	No	6
2ECY	MS Rehab—High	Early—Institutional	Yes	7
2FAN	Behavioral Health—Low	Early—Institutional	No	3

TABLE 40—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED HHGM PAYMENT GROUPS BASED ON CY 2016 UTILIZATION DATA—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Threshold (10th percentile or 2—whichever is higher)
2FAY	Behavioral Health—Low	Early—Institutional	Yes	3
2FBN	Behavioral Health—Medium	Early—Institutional	No	4
2FBY	Behavioral Health—Medium	Early—Institutional	Yes	5
2FCN	Behavioral Health—High	Early—Institutional	No	4
2FCY	Behavioral Health—High	Early—Institutional	Yes	4
3AAN	MMTA—Low	Late—Community	No	2
3AAY	MMTA—Low	Late—Community	Yes	2
3ABN	MMTA—Medium	Late—Community	No	2
3ABY	MMTA—Medium	Late—Community	Yes	2
3ACN	MMTA—High	Late—Community	No	2
3ACY	MMTA—High	Late—Community	Yes	2
3BAN	Neuro—Low	Late—Community	No	2
3BAY	Neuro—Low	Late—Community	Yes	2
3BBN	Neuro—Medium	Late—Community	No	2
3BBY	Neuro—Medium	Late—Community	Yes	3
3BCN	Neuro—High	Late—Community	No	2
3BCY	Neuro—High	Late—Community	Yes	3
3CAN	Wound—Low	Late—Community	No	3
3CAY	Wound—Low	Late—Community	Yes	3
3CBN	Wound—Medium	Late—Community	No	3
3CBY	Wound—Medium	Late—Community	Yes	3
3CCN	Wound—High	Late—Community	No	3
3CCY	Wound—High	Late—Community	Yes	3
3DAN	Complex—Low	Late—Community	No	2
3DAY	Complex—Low	Late—Community	Yes	2
3DBN	Complex—Medium	Late—Community	No	2
3DBY	Complex—Medium	Late—Community	Yes	2
3DCN	Complex—High	Late—Community	No	2
3DCY	Complex—High	Late—Community	Yes	2
3EAN	MS Rehab—Low	Late—Community	No	2
3EAY	MS Rehab—Low	Late—Community	Yes	2
3EBN	MS Rehab—Medium	Late—Community	No	2
3EBY	MS Rehab—Medium	Late—Community	Yes	2
3ECN	MS Rehab—High	Late—Community	No	2
3ECY	MS Rehab—High	Late—Community	Yes	3
3FAN	Behavioral Health—Low	Late—Community	No	2
3FAY	Behavioral Health—Low	Late—Community	Yes	2
3FBN	Behavioral Health—Medium	Late—Community	No	2
3FBY	Behavioral Health—Medium	Late—Community	Yes	2
3FCN	Behavioral Health—High	Late—Community	No	2
3FCY	Behavioral Health—High	Late—Community	Yes	3
4AAN	MMTA—Low	Late—Institutional	No	3
4AAY	MMTA—Low	Late—Institutional	Yes	3
4ABN	MMTA—Medium	Late—Institutional	No	3
4ABY	MMTA—Medium	Late—Institutional	Yes	3
4ACN	MMTA—High	Late—Institutional	No	3
4ACY	MMTA—High	Late—Institutional	Yes	3
4BAN	Neuro—Low	Late—Institutional	No	4
4BAY	Neuro—Low	Late—Institutional	Yes	4
4BBN	Neuro—Medium	Late—Institutional	No	4
4BBY	Neuro—Medium	Late—Institutional	Yes	4
4BCN	Neuro—High	Late—Institutional	No	4
4BCY	Neuro—High	Late—Institutional	Yes	4
4CAN	Wound—Low	Late—Institutional	No	3
4CAY	Wound—Low	Late—Institutional	Yes	3
4CBN	Wound—Medium	Late—Institutional	No	4
4CBY	Wound—Medium	Late—Institutional	Yes	4
4CCN	Wound—High	Late—Institutional	No	4
4CCY	Wound—High	Late—Institutional	Yes	4
4DAN	Complex—Low	Late—Institutional	No	2
4DAY	Complex—Low	Late—Institutional	Yes	3
4DBN	Complex—Medium	Late—Institutional	No	3
4DBY	Complex—Medium	Late—Institutional	Yes	3
4DCN	Complex—High	Late—Institutional	No	3
4DCY	Complex—High	Late—Institutional	Yes	3
4EAN	MS Rehab—Low	Late—Institutional	No	4
4EAY	MS Rehab—Low	Late—Institutional	Yes	4

TABLE 40—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED HHGM PAYMENT GROUPS BASED ON CY 2016 UTILIZATION DATA—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Threshold (10th percentile or 2—whichever is higher)
4EBN	MS Rehab—Medium	Late—Institutional	No	4
4EBY	MS Rehab—Medium	Late—Institutional	Yes	4
4ECN	MS Rehab—High	Late—Institutional	No	4
4ECY	MS Rehab—High	Late—Institutional	Yes	5
4FAN	Behavioral Health—Low	Late—Institutional	No	2
4FAY	Behavioral Health—Low	Late—Institutional	Yes	3
4FBN	Behavioral Health—Medium	Late—Institutional	No	3
4FBY	Behavioral Health—Medium	Late—Institutional	Yes	3
4FCN	Behavioral Health—High	Late—Institutional	No	3
4FCY	Behavioral Health—High	Late—Institutional	Yes	3

We invite public comments on the LUPA threshold methodology proposed for the HHGM and the associated regulations text changes in section VIII. of this proposed rule.

10. HH PPS Case-Mix Weights Under the HHGM

Section 1895(b)(4)(B) of the Act requires the Secretary to establish appropriate case mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services. We are proposing the HHGM case-mix adjustment methodology, which sorts 30-day periods of care into different payment groups based on five categories (admission source, timing, clinical group, functional level, and comorbidity group), for 30-day periods of care that begin on or after January 1, 2019. In combination, this would yield a total of 144 HHGM payment groups, which we would still refer to as Home Health Resource Groups (HHRGs) under the HHGM. To generate HHGM case-mix weights, we utilized a data file based on home health episodes of care, as reported in Medicare home health claims, as well as OASIS assessment data. The claims data provide episode-level data, as well as visit-level data. The claims also provide data on whether NRS was provided during the episode and the total charges for NRS. We determined the case-mix weight for each of the different HHGM payment groups by regressing resource use on a series of indicator variables for each of the five categories listed above using a fixed effects model. The regression measures resource use with the proposed Cost per Minute (CPS) + NRS approach outlined in section III.E.2 of this proposed rule.

To normalize the results from the fixed effects regression model, we divided the predicted resource use for each 30-day period by the overall average resource use for all 30-day periods used to estimate the model to calculate the case mix weight of all 30-day periods within a particular payment group, where each payment group is defined as the unique combination of the subgroups within the five HHGM categories (admission source, timing of the episode, clinical grouping, functional level, and comorbidity adjustment). The case-mix weight is then used to adjust the 30-day payment rate to determine each 30-day period payment. Table 41 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.E.6 of this proposed rule for the clinical groups, section III.E.7 of this proposed rule for the functional levels, section III.E.5 of this proposed rule for admission source, section III.E.4 of this proposed rule for episode timing, and section III.E.8 of this proposed rule for the comorbidity adjustment.

TABLE 41—COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR HHGM PAYMENT GROUP

	Coefficient	Coefficient divided by average resource use
Clinical Group and Functional Level (MMTA—Low is excluded)		
MMTA—Medium	$238.93	0.151
MMTA—High	434.36	0.274
Behavioral Health—Low	−116.43	−0.073
Behavioral Health—Medium	177.47	0.112
Behavioral Health—High	350.98	0.221
Complex—Low	99.82	0.063
Complex—Medium	472.79	0.298
Complex—High	638.62	0.403
MS Rehab—Low	154.72	0.098
MS Rehab—Medium	353.44	0.223
MS Rehab—High	597.31	0.377
Neuro—Low	356.33	0.225
Neuro—Medium	636.52	0.401
Neuro—High	804.50	0.507
Wound—Low	582.68	0.368

TABLE 41—COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR HHGM PAYMENT GROUP—Continued

	Coefficient	Coefficient divided by average resource use
Wound—Medium	812.76	0.513
Wound—High	1,048.55	0.661
Referral Source With Timing (Community Early excluded)		
Community Late	−618.74	−0.390
Institutional Early	271.07	0.171
Institutional Late	83.61	0.053
Comorbidity Adjustment (No Comorbidity Adjustment Group is excluded)		
Comorbidity Adjustment Group	244.01	0.154
Constant	1,533.33	0.967
N	8,642,107	
Adjusted R2	0.2704	
Average Resource Use	1,585.48	

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 (as of March 17, 2017) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Table 42 presents the case-mix weight for each HHRG in the regression model (from Table 46's coefficients). LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded. These are the case-mix weights for the HHGM based on the most current, complete data available (CY 2016 data as of March 17, 2017). We would propose updated case-mix weights using the latest CY 2017 data in the CY 2019 HH PPS proposed rule. LUPA information can be found in section III.E.9 of this proposed rule. Weights are determined by first calculating the predicted resource use for episodes with a particular combination of admission source, episode timing, clinical grouping, functional level, and comorbidity adjustment. This combination specific calculation is then divided by the average resource use of all the episodes that were used to estimate, which is $1,585.48. The resulting ratio represents the case-mix weight for that particular combination of a HHRG payment group. The adjusted R-squared value for this model is 0.2704. 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. In this instance, the fixed effects regression model used to generate the case-mix weight under the HHGM predicts about 27 percent of the variation in resource use in a given 30-day period of home health care.

As noted above, there are 144 different HHRG payment groups under the HHGM. There are 9 HHRG payment groups that represent roughly 50.5 percent of the total episodes. There are 33 HHRG payment groups that represent roughly 1.0 percent of total episodes. The HHRG payment group with the smallest weight has a weight of 0.5034 (community, late, behavioral health, low functional level, with no comorbidity adjustment). The HHRG payment group with the largest weight has a weight of 1.9533 (institutional admission, early, wound, high functional level, with comorbidity adjustment).

TABLE 42—CASE-MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP, BASED ON 2016 DATA

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Weight based on CY 2016 data
1AAN	MMTA—Low	Early—Community	No	0.9671
1AAY	MMTA—Low	Early—Community	Yes	1.1210
1ABN	MMTA—Medium	Early—Community	No	1.1178
1ABY	MMTA—Medium	Early—Community	Yes	1.2717
1ACN	MMTA—High	Early—Community	No	1.2411
1ACY	MMTA—High	Early—Community	Yes	1.3950
1BAN	Neuro—Low	Early—Community	No	1.1919
1BAY	Neuro—Low	Early—Community	Yes	1.3458
1BBN	Neuro—Medium	Early—Community	No	1.3686
1BBY	Neuro—Medium	Early—Community	Yes	1.5225
1BCN	Neuro—High	Early—Community	No	1.4745
1BCY	Neuro—High	Early—Community	Yes	1.6284
1CAN	Wound—Low	Early—Community	No	1.3346
1CAY	Wound—Low	Early—Community	Yes	1.4885
1CBN	Wound—Medium	Early—Community	No	1.4797
1CBY	Wound—Medium	Early—Community	Yes	1.6336
1CCN	Wound—High	Early—Community	No	1.6284

TABLE 42—CASE-MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP, BASED ON 2016 DATA—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Weight based on CY 2016 data
1CCY	Wound—High	Early—Community	Yes	1.7823
1DAN	Complex—Low	Early—Community	No	1.0301
1DAY	Complex—Low	Early—Community	Yes	1.1840
1DBN	Complex—Medium	Early—Community	No	1.2653
1DBY	Complex—Medium	Early—Community	Yes	1.4192
1DCN	Complex—High	Early—Community	No	1.3699
1DCY	Complex—High	Early—Community	Yes	1.5238
1EAN	MS Rehab—Low	Early—Community	No	1.0647
1EAY	MS Rehab—Low	Early—Community	Yes	1.2186
1EBN	MS Rehab—Medium	Early—Community	No	1.1900
1EBY	MS Rehab—Medium	Early—Community	Yes	1.3439
1ECN	MS Rehab—High	Early—Community	No	1.3438
1ECY	MS Rehab—High	Early—Community	Yes	1.4977
1FAN	Behavioral Health—Low	Early—Community	No	0.8937
1FAY	Behavioral Health—Low	Early—Community	Yes	1.0476
1FBN	Behavioral Health—Medium	Early—Community	No	1.0790
1FBY	Behavioral Health—Medium	Early—Community	Yes	1.2329
1FCN	Behavioral Health—High	Early—Community	No	1.1885
1FCY	Behavioral Health—High	Early—Community	Yes	1.3424
2AAN	MMTA—Low	Early—Institutional	No	1.1381
2AAY	MMTA—Low	Early—Institutional	Yes	1.2920
2ABN	MMTA—Medium	Early—Institutional	No	1.2888
2ABY	MMTA—Medium	Early—Institutional	Yes	1.4427
2ACN	MMTA—High	Early—Institutional	No	1.4120
2ACY	MMTA—High	Early—Institutional	Yes	1.5659
2BAN	Neuro—Low	Early—Institutional	No	1.3628
2BAY	Neuro—Low	Early—Institutional	Yes	1.5167
2BBN	Neuro—Medium	Early—Institutional	No	1.5395
2BBY	Neuro—Medium	Early—Institutional	Yes	1.6934
2BCN	Neuro—High	Early—Institutional	No	1.6455
2BCY	Neuro—High	Early—Institutional	Yes	1.7994
2CAN	Wound—Low	Early—Institutional	No	1.5056
2CAY	Wound—Low	Early—Institutional	Yes	1.6595
2CBN	Wound—Medium	Early—Institutional	No	1.6507
2CBY	Wound—Medium	Early—Institutional	Yes	1.8046
2CCN	Wound—High	Early—Institutional	No	1.7994
2CCY	Wound—High	Early—Institutional	Yes	1.9533
2DAN	Complex—Low	Early—Institutional	No	1.2010
2DAY	Complex—Low	Early—Institutional	Yes	1.3549
2DBN	Complex—Medium	Early—Institutional	No	1.4363
2DBY	Complex—Medium	Early—Institutional	Yes	1.5902
2DCN	Complex—High	Early—Institutional	No	1.5409
2DCY	Complex—High	Early—Institutional	Yes	1.6948
2EAN	MS Rehab—Low	Early—Institutional	No	1.2357
2EAY	MS Rehab—Low	Early—Institutional	Yes	1.3896
2EBN	MS Rehab—Medium	Early—Institutional	No	1.3610
2EBY	MS Rehab—Medium	Early—Institutional	Yes	1.5149
2ECN	MS Rehab—High	Early—Institutional	No	1.5148
2ECY	MS Rehab—High	Early—Institutional	Yes	1.6687
2FAN	Behavioral Health—Low	Early—Institutional	No	1.0646
2FAY	Behavioral Health—Low	Early—Institutional	Yes	1.2185
2FBN	Behavioral Health—Medium	Early—Institutional	No	1.2500
2FBY	Behavioral Health—Medium	Early—Institutional	Yes	1.4039
2FCN	Behavioral Health—High	Early—Institutional	No	1.3594
2FCY	Behavioral Health—High	Early—Institutional	Yes	1.5133
3AAN	MMTA—Low	Late—Community	No	0.5769
3AAY	MMTA—Low	Late—Community	Yes	0.7308
3ABN	MMTA—Medium	Late—Community	No	0.7276
3ABY	MMTA—Medium	Late—Community	Yes	0.8815
3ACN	MMTA—High	Late—Community	No	0.8508
3ACY	MMTA—High	Late—Community	Yes	1.0047
3BAN	Neuro—Low	Late—Community	No	0.8016
3BAY	Neuro—Low	Late—Community	Yes	0.9555
3BBN	Neuro—Medium	Late—Community	No	0.9783
3BBY	Neuro—Medium	Late—Community	Yes	1.1322
3BCN	Neuro—High	Late—Community	No	1.0843
3BCY	Neuro—High	Late—Community	Yes	1.2382
3CAN	Wound—Low	Late—Community	No	0.9444
3CAY	Wound—Low	Late—Community	Yes	1.0983
3CBN	Wound—Medium	Late—Community	No	1.0895

TABLE 42—CASE-MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP, BASED ON 2016 DATA—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Weight based on CY 2016 data
3CBY	Wound—Medium	Late—Community	Yes	1.2434
3CCN	Wound—High	Late—Community	No	1.2382
3CCY	Wound—High	Late—Community	Yes	1.3921
3DAN	Complex—Low	Late—Community	No	0.6398
3DAY	Complex—Low	Late—Community	Yes	0.7937
3DBN	Complex—Medium	Late—Community	No	0.8751
3DBY	Complex—Medium	Late—Community	Yes	1.0290
3DCN	Complex—High	Late—Community	No	0.9796
3DCY	Complex—High	Late—Community	Yes	1.1335
3EAN	MS Rehab—Low	Late—Community	No	0.6744
3EAY	MS Rehab—Low	Late—Community	Yes	0.8283
3EBN	MS Rehab—Medium	Late—Community	No	0.7998
3EBY	MS Rehab—Medium	Late—Community	Yes	0.9537
3ECN	MS Rehab—High	Late—Community	No	0.9536
3ECY	MS Rehab—High	Late—Community	Yes	1.1075
3FAN	Behavioral Health—Low	Late—Community	No	0.5034
3FAY	Behavioral Health—Low	Late—Community	Yes	0.6573
3FBN	Behavioral Health—Medium	Late—Community	No	0.6888
3FBY	Behavioral Health—Medium	Late—Community	Yes	0.8427
3FCN	Behavioral Health—High	Late—Community	No	0.7982
3FCY	Behavioral Health—High	Late—Community	Yes	0.9521
4AAN	MMTA—Low	Late—Institutional	No	1.0198
4AAY	MMTA—Low	Late—Institutional	Yes	1.1737
4ABN	MMTA—Medium	Late—Institutional	No	1.1705
4ABY	MMTA—Medium	Late—Institutional	Yes	1.3244
4ACN	MMTA—High	Late—Institutional	No	1.2938
4ACY	MMTA—High	Late—Institutional	Yes	1.4477
4BAN	Neuro—Low	Late—Institutional	No	1.2446
4BAY	Neuro—Low	Late—Institutional	Yes	1.3985
4BBN	Neuro—Medium	Late—Institutional	No	1.4213
4BBY	Neuro—Medium	Late—Institutional	Yes	1.5752
4BCN	Neuro—High	Late—Institutional	No	1.5273
4BCY	Neuro—High	Late—Institutional	Yes	1.6812
4CAN	Wound—Low	Late—Institutional	No	1.3874
4CAY	Wound—Low	Late—Institutional	Yes	1.5413
4CBN	Wound—Medium	Late—Institutional	No	1.5325
4CBY	Wound—Medium	Late—Institutional	Yes	1.6864
4CCN	Wound—High	Late—Institutional	No	1.6812
4CCY	Wound—High	Late—Institutional	Yes	1.8351
4DAN	Complex—Low	Late—Institutional	No	1.0828
4DAY	Complex—Low	Late—Institutional	Yes	1.2367
4DBN	Complex—Medium	Late—Institutional	No	1.3180
4DBY	Complex—Medium	Late—Institutional	Yes	1.4719
4DCN	Complex—High	Late—Institutional	No	1.4226
4DCY	Complex—High	Late—Institutional	Yes	1.5765
4EAN	MS Rehab—Low	Late—Institutional	No	1.1174
4EAY	MS Rehab—Low	Late—Institutional	Yes	1.2713
4EBN	MS Rehab—Medium	Late—Institutional	No	1.2428
4EBY	MS Rehab—Medium	Late—Institutional	Yes	1.3967
4ECN	MS Rehab—High	Late—Institutional	No	1.3966
4ECY	MS Rehab—High	Late—Institutional	Yes	1.5505
4FAN	Behavioral Health—Low	Late—Institutional	No	0.9464
4FAY	Behavioral Health—Low	Late—Institutional	Yes	1.1003
4FBN	Behavioral Health—Medium	Late—Institutional	No	1.1318
4FBY	Behavioral Health—Medium	Late—Institutional	Yes	1.2857
4FCN	Behavioral Health—High	Late—Institutional	No	1.2412
4FCY	Behavioral Health—High	Late—Institutional	Yes	1.3951

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

We invite comments on the proposed case-mix weight methodology under the HHGM.

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

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 HHGM, we propose the LUPA add-on factors will remain the same as the current payment system, described in section III.C.3. of this

proposed rule. We propose to multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount. For example, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes in CY 2019, if the first skilled visit is SN, the payment for that visit would be the CY 2019 per-visit rate for SN, multiplied by 1.8451, subject to area wage adjustment.

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 or first billable service date through and including the last billable service date under the original plan of care before the intervening event in a home health beneficiary's care 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 propose the process for partial payment adjustments would remain the same as the existing policies pertaining to partial episode payments. When a new 30-day period begins due to the intervening event of the beneficiary elected transfer or there was a discharge and return to home health during the 30-day period, we propose the original 30-day period would be proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event. The proportional payment is the partial payment adjustment. The partial payment adjustment is calculated by using the span of days (first billable service date through and including the last billable service date) under the original plan of care as a proportion of 30. The proportion is multiplied by the original case-mix and wage index to produce the 30-day payment.

12. Payments for High-Cost Outliers Under the HHGM

As described in section III.D. of this proposed rule, section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount in the case of outliers because of unusual variations in the type or amount of medically necessary care. The history of and current methodology for payment of high-cost outliers under the HH PPS is described in detail in section III.D. of this proposed rule. We are proposing to maintain the current methodology for payment of high-cost outliers upon implementation of the HHGM in CY 2019 and we would calculate payment for high-cost outliers on 30-day periods of care.

Simulating payments using preliminary CY 2016 claims data and the CY 2018 payment rates, we estimate that outlier payments under the proposed HHGM with 30-day periods of care would comprise approximately 4.50 percent of total HH PPS payments in CY 2018. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we currently estimate that the FDL ratio under the HHGM would need to change from 0.55 to 0.93. However, given the proposed implementation of the HHGM for 30-day periods of care beginning on or after January 1, 2019, 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 2019 rate-setting. We would propose a change in the FDL ratio for CY 2019, if needed.

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

13. Conforming Regulations Text Revisions for the Implementation of the HHGM in CY 2019

We are proposing to make a number of revisions to the regulations to implement the HHGM for periods beginning on or after January 1, 2019, as outlined in sections III.E.1. through III.E.12. of this proposed rule. We propose to make conforming changes in § 409.43 and part 484 subpart E to revise the unit of service from a 60-day episode to a 30-day period. In addition, we are proposing to restructure § 484.205. These revisions would be effective on January 1, 2019. We are not proposing any revisions to the regulations for CY 2018. These revisions and others are discussed below. Specifically, we propose to:

- Revise § 409.43, which outlines plan of care requirements. We propose to revise several paragraphs to phase out the unit of service from a 60-day episode for episodes beginning on or before December 31, 2018, and to implement a 30-day period as the new unit of service for periods beginning on or after January 1, 2019 under the HHGM.
- Revise the definitions of rural area and urban area in § 484.202 to remove ''with respect to home health episodes ending on or after January 1, 2006'' from each definition, as this verbiage is no longer necessary.
- Restructure § 484.205 to provide more logical organization. Specifically, we propose to add paragraphs to paragraph (b) to define the unit of payment. We propose to move language which addresses the requirement for OASIS submission from § 484.210 and insert it into § 484.205 as new paragraph (c). We also propose to add paragraph (f) to discuss split percentage payments under the current model and the proposed HHGM. In addition, we propose to revise § 484.205 to remove references to ''60-day episode'' and to refer more generally to the ''national, standardized prospective payment''. While we are proposing to revise § 484.205 to account for the change in the unit of payment under the HH PPS for CY 2019, we are not proposing to change the requirements or policies relating to durable medical equipment or furnishing negative pressure wound therapy using a disposable device.
- Remove § 484.210 which discusses data used for the calculation of the national prospective 60-day episode payment as we believe that this information is incorporated in other sections of part 484 subpart E, such as § 484.205(c), § 484.215(a) and (b), § 484.220 and § 484.215.
- Revise the section heading of § 484.215 from ''Initial establishment of the calculation of the national 60-day episode payment'' to ''Initial establishment of the calculation of the national, standardized prospective 60-day episode payment and 30-day payment rates.'' Also, we propose to add paragraph (f) to this section to describe how the national, standardized prospective 60-day episode payment rate is converted into a national, standardized prospective 30-day period payment and when it applies.
- Revise the section heading of § 484.220 from ''Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels'' to ''Calculation of the case-mix and wage area adjusted prospective payment rates.'' We propose to remove the reference to ''national 60-day episode payment rate'' and replace it with ''national, standardized prospective payment''.
- Revise the section heading in § 484.225 from ''Annual update of the unadjusted national prospective 60-day episode payment rate'' to ''Annual update of the unadjusted national, standardized prospective 60-day

episode and 30-day payment rates''. Also, we propose to revise § 484.225 to remove references to ''60-day episode'' and to refer more generally to the ''national, standardized prospective payment''. In addition, we propose to add paragraph (d) to describe the annual update for CY 2019.

- Revise the section heading of § 484.230 from ''Methodology used for the calculation of low-utilization payment adjustment'' to ''Low utilization payment adjustment''. Also, we propose to designate the current text to paragraph (a) and insert language such that proposed paragraph (a) applies to episodes beginning on or before December 31, 2018, using the current payment system. We propose to add paragraph (b) to describe how low utilization payment adjustments are determined for periods beginning on or after January 1, 2019, using the proposed HHGM.
- Revise the section heading of § 484.235 from ''Methodology used for the calculation of partial episode payment adjustments'' to ''Partial payment adjustments''. We propose to remove paragraphs (a), (b), and (c). We propose to remove paragraphs (1), (2), and (3) which describe partial payment adjustments from paragraph (d) in § 484.205 and incorporate them into § 484.235. We propose to add paragraph (a) to describe partial payment adjustments under the current system, that is, for episodes beginning on or before December 31, 2018, and paragraph (b) to describe partial payment adjustments under the proposed HHGM, that is, for periods beginning on or after January 1, 2019.
- Revise the section heading for § 484.240 from ''Methodology used for the calculation of the outlier payment'' to ''Outlier payments.'' In addition, we propose to remove language at paragraph (b) and append it to paragraph (a). We propose to add language to proposed revised paragraph (a) such that paragraph (a) will apply to payments under the current system, that is, for episodes beginning on or before December 31, 2018. We propose to revise paragraph (b) to describe payments under the proposed HHGM, that is, for periods beginning on or after January 1, 2019. In paragraph (c), we propose to replace the ''estimated'' cost with ''imputed'' cost. Lastly, we propose to revise paragraph (d) to reflect the per-15 minute unit approach to imputing the cost for each claim.

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

IV. Proposed Provisions of the 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, nine states were selected for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified 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 will utilize 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 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 will be based on each HHA's Total Performance Score (TPS) in a given performance year (PY) on (1) a set of measures already reported via OASIS and HHCAHPS for all patients serviced by the HHA and select claims data elements, and (2) three New Measures where points are achieved for reporting data.

As finalized in the CY 2017 HH PPS final rule (81 FR 76741 through 76752), in addition to providing an update on the progress towards developing public reporting of performance under the HHVBP Model, we finalized the following changes related to the HHVBP Model:

- Calculating benchmarks and achievement thresholds at the state level rather than the level of the size-cohort and revising the definition for benchmark to state that benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline period, calculated for each state;
- Requiring a minimum of eight HHAs in a size-cohort;
- Increasing the timeframe for submitting New Measure data from seven calendar days to 15 calendar days following the end of each reporting period to account for weekends and holidays;
- Removing four measures (Care Management: Types and Sources of Assistance, Prior Functioning Activities of Daily Living (ADL)/Instrumental ADL (IADL), Influenza Vaccine Data Collection Period, and Reason Pneumococcal Vaccine Not Received) from the set of applicable measures;
- Adjusting the reporting period and submission date for the Influenza Vaccination Coverage for Home Health Personnel measure from a quarterly submission to an annual submission; and
- Allowing for an appeals process that includes the recalculation process finalized in the CY 2016 HH PPS final rule (80 FR 68688 through 68689), as modified, and adds a reconsideration process.

B. Quality Measures

1. Proposed Adjustment to the Minimum Number of Completed Home Health Care Consumer Assessment of Healthcare Providers and System (HHCAHPS) Surveys

The HHCAHPS survey presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care. The survey is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies and meet the following three broad goals to: (1)

Produce comparable data on the patient's perspective that allows objective and meaningful comparisons between home health agencies on domains that are important to consumers; (2) create incentives through public reporting of survey results for agencies to improve their quality of care; and (3) enhance public accountability in health care by increasing the transparency of the quality of care provided in return for public investment through public reporting.

As finalized in the CY 2016 HH PPS final rule (80 FR 68685 through 68686), if a HHA does not have a minimum of 20 episodes of care during a performance year to generate a performance score on at least five measures, that HHA would not be included in the Linear Exchange Function (LEF) and would not have a payment adjustment percentage calculated. The LEF is used to translate an HHA's Total Performance Score (TPS) into a percentage of the value-based payment adjustment earned by each HHA under the HHVBP Model. For the HHCAHPS measures, a minimum of 20 HHCAHPS completed surveys would be necessary in order for scores to be generated for the HHCAHPS quality measures that can be included in the calculation of the TPS.

We believe, however, that using a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, would better align the Model with HHCAHPS policy for the Patient Survey Star Ratings on Home Health Compare.[100] The decision to use a minimum of 40 completed surveys for these star ratings was a result of balancing two competing goals. One goal was to provide star ratings that were meaningful and minimized random variations. This goal was best served by calculating star ratings for large numbers of cases by having a larger minimum of completed HHCAHPS surveys (for example, 50 or 100 completed HHCAHPS surveys). At the same time, we also wanted to be able to provide star ratings for as many HHAs as possible. This goal was best served by using a lower minimum of completed HHCAHPS surveys (for example, 20 completed HHCAHPS surveys). We chose to balance these opposing and necessary goals by using 40 completed HHCAHPS surveys for the Patient Survey Star Ratings. Because we believe that aligning the Patient Survey Star Ratings system and the HHVBP model provides uniformity, consistency, and standard transformability for different healthcare platforms, we therefore propose using a minimum of 40 instead of 20 completed HHCAHPS surveys under the HHVBP.

We note that we received a comment in response to the CY 2016 HH PPS proposed rule in support of using a higher minimum threshold for HHCAHPS completed surveys for the Patient Survey Star Ratings if the data are going to be used in HHVBP or any other quality assessment program (80 FR 68709). We also note that we received public comment in response to the CY 2017 HH PPS proposed rule in support of using a higher minimum threshold for HHCAHPS completed surveys in the HHVBP Model, including a recommendation to use a minimum of 100 HHCAHPS rather than a sample size of 20 surveys (81 FR 76747). We believe that proposing a minimum of 40 completed HHCAHPS surveys for the Model would be more appropriate than the higher minimums previously recommended by some commenters because it represents a balance between providing meaningful data and having sufficient numbers of HHAs with performance scores for at least 5 measures in the cohorts. Moreover, as we noted, it aligns with the Patient Survey Star Ratings on Home Health Compare.

To understand the possible impact of our proposal to use a minimum of 40 HHCAHPS completed surveys, we note that HHAs may refer to the Interim Performance Reports (IPRs) issued in October 2016, January 2017 and April 2017, which analyzed 40 or more completed HHCAHPS surveys across both small and large cohorts in determining each HHA's HHCAHPS quality measure scores. As a point of comparison to the minimum of 40 HHCAHPS completed surveys, we note that these IPRs will be reissued using 20 or more completed HHCAHPS surveys and include quality measure scores, for these same time periods, calculated with HHAs that qualify for the LEF by having sufficient data for at least five measures. HHAs will have the opportunity to submit a request for recalculation of the revised interim performance scores.

HHAs have an opportunity to evaluate these IPRs in light of our proposal to change to a minimum of 40 HHCAHPS completed surveys, as well as seek clarification on the difference in their reports. The participating HHAs will receive concurrent IPRs in July 2017 and concurrent Annual Total Performance Score and Payment Adjustment Reports, which we plan to make available in the last week of August 2017. The concurrent reports will show one report with HHCAHPS quality measure scores calculated based on a minimum of 40 completed surveys and one report with HHCAHPS quality measure scores calculated based on a minimum of 20 completed surveys. Because this proposed rule will not be finalized before the timeline for submission of recalculation and reconsideration requests, HHAs will have the opportunity to submit recalculation requests for the interim performance scores based on both a minimum of 40 and 20 completed surveys, and recalculation and reconsideration requests, as applicable, for the annual total performance scores included in these reports for these thresholds in accordance with the appeals process set forth at § 484.335, which was finalized in the CY 2017 HH PPS final rule.

We analyzed the effects on participating HHAs of using the proposed 40 or more completed HHCAHPS surveys as compared to using 20 or more completed HHCAHPS surveys by examining OASIS measures submitted from January 1, 2015 through December 31, 2016, claims measures submitted from September 1, 2015 through September 30, 2016, and 12 months ending June 30, 2016 for HHCAHPS-based measures. We also found that achievement thresholds, which are calculated as the median of all HHAs' performance on the specified quality measures during the 2015 baseline year for each state, would not change by more than ±1.1 percent, with the largest changes occurring in the statewide achievement thresholds for the HHCAHPS *Willingness to Recommend the Agency* measure in Arizona (+1.1 percent) and Nebraska (−1.1 percent). Benchmarks (the mean of the top decile of Medicare-certified HHA performance on the specified quality measures during the 2015 baseline year, calculated for each state) had greater potential for change, ranging down to −3.2 percent. For instance, we found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a −2.0 percent reduction in the benchmark for the HHCAHPS Willingness to Recommend the Agency measure for Arizona and a −1.7 percent reduction in the benchmark for Nebraska. We also found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a −1.7 percent reduction in the benchmark for the HHCAHPS Communications between

[100] Patient Survey Star Ratings *https://www.medicare.gov/HomeHealthCompare/Data/Patient-Survey-Star-Ratings.html.*

Providers and Patients measure for Arizona, a −1.7 percent reduction in the benchmark for Florida, and a −3.2 percent reduction in the benchmark for Nebraska.

Overall, the proposed change in the HHCAHPS minimum of 40 completed surveys is estimated to result in a limited percent change in the average statewide TPS for larger-volume HHAs, ranging from −0.4 through +2.2 percent. Because the underlying data does not cover the full 2016 calendar year, the data limitation may impact the final total performance scores and corresponding payment adjustment percentages. We provide estimates of the expected payment adjustment distribution based on the proposed minimum of 40 completed HHCAHPS surveys in the impact analysis of this proposed rule.

We are inviting public comments on our proposal to use 40 or more completed HHCAHPS surveys as the minimum to generate a quality measure score on the HHCAHPS measures, as is currently used in Home Health Compare and the Patient Survey Star Ratings. Therefore, we propose to revise the definition of ''applicable measure'' at § 484.305 to reflect this proposal, from a measure for which the competing HHA has provided 20 home health episodes of care per year to a measure for which a competing HHA has provided a minimum of 20 home health episodes of care per year for the OASIS-based measures, 20 home health episodes of care per year for the claims-based measures, or 40 completed surveys for the HHCAHPS measures. This proposal, if finalized, would apply to the calculation of the benchmark and achievement thresholds and the calculation of performance scores for all Model years, beginning with Performance Year (PY) One.

2. Proposal To Remove One OASIS-Based Measure Beginning With Performance Year 3

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 the first performance year (PY1), referred to as the starter set.

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 the 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 [101] (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 Outcome and Assessment Information Set (OASIS), and two from the Chronic Care Warehouse (claims)), and nine process measures (six from OASIS, and three New Measures, which were not previously reported in the home health setting).

In the CY 2017 HH PPS final rule, we removed the following four measures from the measure set for PY 1 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).

For Performance Year 3 (PY 3), we are proposing to remove one OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures. As part of our ongoing monitoring efforts, we found that based on the standard metrics of measure performance, many providers have achieved full performance on the Drug Education measure. For example, for the January 2017 IPRs (which covered the 12-month period of October 1, 2015 through September 30, 2016), the average value for this measure across all participating HHAs was 95.69 percent from October 2015 through September 2016. When looking at just September 2016, the mean value on this measure across all participating HHAs had increased to 97.8 percent. Also, there are few HHAs with poor performance on the measure. Based on the January 2017 IPRs, across all participating HHAs, the 10th percentile was 89 percent and the 5th percentile was 81.8 percent, but only 1.8 percent of HHAs had a value below 70 percent on the measure. We believe that removing this measure would be consistent with our policy, as noted in the CY 2017 HH PPS final rule (81 FR 76746), that when a measure has achieved full performance, we may propose the removal of the measure in future rulemaking. In addition, our contractor's Technical Expert Panel (TEP), which consists of 11 panelists with expertise in home health care and quality measures, expressed concern that the Drug Education measure does not capture whether the education provided by the HHA was meaningful.

The revised set of applicable measures, if our proposal to remove the OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, is finalized, is presented in Table 43. This measure set would be applicable to PY3 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.

[101] 2015 Annual Report to Congress, *http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm.*

[102] For more detailed information on the proposed measures utilizing OASIS refer to the *OASIS–C1/ICD–9, Changed Items & Data Collection Resources* dated September 3, 2014 available at *www.oasisanswers.com/LiteratureRetrieve.aspx?ID=215074.*

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 *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQuality Measures.html.* For information on HHCAHPS measures see *https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx.*

TABLE 43—MEASURE SET FOR THE HHVBP MODEL [102] BEGINNING PY 3

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care.	Improvement in Ambulation-Locomotion.	Outcome	NQF0167	OASIS (M1860).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in ambulation/locomotion 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.
Clinical Quality of Care.	Improvement in Bed Transferring.	Outcome	NQF0175	OASIS (M1850).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bed transferring 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.
Clinical Quality of Care.	Improvement in Bathing.	Outcome	NQF0174	OASIS (M1830).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bathing 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.
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.
Population/Community Health.	Influenza Immunization Received for Current Flu Season.	Process	NQF0522	OASIS (M1046).	Number of home health episodes during which patients (a) received vaccination from the HHA or (b) had received vaccination from HHA during earlier episode of care, or (c) was determined to have received vaccination from another provider.	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.
Population/Community Health.	Pneumococcal Polysaccharide Vaccine Ever Received.	Process	NQF0525	OASIS (M1051).	Number of home health episodes during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV).	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.
Patient & Caregiver-Centered Experience.	Care of Patients ..	Outcome	.....	CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Communications between Providers and Patients.	Outcome	.....	CAHPS	NA	NA.

TABLE 43—MEASURE SET FOR THE HHVBP MODEL [102] BEGINNING PY 3—Continued

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

We invite public comment on the proposal to remove one OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures for PY3 and subsequent performance years and Table 43.

C. Quality Measures for Future Consideration

The CY 2016 HH PPS final rule discusses the HHVBP Model design, the guiding principles to select measures, and the six priority areas of the National Quality Strategy (NQS) we considered for the Model (80 FR 68656 through 68678). Under the HHVBP Model, any measures we determine to be good indicators of quality will be considered for use in the HHVBP Model in future years, and may be added or removed through the rulemaking process. To further our commitment to objectively assess HHVBP quality measures, we are utilizing an implementation contractor that invited a group of measure experts to provide advice on the adjustment of the current measure set for consideration. The contractor convened a technical expert panel (TEP) consisting of 11 panelists with expertise in home health care and quality measures that met on September 7, 2016, in Baltimore, Maryland and via conference call on December 2, 2016. The TEP discussed developing a composite total change in ADL/IADL measure; a composite functional decline measure; a measure to capture when an HHA correctly identifies the patient's need for mental and behavioral health supervision; and a measure to identify if a caregiver is able to provide the patient's mental or behavioral health supervision, to align with § 409.45(b)(3)(iii) and the Medicare Benefit Policy Manual (Pub. 100–02), Chapter 7, Section 20.2. We discuss each of these potential measures in further detail in this section of the proposed rule. While any new measures would be proposed for use in future rulemaking, we are inviting comment on these potential measures now to inform measure development and selection.

As noted in the CY 2017 HH PPS final rule (81 FR 76747), we received several comments expressing concern that the measures under the Model do not reflect the patient population served under the Medicare Home Health benefit as the outcome measures focus on a patient's clinical improvement and do not address patients with chronic illnesses; deteriorating neurological, pulmonary, cardiac, and other conditions; and some with terminal illness. These commenters opined that the value of

including stabilization measures in the HHVBP Model is readily apparent as it aligns the Model with the Medicare Home Health benefit. Commenters also expressed concerns that improvement is not always the goal for each patient and that stabilization is a reasonable clinical goal for some patients. Commenters suggested the addition of stabilization or maintenance measures be considered for the HHVBP Model. Many commenters objected to the use of improvement measures in the HHVBP Model. We did not receive any specific measures for future consideration. In the subsections that follow, we are identifying measures that we are considering for possible inclusion under the Model in future rulemaking and are seeking input from the public on the measures mentioned, as well as any input about the development or construction of the measures and their features or methodologies.

1. Total Change in ADL/IADL Performance by HHA Patients

The measure set finalized in the CY 2016 HH PPS final rule included Change in Daily Activity Function as Measured by the Activity Measure for Post-Acute Care (AM–PAC) (NQF #0430). However, the measure was removed in the CY 2017 HH PPS final rule and never used in the HHVBP Model because the measure required use of a proprietary data collection instrument in the home health environment. We are considering replacing Change in Daily Activity Function as Measured by AM–PAC (NQF #0430) with a composite total ADL/IADL change performance measure. During the September 2016 TEP meeting, an alternative to the Change in Daily Activity Function measure was presented. The TEP requested that a composite Total ADL/IADL Change measure be investigated empirically. This measure was discussed as part of the follow-up conference call, and the TEP supported continued development of the measure in the HHVBP Model as a way of including a measure that captures all three potential outcomes for home health patients: Stabilization; decline; and improvement. They provided input on the technical specifications of the potential composite measure, including the feasibility of implementing the measure and the overall measure reliability and validity. We have reviewed this suggested alternative and believe this measure would provide actionable and transparent information that would support HHA efforts to improve care and prevent functional decline for all patients across a broad range of patient functional outcomes. The measure would also improve accountability during an episode of care when the patient is directly under the HHA's care.

The name of this potential composite measure could be *Total Change in ADL/IADL Performance by HHA Patients.* The measure would report the average, normalized, total improved functioning across the 11 ADL/IADL items on the current OASIS–C2 instrument. The measure is calculated by comparing scores from the start-of-care/resumption of care to scores at discharge. For each item the patient's discharge assessed performance score is subtracted from the patient's start of care/resumption of care assessed performance score, and then divided by the maximum improvement value based on the number of response options for that item. These values are summed into a total normalized change score that can range from −11 (that is, for an episode where there is maximum decline on all 11 items used in the measure) to +11 (that is, for an episode where there is the maximum improvement on all 11 items). An HHA's score on the measure is based on its average across all eligible episodes. Patients who are independent on all 11 ADL/IADL items at Start of Care (SOC)/Resumption of Care (ROC) would also be included in the measure. The HHA's observed score on the measure is the average of the normalized total scores for all eligible episodes for its patients during the reporting period.

The following 11 ADLs/IADL-related items from OASIS–C2 items were included in developing a composite measure:

ADL OASIS–C2 items related to Self-Care:

- M1800 (Grooming).
- M1810 (Upper body dressing).
- M1820 (Lower body dressing).
- M1845 (Toileting hygiene).
- M1870 (Eating).

ADL OASIS–C2 items related to Mobility:

- M1840 (Toilet transferring).
- M1840 (Bed transferring).
- M1860 (Ambulation).

Other IADLs OASIS items:

- M1880 (Light meal preparation).
- M1890 (Telephone use).
- M2020 (Oral medication management).

Based on the measures identified above, we would risk-adjust using OASIS–C2 items to account for case-mix variation and other factors that affect functional decline but are beyond the influence of the HHA. The risk-adjustment model uses an ordinary least squares (OLS) [103] [104] regression framework because the outcome measure (normalized change in ADL/IADL performance) is a continuous variable.

The prediction model for this outcome measure was derived using the predicted values from the 11 individual outcomes that are currently used to risk adjust these 11 individual quality measures. Of the 11 values tested, the 8 identified in this proposed rule were found to be statistically related to the *Total Change in ADL/IADL Performance by HHA Patients* measure at $p < 0.0001$ level and would be used in the prediction model that we are considering proposing to use to risk adjust the HHA's observed value with respect to this potential future measure. The prediction model for this outcome measure uses predicted values from the following individual outcomes (*Note:* The primary source OASIS item is listed in parenthesis after the name of the quality measure):

- Improvement in Upper Body Dressing (M1810).
- Improvement in Management of Oral Medications (M2020).
- Improvement in Bed Transferring (M1850).
- Improvement in Ambulation/Locomotion (M1860).
- Improvement in Grooming (M1800).
- Improvement in Toileting Hygiene (M1845).
- Discharged to the Community (M2420).
- Improvement in Toileting Transfer (M1840).

Two predictive models, one based on predicted values from CY2014 and one from CY2015, were computed. The correlations at the episode level between observed and predicted values for the target outcome measure *Total Change in ADL/IADL Performance by HHA Patients* are shown in Table 44.

[103] Fox, John (1997). Applied Regression Analysis, Linear Models, and Related Methods/Edition 1, 1997, SAGE.

[104] Green, William H. (2017). Econometric analysis (8th ed.). New Jersey: Pearson. ISBN 978–0134461366.

TABLE 44—CORRELATIONS AT THE EPISODE LEVEL BETWEEN OBSERVED AND PREDICTED VALUES FOR THE TARGET OUTCOME MEASURE TOTAL CHANGE IN ADL/IADL PERFORMANCE BY HHA PATIENTS

Data group	Correlation	Significance (p <)	r^2 (Coeff. Determination) (%)
CY2014, National	0.5022	0.0001	25.22
CY2014, HHVBP states	0.5094	0.0001	25.95
CY2015, National	0.5011	0.0001	25.11
CY2015, HHVBP states	0.5076	0.0001	25.76

The results in Table 44 suggest that either model would account for 25 percent or more of the variability in the outcome measure. These models could be considered very strong predictive models for the target outcome measure. Although the analysis supports developing a composite measure, the analysis assumes that the OASIS–C2 items identified to be used in the composite measure do not change; however, we recognize that OASIS–C2 items could be removed or added in any given year. We expect to conduct an additional analysis, in advance of any future proposal, to assess whether changes to OASIS–C2 items that are removed or added could significantly impact a HHA's ability to address several measures to improve its overall score in the composite measure. We are soliciting public comments on whether or not to include a composite total ADL/IADL change performance measure in the set of applicable measures, the name of any such measure, the risk adjustment method, and whether we should conduct an analysis of the impact of removal/addition of OASIS–C2 items.

2. Composite Functional Decline Measure

The second measure we are considering for possible inclusion under the Model in future rulemaking is a *Composite Functional Decline Measure* that could be the percentage of episodes where there was decline on one or more of the eight ADL items used in the measure. As noted in this proposed rule, we received comments on the CY 2017 HH PPS proposed rule suggesting that we consider the addition of stabilization or maintenance measures. To address this suggestion, we are considering a composite functional decline measure because the existing functional stabilization measures, taken individually, are topped out, with HHA level means of 95 percent or higher. This type of composite functional decline measure is similar to the composite ADL decline measure that is used in the Skilled Nursing Facility (SNF) Quality Reporting program (QRP).[105] The SNF QRP measure is constructed from four ADL items: Bed mobility; transfer; eating; and toileting.

An HHVBP composite functional decline measure could provide actionable and transparent information that could support HHA efforts to improve care and prevent functional decline for all patients, including those for whom improvement in functional status is not a realistic care goal. This concept was discussed during the TEP meeting on September 7, 2016, with a follow-up conference call held on December 2, 2016. The TEP supported the inclusion of measures of stabilization and decline in the HHVBP Model, as well as further development of the composite functional decline measure. They provided input on the technical specifications of the potential composite measure, including the feasibility of implementing the measure and the overall measure reliability and validity.

When calculating the composite functional decline measure, we could use the following 8 existing OASIS–C2 items identified below:

- Ambulation/Locomotion (M1860).
- Bed Transferring (M1840).
- Toilet Transferring (M1840).
- Bathing (M1830).
- Toilet Hygiene (M1845).
- Lower Body Dressing (M1820).
- Upper Body Dressing (M1810).
- Grooming (M1800).

The measure could be defined as 1 if there is decline reported in one or more of these items between the Start of Care and the Discharge assessments and zero if no decline is reported on any of these items. As with other OASIS-based measures, a performance score for the measure would only be calculated for HHAs that have 20 or more episodes of care during a performance year.

The measure could be risk-adjusted using OASIS–C2 items to account for case-mix variation and other factors that affect functional decline but are beyond the influence of the HHA. The risk-adjustment model uses a logistic regression framework. The model includes a large number of patient clinical conditions and other characteristics measured at start of care. A logistic regression model is estimated to predict whether the patient will have length of stay of greater than 60 days. The predicted probability of length of stay of greater than 60 days is used, along with other patient characteristics, to construct a logistic regression model to predict the probability of decline in any of eight ADLs. This model is used to estimate the predicted percent of ADL decline at the HHA level. To calculate case-mix adjusted values, the observed value of the measure is adjusted by the difference between the HHA predicted percent and the national predicted percent. The risk-adjustment model reduces the adjusted difference between HHAs that serve a disproportionate number of longer-stay patients and those that serve patients with more typical lengths of stay of one episode.

Across all participating HHAs in the HHVBP Model, for HHAs that had less than 20 percent of episodes lasting more than 60 days, the average on the functional decline measure was 8.08 percent. This increased to 11.08 percent for HHAs with 20 percent to 40 percent of episodes lasting more than 60 days, 14.23 percent for HHAs with 40 percent to 60 percent of episodes lasting more than 60 days, and 20.59 percent for HHAs with more than 60 percent of episodes lasting more than 60 days. This finding suggests that, in addition to focusing on prevention of functional decline, we should also attempt to better predict a patient's functional trajectory and potentially stratify the population to exclude those on a likely downward trajectory. However, in spite of this finding, the inclusion of a measure that rewards providers for avoiding functional decline has the advantage of diversifying the set of measures for the HHVBP model. We are soliciting public comments on whether or not to include

[105] "Long-stay Nursing Home Care: Percent of Residents Whose Need for help with Activities of Daily Living has Increased." *https://www.qualitymeasures.ahrq.gov/summaries/summary/50060.*

a composite functional decline measure in the set of applicable measures, the name of any such measure, the risk adjustment method, and whether we should conduct an analysis of the impact of removal/addition of OASIS–C2 items.

3. Behavioral Health Measures

Although we did not receive comments or suggestions through the rulemaking process for the HHVBP Model regarding behavioral or mental health measures, we recognize that the Model does not include such measures. The OASIS–C2 collects several items related to behavioral and mental health (M1700 Cognitive Functioning; M1710 Confusion Frequency; M1720 Anxiety; M1730 Depression Screening; M1740 Cognitive, Behavioral, and Psychiatric Symptoms; M1745 Frequency of Disruptive Behavior Symptoms; and M1750 Psychiatric Nursing Services). These items are used to compute both Improvement and Process measures as well as Potentially Avoidable Events. The inclusion of behavioral health measures is important for care transformation and improvement activities as many persons served by the Home Health program may have behavioral health needs.

The TEP made several suggestions during the December 2016 conference call as to whether the focus of a behavioral or mental health measure could be identifying whether a patient needed mental or behavioral health assistance compared to the supervision of the patient or advocacy assistance. The TEP supports the supervision type measure due to its opportunity for potential improvement. In further analyses, we identified two underlying components to outcomes for providing assistance. We developed a method, described below, to identify patients who have or do not have needs for mental or behavioral health supervision. We are considering further refining this method by identifying the involvement of the caregiver in addressing the patient's mental or behavioral health supervision needs as an important outcome measure, and we seek comment on whether this is an appropriate factor or feature that we should consider in developing such a measure in future rulemaking.

a. HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision

We are considering adding a *HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision* measure to the HHVBP Model in the future to capture a patient's need for mental or behavioral health supervision based on an identifier. This identifier is based on information from existing Neuro/Emotional/Behavioral Status OASIS items, along with other indicators of mental/behavioral health problems to identify a patient in need of supervisory assistance. The outcome measure assesses whether the HHA correctly identifies whether or not the patient needs mental or behavioral health supervision based on the OASIS SOC/ROC assessment item M2102f, Types and Sources of Assistance: Supervision and Safety.

A composite Mental/Behavioral Health measure could be a dichotomous measure that reports the percentage of episodes of care where the HHA correctly identifies: (a) Patients who need mental or behavioral health supervision; and (b) patients who don't need mental or behavioral health supervision. The numerator could be a combination of two values: (1) The number of episodes of care where the HHA correctly identifies patients who need mental or behavioral health supervision; plus (2) the number of episodes of care where the HHA correctly identifies patients who don't need mental or behavioral health supervision. The denominator is all episodes of care.

The composite measure requires that a patient's need for mental or behavioral health supervision be identified. The following algorithm was designed to identify if a patient was in need of mental or behavioral health supervision. If the patient met any of the following conditions, the patient was identified by the algorithm as in need of mental or behavioral health supervision:

- Was discharged from a psychiatric hospital prior to entering home health care (M1000 = 6);
- Is diagnosed as having chronic mental behavioral problems (M1021 and M1023);
- Is diagnosed with a mental illness (M1021 and M1023);
- Is cognitively impaired (M1700 > = 2);
- Is confused (M1710 > = 2);
- Is identified as having a memory deficit (M1740 = 1);
- Is identified as having impaired decision-making (M1740 = 2);
- Is identified as being verbally disruptive (M1740 = 3);
- Is identified as being physically aggressive (M1740 = 4);
- Is identified as exhibiting disruptive, infantile, or inappropriate behaviors (M1740 = 5);
- Is identified as being delusional (M1740 = 6); or
- Has a frequency of disruptive symptoms (M1745 >= 2.

The measure also requires that the HHA identify if the patient is in need of mental or behavioral health supervision. This requirement is based on the SOC/ROC code for M2102f, Types and Sources of Assistance: Supervision and Safety. If the HHA codes a value of 0, then the HHA has identified this patient as not needing mental or behavioral health supervision. If the HHA codes another value for M2102f, Types and Sources of Assistance: Supervision and Safety, then the HHA has identified this patient as needing mental or behavioral health supervision. The outcome measure is defined as the agreement between the algorithm's identification of a patient's need for mental or behavioral health supervision and the HHA's coding of this need. That is, if—

- The algorithm identifies the patient as not in need of mental or behavioral health supervision and the HHA identifies the patient as not in need of mental or behavioral health supervision, or
- The algorithm identifies the patient as in need of mental or behavioral health supervision and the HHA identifies the patient as in need of mental or behavioral health supervision, then
- The outcome is coded as 1, successful.

As with other OASIS-based measures, a performance score for the measure would only be calculated for HHAs that have 20 or more episodes of care during a performance year.

The measure is risk-adjusted using OASIS–C2 items to account for case-mix variation and other factors that affect functional decline but are beyond the influence of the HHA. The risk-adjustment model uses a logistic regression framework. The model includes a large number of patient clinical conditions and other characteristics measured at the start of care. To calculate case-mix adjusted values, the observed value of the measure is adjusted by the difference between the HHA predicted percent and the national predicted percent.

The prediction model for this outcome measure uses 39 risk factors [106] with each risk factor statistically significant at <0.0001. The correlation for the model between observed and predicted values as estimated by

[106] "Home Health Quality Initiative: Quality Measures" *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Somers' D [107] is 0.427, that yields an estimated coefficient of determination (r2) value based on the Tau-a [108] of 0.201. This suggests that the variability in the model accounts for (predicts) approximately 20 percent of the variability in the outcome measure. The best statistic for evaluating the power of a prediction model that is derived using logistic regression is the c-statistic.[109] This statistic identifies the overall accuracy of prediction by comparing observed and predicted value pairs to the proportion of the time that both predict the outcome in the same direction with 0.500 being a coin-flip. The discussed prediction model has a c-statistic equal to 0.713, which is considered to be strong. Using data from CY 2015, the episode-level mean for the HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision measure is 61.98 percent, nationally, and 62.98 percent for the HHVBP states.

b. Caregiver Can/Does Provide for Patient's Mental or Behavioral Health Supervision Need

We are considering including under the Model in future rulemaking a *Caregiver Can/Does Provide for Patient's Mental or Behavioral Health Supervision Need* measure that would encourage HHAs to ensure that patients who need mental or behavioral health supervision are receiving such care from the patient's caregivers, and would be a realistic care goal.

When considering how to develop a measure to determine whether or not the caregiver can/does provide the patient's mental or behavioral health supervision, we would create an identifier of a patient's need for mental or behavioral health supervision. This identifier is based on the same algorithm described in the previous section from existing Neuro/Emotional/Behavioral Status OASIS items along with other indicators of mental/behavioral health problems to identify a patient in need of supervisory assistance. The outcome measure is whether the HHA correctly identifies this patient as having the need for mental or behavioral health supervision based on the OASIS SOC/ROC assessment item M2102f, Types and Sources of Assistance: Supervision and Safety.

The measure could be a dichotomous measure that reports the percentage of episodes where patients with identified mental or behavioral health supervision needs have their needs met or could have their needs met by the patient's caregiver with additional training (if needed) and support by the HHA. The numerator is the intersection of: (1) The number of episodes of care where the patient needs mental or behavioral health supervision; and (2) the number of episodes of care where these patients have their needs met or could have their needs met by the patient's caregiver with additional training (if needed) and support by the HHA. By intersection, we mean that, for the numerator to equal one, a patient has to need mental or behavioral health supervision and has to have these needs met by his or her caregiver, or could have their needs met by the caregiver with additional training and/or support by the HHA. The denominator is all episodes of care. The algorithm discussed above for *HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision* could also be used to first identify if a patient was in need of mental or behavioral health supervision.

To identify whether caregivers are able to provide supervisory care or, with training, could be able to provide supervisory care for these patients, we could use the SOC/ROC code for M2102f, Types and Sources of Assistance: Supervision and Safety. If the HHA codes a value of 1 (Non-agency caregiver(s) currently provide assistance) or 2 (Non-agency caregiver(s) need training/supportive services to provide assistance), then the measure identifies that a caregiver does or could provide supervision to a patient who has been identified as needing mental or behavioral health supervision.

The outcome measure is defined as the agreement between the algorithm's identification of a patient's need for mental or behavioral health supervision and the availability of supervision from the patient's caregiver(s). That is, if—

- The algorithm identifies the patient as in need of mental or behavioral health supervision and there is documentation that the patient's caregiver(s) do or could provide this supervision; then
- The outcome is coded as 1, successful.

As with other OASIS-based measures, a performance score for the measure would only be calculated for HHAs that have 20 or more episodes during a performance year. We would use the same methodology to risk-adjust by using OASIS–C2 items and the prediction model described above. The prediction model for this outcome measure uses 55 risk factors with each risk factor significant at $p < 0.0001$. The correlation for the model between observed and predicted values as estimated by Somers' D is 0.672, that yields an estimated coefficient of determination (r^2) value based on the Tau-a of 0.205. This suggests that the variability in the model accounts for (predicts) approximately 20 percent of the variability in the outcome measure. The best statistic for evaluating the power of a prediction model that is derived using logistic regression is the c-statistic. This statistic identifies the overall accuracy of prediction by comparing observed and predicted value pairs to the proportion of the time that both predict the outcome in the same direction with 0.500 being a coin-flip. The prediction model has a c-statistic equal to 0.836, which is considered to be extremely strong.

We are considering whether the *HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision* measure or the *Caregiver Can/Does Provide for Patient's Mental or Behavioral Health Supervision Need* measure would be most meaningful to include in the Model. We are also considering the interactions between the Home Health Grouping Model (HHGM) proposal on quality measures discussed in section III of this proposed rule and the HHVBP Model for the quality measures discussed in section IV.B of this proposed rule. We are soliciting public comments on the methodologies, analyses used to test the quality measure, and issues described in this section for future measure considerations. We will continue to share analyses as they become available with participating HHAs during future webinars.

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[107] Somers' D is a statistic that is based on the concept of concordant vs. discordant pairs for two related values. In this case, if both the observed and predicted values are higher than the average or if both values are less than the average, then the pair of numbers is considered concordant. However, if one value is higher than average and the other is lower than average—or vice versa, then the pair of values is considered discordant. The Somer's D is (# of concordant pairs − # of discordant pairs)/total # of pairs. The higher the ratio, the stronger the concordance between the two set of values.

[108] The Kendall Tau-a assumes that if there is a correlation between two variables, then sorting the variables based on one of the values will result in ordering the second variable. It uses the same concept of concordant pairs in Somers' D but a different formula: $t = [(4P)/[(n)(n-1)]-1$ where p = # of concordant pairs and n = # of pairs. This correlation method reduces the effect of outlier values as the values are essentially ranked.

[109] The C-statistic (sometimes called the ''concordance'' statistic or C-index) is a measure of goodness of fit for binary outcomes in a logistic regression model. In clinical studies, the C-statistic gives the probability a randomly selected patient who experienced an event (for example, a disease or condition) had a higher risk score than a patient who had not experienced the event. It is equal to the area under the Receiver Operating Characteristic (ROC) curve and ranges from 0.5 to 1.

- A value below 0.5 indicates a very poor model.
- A value of 0.5 means that the model is no better than predicting an outcome than random chance.
- Values over 0.7 indicate a good model.
- Values over 0.8 indicate a strong model.

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

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of 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 in accordance with this clause, the Secretary is directed to reduce the home health 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, 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.

We use the terminology ''CY [year] HH QRP'' to refer to the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for an HHA to avoid a 2 percentage point reduction to its market basket percentage increase under section 1895(b)(3)(B)(v)(I) of the Act when calculating the payment rates applicable to it for that calendar year.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted on October 6, 2014) (IMPACT Act) amended Title XVIII of the Act, in part, by adding new section 1899B of the Act, entitled ''Standardized Post-Acute Care Assessment Data for Quality, Payment, and Discharge Planning,'' and by enacting new data reporting requirements for certain post-acute care (PAC) providers, including Home Health Agencies (HHAs). Specifically, new sections 1899B(a)(1)(A)(ii) and (iii) of the Act require HHAs, Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Skilled Nursing Facilities (SNFs), under each of their respective quality reporting program (which, for HHAs, is found at section 1895(b)(3)(B)(v) of the Act), to report data on quality measures specified under section 1899B(c)(1) of the Act for at least five domains, and data on resource use and other measures specified under section 1899B(d)(1) of the Act for at least three domains. Section 1899B(a)(1)(A)(i) of the Act further requires each of these PAC providers to report under their respective quality reporting program standardized patient assessment data in accordance with subsection (b) for at least the quality measures specified under subsection (c)(1) and that is for five specific categories: Functional status; cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities; and impairments. All of the data that must be reported in accordance with section 1899B(a)(1)(A) of the Act must be standardized and interoperable, so as to allow for the exchange of the information among PAC providers and other providers, as well as for the use of such data to enable access to longitudinal information and to facilitate coordinated care. We refer readers to the CY 2016 HH PPS final rule (80 FR 68690 through 68692) for additional information on the IMPACT Act and its applicability to HHAs.

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

We refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68698) for a detailed discussion of the considerations we apply in measure selection for the HH QRP, such as alignment with the CMS Quality Strategy,[110] which incorporates the three broad aims of the National Quality Strategy.[111] As part of our consideration for measures for use in the HH QRP, we review and evaluate measures that have been implemented in other programs and take into account measures that have been endorsed by NQF for provider settings other than the HH setting. We have previously adopted measures with the term ''Application of'' in the names of those measures. We have received questions pertaining to the term ''application'' and want to clarify that when we refer to a measure as an ''Application of'' the measure, we mean that the measure would be used in a setting other than the setting for which it was endorsed by the NQF. For example, in the FY 2016 SNF PPS Rule (80 FR 46440 through 46444 we adopted an Application of Percent of Residents with Experiencing Falls with Major Injury (Long Stay) (NQF #0674), which is endorsed for the Nursing Home setting but not the SNF setting. For such measures, we intend to seek NQF endorsement for the HH setting, and if the NQF endorses one or more of them, we will update the title of the measure to remove the reference to ''Application of.''

C. Accounting for Social Risk Factors in the HH QRP

We consider related factors that may affect measures in the HH QRP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE[112]) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[113] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential

[110] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[111] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

[112] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[113] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

methods for measuring and accounting for social risk factors, including stratified public reporting.[114]

As discussed in the CY 2017 HH PPS final rule, the NQF has undertaken a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. Measures from the HH QRP, Rehospitalization During the First 30 Days of Home Health (NQF #2380), and Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF #2505) are being addressed in this trial. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for quality measures.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in measures in the HH QRP, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors, public reporting of stratified measure rates, and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, we are seeking public comment on which social risk factors might be most appropriate for reporting stratified measure scores and potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We are seeking comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the HH QRP. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also welcome comment on operational considerations. We are committed to ensuring that beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

D. Proposed Data Elements for Removal From OASIS

We are proposing to remove 247 data elements from 35 OASIS items collected at specific time points during a home health episode. These data elements are not used in the calculation of quality measures already adopted in the HH QRP, nor are they being used for previously established purposes unrelated to the HH QRP, including payment, survey, the HH VBP Model or care planning. A list of the proposed 35 OASIS items and data elements are listed in Table 45 and also at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html*.

TABLE 45—PROPOSED DATA ELEMENTS TO BE REMOVED FROM OASIS ON JANUARY 1, 2019

OASIS item	Specific time point					
	Start of care	Resumption of care	Follow-up	Transfer to an inpatient facility	Death at home	Discharge from agency
M0903				1	1	1
M1011	6	6	6			
M1017	6	6				
M1018	6	6				
M1025	12	12	12			
M1034	1	1				
M1036	4	4				
M1200	1	1	1			
M1210	1	1				
M1220	1	1				
M1230	1	1				1
M1240	1	1				
M1300	1	1				
M1302	1	1				
M1320	1	1				1
M1322						1
M1332						1
M1350	1	1				
M1410	3	3				
M1501				1		1

[114] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

TABLE 45—PROPOSED DATA ELEMENTS TO BE REMOVED FROM OASIS ON JANUARY 1, 2019—Continued

OASIS item	Specific time point					
	Start of care	Resumption of care	Follow-up	Transfer to an inpatient facility	Death at home	Discharge from agency
M1511	.....	.....	.....	5	.....	5
M1610	.....	.....	.....	.....	.....	1
M1615	1	1	.....	.....	.....	1
M1730	3	3	.....	.....	.....	.....
M1750	1	1	.....	.....	.....	.....
M1880	1	1	.....	.....	.....	1
M1890	1	1	.....	.....	.....	1
M1900	4	4	.....	.....	.....	.....
M2030	1	1	1	.....	.....	1
M2040	2	2	.....	.....	.....	.....
M2102 *	6	6	.....	.....	.....	** 3
M2110	1	1	.....	.....	.....	.....
M2250	7	7	.....	.....	.....	.....
M2310	.....	.....	.....	*** 15	.....	*** 15
M2430	.....	.....	.....	20	.....	.....
Total	75	75	20	42	1	34

* M2102 row f to remain collected at Start of Care, Resumption of Care and Discharge from Agency as part of the HH VBP program.
** M2102 rows a,c,d to remain collected at Discharge from Agency for survey purposes.
*** M2310 responses 1,10,OTH,UK to remain collected at Transfer to an Inpatient Facility and Discharge from Agency for survey purposes.

We are inviting public comment on this proposal.

E. Proposed Collection of Standardized Patient Assessment Data Under the HH QRP

1. Proposed Definition of Standardized Patient Assessment Data

Section 1895(b)(3)(B)(v)(IV)(bb) of the Act requires that beginning with the CY 2019 HH QRP, HHAs report standardized patient assessment data required under section 1899B(b)(1) of the Act. For purposes of meeting this requirement, section 1895(b)(3)(B)(v)(IV)(cc) of the Act requires that a HHA submit the standardized patient assessment data required under section 1899B(b)(1) of the Act in the form and manner, and at the time, as specified by the Secretary.

Section 1899B(b)(1)(B) of the Act describes standardized patient assessment data as data required for at least the quality measures described in sections 1899B(c)(1) of the Act and regarding the following categories:

- Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider;
- Cognitive function, such as ability to express and understand ideas, and mental status, such as depression and dementia;
- Special services, treatments and interventions such as the need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition;
- Medical conditions and comorbidities such as diabetes, congestive heart failure and pressure ulcers;
- Impairments, such as incontinence and an impaired ability to hear, see or swallow; and
- Other categories deemed necessary and appropriate by the Secretary.

As required under section 1899B(b)(1)(A) of the Act, the standardized patient assessment data must be reported at least for the beginning of the home health episode (for example, HH start of care/resumption of care) and end of episode (discharge), but the Secretary may require the data to be reported more frequently.

In this proposed rule, we are proposing to define the standardized patient assessment data that HHAs must report under the HH QRP, as well as the requirements for the reporting of these data. The collection of standardized patient assessment data is critical to our efforts to drive improvement in healthcare quality across the four post-acute care (PAC) settings to which the IMPACT Act applies. We intend to use these data for a number of purposes, including facilitating their exchange and longitudinal use among healthcare providers to enable high quality care and outcomes through care coordination, as well as for quality measure calculation, and identifying comorbidities that might increase the medical complexity of a particular admission.

HHAs are currently required to report patient assessment data through the Outcome and Assessment Information Set (OASIS) by responding to an identical set of assessment questions using an identical set of response options (we refer to a solitary question/response option as a data element and we refer to a group of questions/responses as data elements), both of which incorporate an identical set of definitions and standards. The primary purpose of the identical questions and response options is to ensure that we collect a set of standardized data elements across HHAs, which we can then use for a number purposes, including HH payment and measure calculation for the HH QRP.

LTCHs, IRFs, and SNFs are also required to report patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response options (which incorporate an identical set of definitions and standards). Like the OASIS, the questions and response options for each of these other PAC assessment instruments are standardized across the PAC provider type to which the PAC assessment instrument applies. However, the assessment questions and response options in the four PAC assessment instruments are not currently standardized with each other. As a result, questions and response options that appear on the OASIS

cannot be readily compared with questions and response options that appear, for example, on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI) the PAC assessment instrument used by IRFs. This is true even when the questions and response options are similar. This lack of standardization across the four PAC provider types has limited our ability to compare one PAC provider type with another for purposes such as care coordination and quality improvement.

To achieve a level of standardization across HHAs, LTCHs, IRFs, and SNFs that enables us to make comparisons between them, we are proposing to define ''standardized patient assessment data'' as patient or resident assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. Standardizing the questions and response options across the four PAC assessment instruments is an essential step in making that data interoperable, allowing it to be shared electronically, or otherwise, between PAC provider types. It will enable the data to be comparable for various purposes, including the development of cross-setting quality measures and to inform payment models that take into account patient characteristics rather than setting, as described in the IMPACT Act.

We are inviting public comment on this proposed definition.

2. General Considerations Used for the Selection of Proposed Standardized Patient Assessment Data

As part of our effort to identify appropriate standardized patient assessment data for purposes of collecting under the HH QRP, we sought input from the general public, stakeholder community, and subject matter experts on items that would enable person-centered, high quality health care, as well as access to longitudinal information to facilitate coordinated care and improved beneficiary outcomes.

To identify optimal data elements for standardization, our data element contractor organized teams of researchers for each category, with each team working with a group of advisors made up of clinicians and academic researchers with expertise in PAC. Information-gathering activities were used to identify data elements, as well as key themes related to the categories described in section 1899B(b)(1)(B) of the Act. In January and February 2016, our data element contractor also conducted provider focus groups for each of the four PAC provider types, and a focus group for consumers that included current or former PAC patients and residents, caregivers, ombudsmen, and patient advocacy group representatives. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Focus Group Summary Report is available at *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.*

Our data element contractor also assembled a 16-member TEP that met on April 7 and 8, 2016, and January 5 and 6, 2017, in Baltimore, Maryland, to provide expert input on data elements that are currently in each PAC assessment instrument, as well as data elements that could be standardized. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data TEP Summary Reports are available at *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.*

As part of the environmental scan, data elements currently in the four existing PAC assessment instruments were examined to see if any could be considered for proposal as standardized patient assessment data. Specifically, this evaluation included consideration of data elements in OASIS–C2 (effective January 2017); IRF–PAI, v1.4 (effective October 2016); LCDS, v3.00 (effective April 2016); and MDS 3.0, v1.14 (effective October 2016). Data elements in the standardized assessment instrument that we tested in the Post-Acute Care Payment Reform Demonstration (PAC PRD)—the Continuity Assessment Record and public reporting Evaluation (CARE)—were also considered. A literature search was also conducted to determine whether additional data elements to propose as standardized patient assessment data could be identified.

Additionally, we held four Special Open Door Forums (SODFs) on October 27, 2015; May 12, 2016; September 15, 2016; and December 8, 2016, to present data elements we were considering and to solicit input. At each SODF, some stakeholders provided immediate input, and all were invited to submit additional comments via the CMS IMPACT Mailbox: *PACQualityInitiative@cms.hhs.gov.*

We also convened a meeting with federal agency subject matter experts (SMEs) on May 13, 2016. In addition, a public comment period was open from August 12 to September 12, 2016 to solicit comments on detailed candidate data element descriptions, data collection methods, and coding methods. The IMPACT Act Public Comment Summary Report containing the public comments (summarized and verbatim) and our responses is available at *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.*

We specifically sought to identify standardized patient assessment data that we could feasibly incorporate into the LTCH, IRF, SNF, and HHA assessment instruments and that have the following attributes: (1) Being supported by current science; (2) testing well in terms of their reliability and validity, consistent with findings from the Post-Acute Care Payment Reform Demonstration (PAC PRD); (3) the potential to be shared (for example, through interoperable means) among PAC and other provider types to facilitate efficient care coordination and improved beneficiary outcomes; (4) the potential to inform the development of quality, resource use and other measures, as well as future payment methodologies that could more directly take into account individual beneficiary health characteristics; and (5) the ability to be used by practitioners to inform their clinical decision and care planning activities. We also applied the same considerations that we apply with quality measures, including the CMS Quality Strategy which is framed using the three broad aims of the National Quality Strategy.

3. Policy for Retaining HH QRP Measures and Proposal To Apply That Policy to Standardized Patient Assessment Data

In the CY 2017 HH PPS final rule (81 FR 76702), we adopted a policy that would allow for any quality measure adopted for use in the HH QRP to remain in effect until the measure is removed, suspended, or replaced. For further information on how measures are considered for removal, suspension or replacement, we refer readers to the CY 2017 HH PPS final rule (81 FR 76702). We propose to apply this same policy to the standardized patient assessment data that we adopt for the HH QRP.

We are inviting public comment on our proposal.

4. Policy for Adopting Changes to HH QRP Measures and Proposal To Apply That Policy to Standardized Patient Assessment Data

In the CY 2017 HH PPS final rule (81 FR 76702), we adopted a subregulatory process to incorporate updates to HH quality measure specifications that do not substantively change the nature of the measure. Substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process for nonsubstantive changes, we refer readers to the CY 2017 HH PPS final rule (81 FR 76702). We propose to apply this policy to the standardized patient assessment data that we adopt for HH QRP.

We are inviting public comment on our proposal.

5. Quality Measures Previously Finalized for the HH QRP

The HH QRP currently has 23 measures, as outlined in Table 47.

TABLE 47—MEASURES CURRENTLY ADOPTED FOR THE HH QRP

Short name	Measure name & data source
OASIS-based	
Pressure Ulcers	Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (NQF #0678).*+
DRR	Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care (PAC) Home Health Quality Reporting Program.+
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Bathing	Improvement in Bathing (NQF #0174).
Dyspnea	Improvement in Dyspnea.
Oral Medications	Improvement in Management of Oral Medication (NQF #0176).
Pain	Improvement in Pain Interfering with Activity (NQF #0177).
Surgical Wounds	Improvement in Status of Surgical Wounds (NQF #0178).
Bed Transferring	Improvement in Bed Transferring (NQF #0175).
Timely Care	Timely Initiation Of Care (NQF #0526).
Depression Assessment	Depression Assessment Conducted.
Influenza	Influenza Immunization Received for Current Flu Season (NQF #0522).
PPV	Pneumococcal Polysaccharide Vaccine Ever Received (NQF #0525).
Falls Risk	Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537).
Diabetic Foot Care	Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care (NQF #0519).
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Claims-based	
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP).+
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP).+
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health Quality Reporting Program.+
ACH	Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171).
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of Home Health (NQF #0173).
Rehospitalization	Rehospitalization During the First 30 Days of Home Health (NQF #2380).
ED Use without Readmission	Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF #2505).
HHCAHPs-based	
Professional Care	How often the home health team gave care in a professional way.
Communication	How well did the home health team communicate with patients.
Team Discussion	Did the home health team discuss medicines, pain, and home safety with patients.
Overall Rating	How do patients rate the overall care from the home health agency.
Willing to Recommend	Would patients recommend the home health agency to friends and family.

* Not currently NQF-endorsed for the HH Setting.

+ The data collection period will begin with CY 2017 Q1&2 reporting for CY 2018 APU determination, followed by the previously established HH QRP use of 12 months (July 1, 2017–June 30, 2018) of CY 2017 reporting for CY 2019 APU determination. Subsequent years will be based on the HH July 1–June 30 timeframe for APU purposes. For claims data, the performance period will use rolling CY claims for subsequent reporting purposes.

F. HH QRP Quality Measures Proposed Beginning With the CY 2020 HH QRP

Beginning with the CY 2020 HH QRP, in addition to the quality measures we are retaining under our policy described in section V.B. of the preamble of this proposed rule, we are proposing to replace the current pressure ulcer measure entitled Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) with a modified version of the measure and to adopt one measure on patient falls and one measure on assessment of patient functional status. We are also proposing to characterize the data elements described below, as standardized patient assessment data under section 1899B(b)(1)(B) of the Act that must be reported by HHAs under the HH QRP through the OASIS, under section 1895(b)(3)(B)(v) of the Act. The proposed measures are as follows:

- Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
- Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674).
- Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional

Assessment and a Care Plan That Addresses Function (NQF #2631).

The measures are described in more detail below.

1. Proposal To Replace the Current Pressure Ulcer Quality Measure, Entitled Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), With a Modified Pressure Ulcer Measure, Entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

a. Measure Background

In this rule, we are proposing to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), from the HH QRP measure set and to replace it with a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP. The change in the measure name is to reduce confusion about the new modified measure. The modified version differs from the current version of the measure because it includes new or worsened unstageable pressure ulcers, including deep tissue injuries (DTIs), in the measure numerator. The proposed modified version of the measure also contains updated specifications intended to eliminate redundancies in the assessment items needed for its calculation and to reduce the potential for underestimating the frequency of pressure ulcers. The modified version of the measure would satisfy the IMPACT Act domain of ''Skin integrity and changes in skin integrity.''

b. Measure Importance

As described in the CY 2016 HH PPS final rule (80 FR 68697), pressure ulcers are high-cost adverse events and are an important measure of quality. For information on the history and rationale for the relevance, importance, and applicability of having a pressure ulcer measure in the HH QRP, we refer readers to the CY 2016 HH PPS final rule (80 FR 68623).

We are proposing to adopt a modified version of the current pressure ulcer measure because unstageable pressure ulcers, including DTIs, are similar to Stage 2, Stage 3, and Stage 4 pressure ulcers in that they represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful and are often an avoidable outcome of medical care.[115] [116] [117] [118] [119] [120] Studies show that most pressure ulcers can be avoided and can also be healed in acute, post-acute, and long term care settings with appropriate medical care.[121] Furthermore, some studies indicate that DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer.[122] [123]

While there are few studies that provide information regarding the incidence of unstageable pressure ulcers in PAC settings, an analysis conducted by our measure development contractor indicated that adding unstageable pressure ulcers to the quality measure numerator would result in a higher percentage of patients with new or worsened pressure ulcers in HHA settings and increase the variability of measure scores. A higher percentage indicates lower quality. This increased variability serves to improve the measure by improving the ability of the measure to distinguish between high and low quality home health agencies.

Given the low prevalence of pressure ulcers in the home health setting, the addition of unstageable ulcers to this measure should enhance variability. Analysis of 2015 OASIS data found that in approximately 1.2 percent, or more than 70,000 episodes, the patient had an unstageable ulcer upon admission. Patients in more than 13,000 episodes were discharged with an unstageable ulcer. In addition, unstageable ulcers due to slough/eschar worsened between admission and discharge in approximately 5,000 episodes of care. In conclusion, the inclusion of unstageable pressure ulcers, including DTIs, in the numerator of this measure is expected to increase measure scores and variability in measure scores, thereby improving the ability to discriminate among poor- and high-performing HHAs.

Testing shows similar results in other PAC settings. For example, in SNFs, using data from Quarter 4 2015 through Quarter 3 2016, the mean score on the currently implemented pressure ulcer measure is 1.75 percent, compared with 2.58 percent in the proposed measure. In the proposed measure, the SNF mean score is 2.58 percent; the 25th and 75th percentiles are 0.65 percent and 3.70 percent, respectively; and 20.32 percent of facilities have perfect scores. In LTCHs, using data from Quarter 1 through Quarter 4 2015, the mean score on the currently implemented pressure ulcer measure is 1.95 percent, compared with 3.73 percent in the proposed measure. In the proposed measure, the LTCH mean score is 3.73 percent; the 25th and 75th percentiles are 1.53 percent and 4.89 percent, respectively; and 5.46 percent of facilities have perfect scores. In IRFs, using data from Quarter 4 2016, the mean score on the currently implemented pressure ulcer measure is 0.64 percent, compared with 1.46 percent in the proposed measure. In the proposed measure, the IRF mean score is 1.46 percent and the 25th and 75th percentiles are 0 percent and 2.27 percent, respectively. The inclusion of unstageable pressure ulcers, including DTIs, in the numerator of this measure is expected to increase measure scores and variability in measure scores, thereby improving the ability to distinguish between poor and high performing HHAs.

This increased variability of scores across quarters and deciles may improve the ability of the measure to distinguish between high and low performing providers across PAC settings.

c. Stakeholder Feedback

Our measure development contractor sought input from subject matter experts, including Technical Expert Panels (TEPs), over the course of several years on various skin integrity topics and specifically those associated with the inclusion of unstageable pressure ulcers including DTIs. Most recently, on July 18, 2016, a TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, including the feasibility of implementing the proposed measure's

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[115] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' *Nurs N Z* 19(10): 20–24.

[116] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' *Rev Assoc Med Bras* 57(3): 327–331.

[117] Thomas, J.M., et al. (2013). ''Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.'' *J Am Geriatr Soc* 61(6): 902–911.

[118] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' *Clin Geriatr Med* 27(2): 241–258.

[119] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135 (8 Part 2), 744–51.

[120] Bennet, G, Dealy, C, Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging,* 33(3):230–235.

[121] Black, Joyce M., et al. ''Pressure ulcers: avoidable or unavoidable? Results of the national pressure ulcer advisory panel consensus conference.'' *Ostomy-Wound Management* 57.2 (2011): 24.

[122] Sullivan, R. (2013). A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. Ostomy Wound Management 59(9) *http://www.o-wm.com/article/two-year-retrospective-review-suspected-deep-tissue-injury-evolution-adult-acute-care-patien.*

[123] Posthauer, ME, Zulkowski, K. (2005). Special to OWM: The NPUAP Dual Mission Conference: Reaching Consensus on Staging and Deep Tissue Injury. Ostomy Wound Management 51(4) *http://www.o-wm.com/content/the-npuap-dual-mission-conference-reaching-consensus-staging-and-deep-tissue-injury.*

updates across PAC settings. The TEP supported the use of the proposed measure across PAC settings, including the use of different data elements for measure calculation. The TEP supported the updates to the measure across PAC settings, including the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers due to a non-removable dressing or device, and new DTIs. The TEP recommended supplying additional guidance to providers regarding each type of unstageable pressure ulcer. This support was in agreement with earlier TEP meetings, held on June 13, and November 15, 2013, which had recommended that CMS update the specifications for the pressure ulcer measure to include unstageable pressure ulcers in the numerator.[124] [125] Exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including DTIs, will increase the observed incidence of new or worsened pressure ulcers at the facility level and may improve the ability of the proposed quality measure to discriminate between poor- and high-performing agencies.

We solicited stakeholder feedback on this proposed measure by means of a public comment period held from October 17, through November 17, 2016. In general, we received considerable support for the proposed measure. A few commenters supported all of the changes to the current pressure ulcer measure that resulted in the proposed measure, with one commenter noting the significance of the work to align the pressure ulcer quality measure specifications across the PAC settings. Many commenters supported the inclusion of unstageable pressure ulcers due to slough/eschar, due to non-removable dressing/device, and DTIs in the proposed quality measure. Other commenters did not support the inclusion of DTIs in the proposed quality measure because they stated that there is no universally accepted definition for this type of skin injury.

Some commenters provided feedback on the data elements used to calculate the proposed quality measure. We believe that these data elements will promote facilitation of cross-setting quality comparison as mandated by the IMPACT Act, alignment between quality measures and payment, reduction in redundancies in assessment items, and prevention of inappropriate underestimation of pressure ulcers. The currently implemented pressure ulcer measure is calculated using retrospective data elements that assess the number of new or worsened pressure ulcers at each stage, while the proposed measure is calculated using data elements that assess the current number of unhealed pressure ulcers at each stage, and the number of these that were present upon admission, which are subtracted from the current number at that stage. Some commenters did not support the data elements that would be used to calculate the proposed measure, and requested further testing of these data elements. Other commenters supported the use of these data elements stating that these data elements simplified the measure calculation process.

The public comment summary report for the proposed measure is available on the CMS Web site at *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.*

The NQF-convened Measures Application Partnership (MAP) Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup met on December 14 and 15, 2016, and provided input to us about this proposed measure. The MAP provided a recommendation of ''support for rulemaking'' for use of the proposed measure in the HH QRP. The MAP Coordinating Committee met on January 24 and 25, 2017, and provided a recommendation of ''conditional support for rulemaking'' for use of the proposed measure in the HH QRP. The MAP's conditions of support include that, as a part of measure implementation, we provide guidance on the correct collection and calculation of the measure result, as well as guidance on public reporting Web sites explaining the impact of the specification changes on the measure result. The MAP's conditions also specify that CMS continue analyzing the proposed measure to investigate unexpected results reported in public comment. We intend to fulfill these conditions by offering additional training opportunities and educational materials in advance of public reporting, and by continuing to monitor and analyze the proposed measure. We provide private provider feedback reports as well as a Quarterly Quality Measure report that allow HHAs to track their measure outcomes for QI purposes. Aside from those reports, we conduct internal monitoring and evaluation of our measures to ensure that the measures are performing as they were intended to perform during the development of the measure. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452.*

We reviewed the NQF's consensus endorsed measures and were unable to identify any home health measures that address changes in skin integrity related to pressure ulcers. Therefore, based on the evidence previously discussed, we are proposing to adopt the quality measure entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the HH QRP beginning with the CY 2020 HH QRP. We plan to submit the proposed measure to the NQF for endorsement consideration as soon as feasible.

d. Data Collection

The data for this quality measure would be collected using the OASIS data set, which is currently submitted by HHAs through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System. The required items applicable to this measure are already reported by HHAs for patients and episodes of care meeting statutorily-defined criteria. While the inclusion of unstageable wounds in the proposed measure results in a measure calculation methodology that is different from the methodology used to calculate the current pressure ulcer measure, the data elements needed to calculate the proposed measure are already included on the OASIS data set. In addition, our proposal to eliminate duplicative data elements that were used in calculation of the current pressure ulcer measure will result in an overall reduced reporting burden for HHAs for the proposed measure. For more information on OASIS data set submission using the QIES ASAP System, we refer readers to *https://www.qtso.com/.*

[124] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf.*

[125] Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf.*

For technical information about this proposed measure, including information about the measure calculation and the standardized patient assessment data elements used to calculate this measure, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

We are proposing that HHAs would begin reporting the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, which will replace the current pressure ulcer measure, with data collection beginning with respect to admissions and discharges occurring on or after January 1, 2019.

We are inviting public comment on our proposal to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and replace it with a modified version of that measure, entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP.

2. Proposal To Address the IMPACT Act Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: Application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)

a. Measure Background

Sections 1899B(d)(1)(B) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is January 1, 2019 for HHAs, and October 1, 2016 for SNFs, IRFs and LTCHs), the Secretary specify a quality measure to address the domain of ''Functional status, cognitive function, and changes in function and cognitive function.'' We propose to adopt the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) for the HH QRP, beginning with the CY 2020 program year. This is a process measure that reports the percentage of patients with an admission and discharge functional assessment and treatment goal that addresses function. The treatment goal provides evidence that a care plan with a goal has been established for the HH patient.

The National Committee on Vital and Health Statistics' Subcommittee on Health,[126] noted that ''information on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations in other words, their functional status.'' This is supported by research showing that patient and resident functioning is associated with important outcomes such as discharge destination and length of stay in inpatient settings,[127] as well as the risk of nursing home placement and hospitalization of older adults living in the community.[128] For example, many patients who utilize HH services may be at risk for a decline in function due to limited mobility and ambulation.[129] Thus, impairment in function activities such as self-care and mobility is highly prevalent in HH patients. For example, in 98 percent of the over six million HH episodes in 2015, the patient had at least one limitation or was not completely independent in self-care activities such as grooming, upper and lower body dressing, bathing, toilet hygiene, and/or feeding/eating.[130]

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 setting, and/or facilitate transition to end-of-life care as appropriate.[131] [132] Home health care can positively impact functional outcomes. In stroke patients, home-based rehabilitation programs administered by home health clinicians significantly improved ADL function and gait performance.[133] Home health services, delivered by a registered nurse, positively impacted patient Quality of Life (QOL) and clinical outcomes, including significant improvement in dressing lower body, bathing, meal preparation, shopping, and housekeeping. For some home health patients, achieving independence within the living environment and improved community mobility might be the goal of care. For others, the goal of care might be to slow the rate of functional decline to avoid institutionalization.[134]

Patients' functional status is associated with important patient outcomes, so measuring and monitoring the patients' extent of engaging in self-care and mobility is valuable. Functional decline among the elderly;[135] and chronic illness comorbidities, such as chronic pain among the older adult population [136] [137] are associated with decreases in self-sufficiency and patient activation (defined as the patient's knowledge and confidence in self-managing their health). Impaired mobility, frailty, and low physical activity are associated with institutionalization,[138] higher risk of

[126] Subcommittee on Health National Committee on Vital and Health Statistics, ''Classifying and Reporting Functional Status'' (2001).

[127] Reistetter TA, Graham JE, Granger CV, Deutsch A, Ottenbacher KJ. Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. Archives of Physical Medicine and Rehabilitation, 2010; 91:345–350.

[128] Miller EA, Weissert WG. Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. Medical Care Research and Review, 57; 3: 259–297.

[129] Kortebein, P., Ferrando, A., Lombebeida, J., Wolfe, R., & Evans, W.J. (2007). Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

[130] Kortebein, P., Ferrando, A., Lombebeida, J., Wolfe, R., & Evans, W.J. (2007). Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

[131] Riggs, J. S. & Madigan, E. A. (2012). Describing variation in home health care episodes for patients with heart failure. Home Health Care Management and Practice, 24(3): 146–152.

[132] Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). Patient safety and quality: an evidence-based handbook for nurses. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

[133] Asiri, F. Y., Marchetti, G. F., Ellis, J. L., Otis, L., Sparto, P. J., Watzlaf, V., & Whitney, S. L. (2014). Predictors of functional and gait outcomes for persons poststroke undergoing home-based rehabilitation. Journal of Stroke and Cerebrovascular Diseases: The Official Journal of National Stroke Association, 23(7), 1856–1864. *https://doi.org/10.1016/j.jstrokecerebrovasdis.2014.02.025.*

[134] Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). Patient safety and quality: an evidence-based handbook for nurses. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

[135] Gleason, K. T., Tanner, E. K., Boyd, C. M., Saczynski, J. S., & Szanton, S. L. (2016). Factors associated with patient activation in an older adult population with functional difficulties. Patient Education and Counseling, 99(8), 1421–1426. *https://doi.org/10.1016/j.pec.2016.03.011.*

[136] Roberts AR, Betts Adams K, Beckette & Warner C. (2016). Effects of chronic illness on daily life and barriers to self-care for older women: a mixed-methods exploration. J Women Aging, Jul 25:1–11.

[137] Wu, J.-R., Lennie, T. A., & Moser, D. K. (2016). A prospective, observational study to explore health disparities in patients with heart failure-ethnicity and financial status. European Journal of Cardiovascular Nursing: Journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology. *https://doi.org/10.1177/1474515116641296.*

[138] Hajek, A., Brettschneider, C., Lange, C., Posselt, T., Wiese, B., Steinmann, S., Weyerer, S.,

falls and falls-related hip fracture and death,[139] [140] greater risk of undernutrition,[141] higher rates of inpatient admission from the emergency department,[142] and higher prevalence of hypertension and diabetes.[143]

In addition, the assessment of functional ability and provision of treatment plans directed toward improving or maintaining functional ability could impact health care costs. Providing comprehensive home health care, which includes improving or maintaining functional ability for frail elderly adults, can reduce the likelihood of hospital readmissions or emergency department visits, leading to reduced health care service expenditures.[144] [145] [146] Reducing preventable rehospitalizations, which made up approximately 17 percent of Medicare's $102.6 billion in 2004 hospital payments, creates the potential for large health care cost savings.[147] [148]

Further, improving and maintaining functional ability in individuals with high needs, defined as those with three or more chronic conditions, may also account for an increase in healthcare savings. Adults with three or more chronic conditions have nearly four times the average annual per-person spending for health care services and prescription medications than the average for all U.S. adults, and high needs adults with limitations in their ability to perform ADLs, have even higher average annual health care expenditures.[149] High needs individuals with functional limitations spend, on average, $21,021 on annual health care services, whereas the average annual health care expenditures for all U.S. adults are approximately $4,845.[45]

b. Measure Importance

The majority of individuals who receive PAC services, including care provided by HHAs, SNFs, IRFs, and LTCHs, have functional limitations, and many of these individuals are at risk for further decline in function due to limited mobility and ambulation.[150] The patient populations treated by HHAs, SNFs, IRFs, and LTCHs vary in terms of their functional abilities. For example, for home health patients, achieving independence within the home environment and promoting community mobility may be the goal of care. For other home health patients, the goal of care may be to slow the rate of functional decline in order to allow the person to remain at home and avoid institutionalization.[151] The clinical practice guideline *Assessment of Physical Function* [152] recommends that clinicians document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge, as well as establishing a functional goal for discharge as part of the care plan is an important aspect of patient or resident care across PAC settings.

Currently, functional assessment data are collected by all four PAC providers, yet data collection has employed different assessment instruments, scales, and item definitions. The data cover similar topics, but are not standardized across PAC settings. The different sets of functional assessment items coupled with different rating scales makes communication about patient and resident functioning challenging when patients and residents transition from one type of setting to another. Collection of standardized functional assessment data across HHAs, SNFs, IRFs, and LTCHs using common data items would establish a common language for patient and resident functioning, which may facilitate communication and care coordination as patients and residents transition from one type of provider to another. The collection of standardized functional status data may also help improve patient functioning during an episode of care by ensuring that basic daily activities are assessed for all PAC residents at the start and end of care, and that at least one functional goal is established.

The functional assessment items included in the proposed functional status quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize the assessment of a person's status, including functional status, across acute and post-acute settings (HHAs, SNFs, IRFs, and LTCHs). The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge to determine patient or resident needs, evaluate patient or resident progress, and prepare patients, residents, and their families for a transition to home or to another setting. The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set:

Werle, J., Pentzek, M., Fuchs, A., Stein, J., Luck, T., Bickel, H., Mösch, E., Wagner, M., Jessen, F., Maier, W., Scherer, M., Riedel-Heller, S.G., König, H.H., & AgeCoDe Study Group. (2015). Longitudinal Predictors of Institutionalization in Old Age. PLoS One, 10(12):e0144203.

[139] Akahane, M., Maeyashiki, A., Yoshihara, S., Tanaka, Y., & Imamura, T. (2016). Relationship between difficulties in daily activities and falling: loco-check as a self-assessment of fall risk. Interactive Journal of Medical Research, 5(2), e20. *https://doi.org/10.2196/ijmr.5590.*

[140] Zaslavsky, O., Zelber-Sagi, S., Gray, S. L., LaCroix, A. Z., Brunner, R. L., Wallace, R. B., . . . Woods, N. F. (2016). Comparison of Frailty Phenotypes for Prediction of Mortality, Incident Falls, and Hip Fracture in Older Women. Journal of the American Geriatrics Society, 64(9), 1858—1862. *https://doi.org/10.1111/jgs.14233.*

[141] van der Pols-Vijlbrief, R., Wijnhoven, H. A. H., Bosmans, J. E., Twisk, J. W. R., & Visser, M. (2016). Targeting the underlying causes of undernutrition. Cost-effectiveness of a multifactorial personalized intervention in community-dwelling older adults: A randomized controlled trial. Clinical Nutrition (Edinburgh, Scotland). *https://doi.org/10.1016/j.clnu.2016.09.030.*

[142] Hominick, K., McLeod, V., & Rockwood, K. (2016). Characteristics of older adults admitted to hospital versus those discharged home, in emergency department patients referred to internal medicine. Canadian Geriatrics Journal: CGJ, 19(1), 9–14. *https://doi.org/10.5770/cgj.19.195.*

[143] Halaweh, H., Willen, C., Grimby-Ekman, A., & Svantesson, U. (2015). Physical activity and health-related quality of life among community dwelling elderly. J Clin Med Res, 7(11), 845–52.

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[146] Meunier, M. J., Brant, J. M., Audet, S., Dickerson, D., Gransbery, K., & Ciemins, E. L. (2016). Life after PACE (Program of All-Inclusive Care for the Elderly): A retrospective/prospective, qualitative analysis of the impact of closing a nurse practitioner centered PACE site. Journal of the American Association of Nurse Practitioners. *https://doi.org/10.1002/2327-6924.12379.*

[147] Jencks, S.F., Williams, M.V., and Coleman, E.A. (2009). Rehospitalizations among patients in the Medicare fee-for-service program. New England Journal of Medicine; 360(14):1418–28.

[148] Tao, H., Ellenbecker, C. H., Chen, J., Zhan, L., & Dalton, J. (2012). The influence of social environmental factors on rehospitalization among patients receiving home health care services. ANS. Advances in Nursing Science, 35(4), 346–358. *https://doi.org/10.1097/ANS.0b013e318271d2ad.*

[149] Hayes, S.L., Salzberg, C.A., McCarthy, D., Radley, DC, Abrams, M.K., Shah, T., and Anderson, G.F. (2016). High-Need, High-Cost Patients: Who are they and how do they use health care—A population-based comparison of demographics, health care use, and expenditures. The Commonwealth Fund.

[150] Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ. Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

[151] Ellenbecker CH, Samia L, Cushman MJ, Alster K. Patient safety and quality in home health care. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Vol 1.

[152] Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103.

Volume 1 of 3.'' [153] Reliability and validity testing were conducted as part of CMS's Post-Acute Care Payment Reform Demonstration (PAC–PRD), and we concluded that the functional status items have acceptable reliability and validity. Testing for the functional assessment items concluded that the items were able to evaluate all patients on basic self-care and mobility activities, regardless of functional level or PAC setting. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3'' [154] and the report entitled ''The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.'' [155] These reports are available on our Post-Acute Care Quality Initiatives Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.*

Additional testing of these functional assessment items was conducted in a small field test occurring in 2016–2017, capturing data from 12 HHAs. Preliminary data results yielded moderate to substantial reliability for the self-care and mobility data items. More information about testing design and results can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html.* The functional status quality measure we are proposing to adopt beginning with the CY 2020 HH QRP is a process quality measure that is an application of the NQF-endorsed quality measure, the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631). This quality measure reports the percent of patients with both an admission and a discharge functional assessment and a functional treatment goal.

This process measure requires the collection of admission and discharge functional status data by clinicians using standardized patient assessment data elements, which assess specific functional activities, such as self-care and mobility activities. The self-care and mobility function activities are coded using a 6-level rating scale that indicates the resident's level of independence with the activity at both admission and discharge. A higher score indicates more independence. These functional assessment data elements will be collected at Start or Resumption of Care (SOC/ROC) and discharge.

For this quality measure, there must be documentation at the time of admission (SOC) that at least one activity performance (function) goal is recorded for at least one of the standardized self-care or mobility function items using the 6-level rating scale. This indicates that an activity goal(s) has been established. Following this initial assessment, the clinical best practice would be to ensure that the patient's care plan reflected and included a plan to achieve such activity goal(s). At the time of discharge, goal setting and establishment of a care plan to achieve the goal, is reassessed using the same 6-level rating scale, allowing for the ability to evaluate success in achieving the patient's activity performance goals.

To the extent that a patient has an unplanned discharge, for example, transfer to an acute care facility, the collection of discharge functional status data may not be feasible. Therefore, for patients with unplanned discharges, admission functional status data and at least one treatment goal must be reported, but discharge functional status data are not required to be reported.

c. Stakeholder Feedback

Our measures contractor convened a TEP on October 17, and October 18, 2016. The TEP was composed of a diverse group of stakeholders with HH, PAC, and functional assessment expertise. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure of reliability and validity. The TEP additionally provided feedback on the clinical assessment items used to calculate the measure. The TEP reviewed the measure ''Percent of Long-Term Care Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF 2631)'' for potential application to the home health setting. Overall they were supportive of a functional process measure, noting it could have the positive effect of focusing clinician attention on functional status and goals. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web page at *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.*

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 4, 2016 through December 5, 2016. Several stakeholders and organizations supported this measure for implementation and for measure standardization. Some commenters also provided feedback on the standardized patient assessment data elements used to calculate the proposed quality measure. Commenters offered suggestions, including providing education regarding the difference in measure scales for the standardized items relative to current OASIS functional items, and guidance on the type of clinical staff input needed to appropriately complete new functional assessment items. Commenters also addressed the feasibility of collecting data for the individual standardized self-care and mobility items in the home health setting. Finally, commenters noted the importance of appropriate goal setting when functional improvement for a patient may not be feasible. The public comment summary report for the proposed measure is available on the CMS Web site at *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.*

The NQF-convened MAP met on December 14 and 15, 2016, and provided input on the use of this proposed measure in the HH QRP. The MAP recommended ''conditional support for rulemaking'' for this measure. MAP members noted the measure would drive care coordination and improve transitions by encouraging the use of standardized functional assessment items across PAC settings, but recommended submission to the NQF for endorsement to include the home health setting. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2017/02/MAP_2017_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC–LTC.aspx.*

We reviewed the NQF's consensus endorsed measures and were unable to identify any home health measures that address functional assessment, and treatment goals that address function.

[153] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

[154] Ibid.

[155] Ibid.

There are five functional measures in home health that assess functional activities: (1) Improvement in Ambulation/Locomotion (NQF #0167); (2) Improvement in Bathing (NQF #0174); (3) Improvement in Bed Transfer (NQF #0175); (4) Improvement in Management of Oral Medications (NQF # 0176); and (5) Improvement in Pain Interfering with Activity (NQF #0177). Our review determined that these setting-specific measures are not appropriate to meet the specified IMPACT Act domain as they do not include standardized items or are not included for various other PAC populations. Specifically:

- The items used to collect data for the current home health measures are less specific, leading to broader measure results, whereas the standardized patient assessment data items used for the proposed measure assess core activities such as rolling in bed, walking a specified distance, or wheelchair capability.
- The item coding responses are more detailed when compared to the non-standardized OASIS item responses, allowing for more granular data for the measure.
- The proposed functional measure will capture a patient's discharge goal at admission into home health; this detail is not captured in the existing endorsed HH function measures.

Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), for the HH QRP beginning with the CY 2020 HH QRP. We plan to submit the proposed measure to the NQF for endorsement consideration as soon as is feasible.

For technical information about this proposed measure, including information about the measure calculation and the standardized patient assessment data elements used to calculate this measure, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

d. Data Collection

For purposes of assessment data collection, we propose to add new functional status items to the OASIS, to be collected at SOC/ROC and discharge. These items would assess specific self-care and mobility activities, and would be based on functional items included in the PAC–PRD version of the CARE Item Set. More information pertaining to item testing is available on our Post-Acute Care Quality Initiatives Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.*

To allow HHAs to fulfill the requirements of the Home Health Agency Conditions of Participation (HHA CoPs) (82 FR 4504), we are proposing to add a subset of the functional assessment items to the OASIS, with collection of these items at Follow-Up (FU). The collection of these assessment items at FU by HHAs will allow them to fulfill the requirements outlined in the HHA CoPs that suggest that the collection of a patient's current health, including functional status, be collected on the comprehensive assessment.

These new functional status items are standardized across PAC settings and support the proposed standardized measure. They are organized into two functional domains: Self-Care and Mobility. Each domain includes dimensions of these functional constructs that are relevant for home health patients. The proposed function items that we would add to the OASIS for purposes of the calculation of this proposed quality measure do not duplicate existing items currently collected in that assessment instrument for other purposes. The current OASIS function items evaluate current ability, whereas the proposed functional items would evaluate an individual's usual performance at the time of admission and at the time of discharge for goal setting purposes. Additionally, there are several key differences between the existing and new proposed function items that may result in variation in the patient assessment results including: (1) The data collection and associated data collection instructions; (2) the rating scales used to score a resident's level of independence; and (3) the item definitions. A description of these differences is provided with the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Because of the differences between the current function assessment items (OASIS C–2) and the proposed function assessment items that we would collect for purposes of calculating the proposed measure, we would require that HHAs submit data on both sets of items. Data collection for the new proposed function items do not substitute for the data collection under the current OASIS ADL and IADL items. Although providers will collect on the proposed function assessment items as well as the current assessment items, for reasons previously described, we believe these items are not duplicative. However, we request comment on opportunities to streamline reporting to avoid duplication and minimize burden.

We are proposing that data for the proposed quality measure would be collected through the OASIS, which HHAs currently submit through the QIES ASAP system. We refer readers to section V.F.2 of this proposed rule for more information on the proposed data collection and submission timeline for this proposed quality measure. If this measure is finalized, we intend to provide initial confidential feedback to home health agencies, prior to the public reporting of this measure.

We invite public comment on our proposal to adopt the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).

3. Proposal To Address the IMPACT Act Domain of ''Incidence of Major Falls'' Measure: Percent of Residents Experiencing One or More Falls With Major Injury

a. Measure Background

Sections 1899B(c)(1)(D) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(i)(IV) is January 1, 2019 for HHAs, and October 1, 2016 for SNFs, IRFs and LTCHs), the Secretary specify a measure to address the domain of incidence of major falls, including falls with major injury. We propose to adopt the measure, Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), for which we would begin to collect data on January 1, 2019 for the CY 2020 HH QRP to meet this requirement. This proposed outcome measure reports the percentage of residents who have experienced falls with major injury during episodes ending in a 3-month period.

b. Measure Importance

Falls affect an estimated 6 to 12 million older adults each year and are the leading cause of both fatal injury

and nonfatal hospital admissions.[156] [157] Within the home health population, the risk of falling is significant as approximately one third of individuals over the age of 65 experienced at least one fall annually.[158] Major fall-related injuries among older community-dwelling adults are a growing health concern within the United States[159] [160] because they can have high medical and cost implications for the Medicare community.[161] In 2013, the direct medical cost for falls in older adults was $34 billion [162] and is projected to increase to over $101 billion by 2030 due to the aging population.[163]

Evidence from various studies indicates that implementing effective fall prevention interventions and minimizing the impact of falls that do occur reduces overall costs, emergency department visits, hospital readmissions, and overall Medicare resource utilization.[164] [165] [166] [167] In the 2006 Home Assessments and Modification study, a home visit by an occupational therapist or home care worker to identify and mitigate potential home hazards and risky behavior, resulted in a 46 percent reduction in fall rates for those receiving the intervention compared to controls.[168] Overall, patients participating in interventions experienced improved quality of life due to reduced morbidity, improved functional ability and mobility, reduced number of falls and injurious falls, and a decrease in the fear of falling. [169] [170] Falls also represent a significant cost burden to Medicare. Each year, 2.8 million older people are treated in Emergency Departments for fall related injuries and over 800,000 require hospitalization.[171] Adjusted to 2015 dollars, nationally, direct medical costs for non-fatal fall related injuries in older adults were over $31.3 billion.[172] Additional health care costs (in 2010 dollars) can range from $3,500 for a fall without serious injury to $27,000 for a fall with a serious injury.[173] Between 1988 and 2005, fractures accounted for 84 percent of hospitalizations for fall-related injuries among older adults.[174] Researchers evaluated the cost of fall-related hospitalizations among older adults using the 2011 Texas Hospital Inpatient Discharge Data and determined that the average cost for fall-related hip fractures was $61,715 for individuals 50 and older living in metropolitan areas and $55,366 for those living nonmetropolitan areas.[175]

To meet the IMPACT Act provision requiring the development of a standardized quality measure for the domain of Incidence of Major Falls (sections 1899B(c)(1)(D) of the Act), we developed the proposed standardized measure, The Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). This quality measure is NQF-endorsed and has been successfully implemented in the Nursing Home Quality Initiative for nursing facility long-stay residents since 2011, demonstrating the measure is feasible, appropriate for assessing PAC quality of care, and could be used as a platform for standardized quality measure development. This quality measure is standardized across PAC settings and contains items that are collected uniformly in each setting's assessment instruments (that is, MDS, IRF–PAI, and LCDS). Further, an application of the quality measure was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877), revised in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290), and adopted to fulfill IMPACT Act requirements in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739). Data collection began in April 1, 2016 for LTCHs, and October 1, 2016 for SNFs and IRFs.

More information on the NQF-endorsed quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is available at *http://www.qualityforum.org/QPS/0674.*

c. Stakeholder Feedback

A TEP convened by our measure development contractor provided input on the technical specifications of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), including the feasibility of implementing the measure across PAC settings. The TEP was supportive of the implementation of this measure across PAC settings and was also supportive of our efforts to standardize this measure for cross-setting development. More information about this TEP can be found at *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.*

[156] Bohl, A. A., Phelan, E. A., Fishman, P. A., & Harris, J. R. (2012). How are the costs of care for medical falls distributed? The costs of medical falls by component of cost, timing, and injury severity. The Gerontologist, 52(5): 664–675.

[157] National Council on Aging (2015). Falls Prevention Fact Sheet. Retrieved from *https://www.ncoa.org/wp-content/uploads/Fact-Sheet_Falls-Prevention.pdf.*

[158] Avin G., K., Hanke A., T., Kirk-Sanche, N., McDonough M., C., Shubert E., T., Hardage, J., & Hartley, G. (2015). Management of Falls in Community-Dwelling Older Adults: Clinical Guidance Statement From the Academy of Geriatric Physical Therapy of the American Physical Therapy Association. Physical Therapy, 95(6), 815–834. doi:10.2522/ptj.20140415.

[159] Hester, A. L. & Wei, F. (2013). Falls in the community: state of the science. Clinical Interventions in Aging, 8:675–679.

[160] Orces, C. H. & Alamgir, H. (2014). Trends in fall-related injuries among older adults treated in emergency departments in the USA. Injury Prevention, 20: 421–423.

[161] Liu, S. W., Obermeyer, Z., Chang, Y., & Shankar, K. N. (2015). Frequency of ED revisits and death among older adults after a fall. American Journal of Emergency Medicine, 33(8), 1012–1018. doi:10.1016/j.ajem.2015.04.023.

[162] Centers for Disease Control and Prevention (2015b). Important facts about falls. *http://www.cdc.gov/homeandrecreationalsafety/falls/adultfalls.html.* Accessed April 19, 2016.

[163] Houry, D., Florence, C. Bladwin, G., Stevens, J., & McClure, R. (2015). The CDC Injury Center's response to the growing public health problem of falls among older adults. American Journal of Lifestyle Medicine, 10(1), 74–77.

[164] Bamgbade, S., & Dearmon, V. (2016). Fall prevention for older adults receiving home healthcare. Home Healthcare Now, 34(2), 68–75.

[165] Carande-Kulis, V., Stevens, J. A., Florence, C. S., Beattie, B. L., & Arias, I. (2015). A cost-benefit analysis of three older adult fall prevention interventions. Journal of Safety Research, 52, 65–70. doi:10.1016/j.jsr.2014.12.007.

[166] Cohen, A. M., Miller, J., Shi, X., Sandhu, J., & Lipsitz, A. (2015). Prevention program lowered the risk of falls and decreased claims for long-term care services among elder participants. Health Affairs, 34(6), 971–977.

[167] Howland, J., Shankar, K. N., Peterson, E. W., & Taylor, A. A. (2015). Savings in acute care costs if all older adults treated for fall-related injuries completed matter of balance. Injury Epidemiology, 2(25), 1–7.

[168] Pighills AC, Torgerson DJ, Sheldon TA, Drummond AE, Bland JM. Environmental assessment and modification to prevent falls in older people. Journal of the American Geriatrics Society. 2011;59(1):26–33.

[169] Chase, C. A., Mann, K., Wasek, S., & Arbesman, M. (2012). Systematic review of the effect of home modification and fall prevention programs on falls and the performance of community-dwelling older adults. American Journal of Occupational Therapy, 66(3), 284–291.

[170] Patil, R., Uusi-Rasi, K., Tokola, K., Karinkanta, S., Kannus, P., & Sievanen, H. (2015). Effects of a Multimodal Exercise Program on Physical Function, Falls, and Injuries in Older Women: A 2-Year Community-Based, Randomized Controlled Trial. Journal of the American Geriatrics Society, 63(7), 1306–1313.

[171] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. Accessed August 5, 2016.

[172] Burns ER, Stevens JA, Lee R. The direct costs of fatal and non-fatal falls among older adults—United States. J Safety Res 2016;58:99–103.

[173] Wu S, Keeler EB, Rubenstein LZ, Maglione MA, Shekelle PG. A cost-effectiveness analysis of a proposed national falls prevention program. Clin Geriatr Med. 2010;26(4): 751–66.

[174] Orces, C. H. & Alamgir, H. (2014). Trends in fall-related injuries among older adults treated in emergency departments in the USA. Injury Prevention, 20: 421–423.

[175] Towne, S. D., Ory, M. G., & Smith, M. L. (2014). Cost of fall-related hospitalizations among older adults: environmental comparisons from the 2011 Texas hospital inpatient discharge data. Population Health Management, 17(6), 351–356.

In addition, we solicited public comment on this measure from September 19, 2016 through October 14, 2016. Overall, commenters were generally supportive of the measure, but raised concerns about the attribution given that home health clinicians are not present in the home at all times and recommended risk-adjusting the measure. The summary of this public comment period can be found at *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.*

Finally, we presented this measure to the NQF-convened MAP on December 14, 2016. The MAP conditionally supported the use of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) in the HH QRP as a cross-setting quality measure. The MAP highlighted the clinical significance of falls with major injury, while noting potential difficulties in collecting falls data and more limited actionability in the HH setting. The MAP suggested that CMS explore stratification of measure rates by referral origin when public reporting. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2017/02/MAP_2017_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.* We are inviting public comment on the stratification of the proposed measure, specifically on the measure rates for public reporting. The quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is not currently endorsed for the HH setting. We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures for that setting that are focused on falls with major injury. We found one falls-related measure in home health titled, Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate (NQF #0537).

We are also aware of one NQF-endorsed measure, Falls with Injury (NQF #0202), which is a measure designed for adult acute inpatient and rehabilitation patients capturing ''all documented patient falls with an injury level of minor or greater on eligible unit types in a calendar quarter, reported as injury falls per 100 days.'' [176] After careful review, we have determined that these measures are not appropriate to meet the IMPACT Act domain of incidence of major falls. Specifically:

- NQF #0202 includes minor injuries in the numerator definition. Including all falls in an outcome measure could result in providers limiting activity for individuals at higher risk for falls.
- NQF #0537 is a process-based measure of HHAs' efforts to assess the risk for any fall, but not actual falls.
- Neither measure is standardized across PAC settings.

We are unaware of any other cross-setting quality measures for falls with major injury that have been endorsed or adopted by another consensus organization for the HH setting. Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, An Application of the Measure Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), for the HH QRP beginning with the CY 2020 HH QRP. We plan to submit the proposed measure to the NQF for endorsement consideration as soon as it is feasible.

d. Data Collection

For purposes of assessment data collection, we propose to add two new falls-related items to the OASIS. The proposed falls with major injury item used to calculate the proposed quality measure does not duplicate existing items currently collected in the OASIS. We propose to add two standardized items to the OASIS for collection at End of Care (EOC), which comprises the Discharge from Agency, Death at Home, and Transfer to an Inpatient Facility time points: J1800 and J1900. The first item (J1800) is a gateway item that asks whether the patient has experienced any falls since admission/resumption of care (prior assessment). If the answer to J1800 is yes, the next item (J1900) asks for the number of falls with: (a) No injury, (b) injury (except major), and (c) major injury. The measure is calculated using data reported for J1900C (number of falls with major injury). This measure would be calculated at the time of discharge (see Section V.F.3 of this proposed rule). For technical information about this proposed measure, including information pertaining to measure calculation and the standardized patient assessment data element used to calculate this measure, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

We are proposing that data for the proposed quality measure would be collected through the OASIS, which HHAs currently submit through the QIES ASAP system. We refer readers to section V.I.4 of this proposed rule for more information on the proposed data collection and submission timeline for this proposed quality measure.

We are inviting public comments on our proposal to adopt an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for the CY 2020 HH QRP.

G. HH QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We are inviting public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 48 for use in future years in the HH QRP.

TABLE 48—HH QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act domain	Functional status, cognitive function, and changes in function and cognitive function
Measures	A. Application of NQF #2633—Change in Self-Care Score for Medical Rehabilitation Patients. B. Application of NQF #2634—Change in Mobility Score for Medical Rehabilitation Patients. C. Application of NQF #2635—Discharge Self-Care Score for Medical Rehabilitation Patients. D. Application of NQF #2636—Discharge Mobility Score for Medical Rehabilitation Patients.

[176] American Nurses Association (2014, April 9). Falls with injury. Retrieved from *http://www.qualityforum.org/QPS/0202.*

We are considering four measures that would assess a change in functional outcomes such as self-care and mobility across a HH episode. These measures would be standardized to measures finalized in other PAC quality reporting programs, such as the IRF QRP. We invite feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

Based on input from stakeholders, we have identified additional concept areas for potential future measure development for the HH QRP. These include claims-based within stay potentially preventable hospitalization measures. The potentially preventable within-stay hospitalization measures would look at the percentage of HH episodes in which patients were admitted to an acute care hospital or seen in an emergency department for a potentially preventable condition during an HH episode. We invite feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

In alignment with the requirements of the IMPACT Act to develop quality measures and standardize data for comparative purposes, we believe that evaluating outcomes across the post-acute settings using standardized data is an important priority. Therefore, in addition to proposing a process-based measure for the domain of ''Functional status, cognitive function, and changes in function and cognitive function'', included in this year's proposed rule, we also intend to develop outcomes-based quality measures, including functional status and other quality outcome measures to further satisfy this domain.

1. IMPACT Act Implementation Update

As a result of the input and suggestions provided by technical experts at the TEPs held by our measure developer, and through public comment, we are engaging in additional development work for two measures that would satisfy 1899B(c)(1)(E) of the Act, including performing additional testing. We intend to specify these measures under section 1899B(c)(1)(E) of the Act no later than January 1, 2019 and we intend to propose to adopt them for the CY 2021 HH QRP, with data collection beginning on or about January 1, 2020.

H. Proposed Standardized Patient Assessment Data

1. Proposed Standardized Patient Assessment Data Reporting for the CY 2019 HH QRP

Section 1895(b)(3)(B)(v)(IV)(bb) of the Act requires that for calendar years beginning on or after January 1, 2019, HHAs submit to the Secretary standardized patient assessment data required under section 1899B(b)(1) of the Act.

As we describe in more detail above, we are proposing that the current pressure ulcer measure, Application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), be replaced with the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP. The current pressure ulcer measure will remain in the HH QRP until that time. Accordingly, for the requirement that HHAs report standardized patient assessment data for the CY 2019 HH QRP, we are proposing that the data elements used to calculate that measure meet the definition of standardized patient assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(b)(v)(IV)(aa) of the Act for the beginning of the HH episode (for example, HH start of care/resumption of care), as well as the end of the HH episode (discharges) occurring during the first two quarters of CY 2018 would also satisfy the requirement to report standardized patient assessment data beginning with the CY 2019 HH QRP.

The collection of assessment data pertaining to skin integrity, specifically pressure related wounds, is important for multiple reasons. Clinical decision making, care planning, and quality improvement all depend on reliable assessment data collection. Pressure related wounds represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful, and are often avoidable.[177] [178] [179] [180] [181] [182] Pressure related wounds are considered healthcare acquired conditions.

As we note above, the data elements needed to calculate the current pressure ulcer measure are already included on the OASIS data set and reported by HHAs, and exhibit validity and reliability for use across PAC providers. Item reliability for these data elements was also tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.[183] The RAND pilot test of the MDS 3.0 data elements showed good reliability and are applicable to the OASIS because the data elements tested are the same as those used in the OASIS Data Set. Across the pressure ulcer data elements, the average gold-standard nurse to gold-standard nurse kappa statistic was 0.905. The average gold-standard nurse to facility-nurse kappa statistic was 0.937. Data elements used to risk adjust this quality measure were also tested under this same pilot test, and the gold-standard to gold-standard kappa statistic, or percent agreement (where kappa statistic not available), ranged from 0.91 to 0.99 for these data elements. These kappa scores indicate ''almost perfect'' agreement using the Landis and Koch standard for strength of agreement.[184]

The data elements used to calculate the current pressure ulcer measure received public comment on several occasions, including when that measure was proposed in the CY 2016 HH PPS (80 FR 68623). Further, they were discussed in the past by TEPs held by our measure development contractor on June 13 and November 15, 2013, and recently by a TEP on July 18, 2016. TEP members supported the measure and its cross-setting use in PAC. The report, Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (HHAs), Long-Term Care Hospitals

[177] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' *Nurs N Z* 19(10): 20–24.

[178] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' *Rev Assoc Med Bras* 57(3): 327–331.

[179] Thomas, J.M., et al. (2013). ''Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.'' *J Am Geriatr Soc* 61(6): 902–911.

[180] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' *Clin Geriatr Med* 27(2): 241–258.

[181] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135 (8 Part 2), 744–51.

[182] Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging,* 33(3):230–235.

[183] Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0.* Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from *http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.*

[184] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. *Biometrics* 33(1), 159–174.

(LTCHs), and Home Health Agencies (HHAs), is available at and *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.*

We are inviting public comment on this proposal.

2. Proposed Standardized Patient Assessment Data Reporting Beginning With the CY 2020 HH QRP

We describe below our proposals for the reporting of standardized patient assessment data by HHAs beginning with the CY 2020 HH QRP. LTCHs, IRFs, and SNFs are also required to report standardized patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response options (which incorporate an identical set of definitions and standards). HHAs would be required to report these data at admission (SOC/ROC) and discharge beginning on January 1, 2019, with the exception of three data elements (Brief Interview of Mental Status (BIMS), Hearing, and Vision) that will be required at SOC/ROC only, as described below. The BIMS, Hearing and Vision data elements would be assessed at SOC/ROC only due to the relatively stable nature of the types of cognitive function, hearing impairment, and vision impairment, making it unlikely that these assessments would change between the start and end of the HHA episode of care. Assessment of the BIMS, Hearing, and Vision data elements at EOC would introduce additional burden without improving the quality or usefulness of the data, and is deemed unnecessary. Following the initial reporting year (which would be based on 6 months of data) for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on a full calendar year of such data reporting.

In selecting the data elements described below, we carefully weighed the balance of burden in assessment-based data collection and aimed to minimize additional burden through the utilization of existing data in the assessment instruments. We also note that the patient and resident assessment instruments are considered part of the medical record and sought the inclusion of data elements relevant to patient care.

We also took into consideration the following factors for each data element: overall clinical relevance; ability to support clinical decisions, care planning, and interoperable exchange to facilitate care coordination during transitions in care; and the ability to capture medical complexity and risk factors that can inform both payment and quality. In addition, the data elements had to have strong scientific reliability and validity; be meaningful enough to inform longitudinal analysis by providers; had to have received general consensus agreement for its usability; and had to have the ability to collect such data once but support multiple uses. Further, to inform the final set of data elements for proposal, we took into account technical and clinical subject matter expert review, public comment, and consensus input in which such principles were applied.

3. Proposed Standardized Patient Assessment Data by Category

a. Functional Status Data

We are proposing that the data elements that would be reported by HHAs to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), as described in section V.F.2 would also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act. Details on the data used to calculate this measure is discussed in section V.F.2.

To further satisfy the requirements under section 1899B(b)(1)(B)(i) of the Act and specifically our efforts to achieve standardized patient assessment data pertaining to functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider, we are also proposing to adopt the functional status data elements that specifically address mobility and self-care as provided in the Act. These data elements are also used to calculate the function outcome measures implemented and/or proposed for implementation in three other post-acute quality reporting programs to which the IMPACT Act applies (Application of NQF #2633—Change in Self-Care Score for Medical Rehabilitation Patients; Application of NQF #2634—Change in Mobility Score for Medical Rehabilitation Patients; Application of NQF #2635—Discharge Self-Care Score for Medical Rehabilitation Patients; and Application of NQF #2636—Discharge Mobility Score for Medical Rehabilitation Patients). To achieve standardization, we have implemented such data elements, or sub-sets of the items, into the other post-acute care patient/resident assessment instruments and we are proposing that they also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of such data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act. These data elements currently are collected in the Section GG: Functional Abilities and Goals located in current versions of the MDS and the IRF–PAI assessment instruments.

As previously described, these patient assessment data that assess for functional status are from the CARE Item Set. They were specifically developed for cross-setting application and are the result of consensus building and public input. Further, we received public comment and input. Their reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. We refer the reader to section V.F.2 for a full description of the CARE Item Set and description of the testing methodology and results that are available in several reports. For more information about this quality measure and the data elements used to calculate it, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747), the FY 2016 IRF PPS final rule (80 FR 47100 through 47111), and the FY 2016 SNF PPS final rule (80 FR 46444 through 46453).

Therefore, we are proposing to adopt the functional status data elements that as for the CY 2020 HH QRP, HHAs would be required to report these data at SOC/ROC or discharge starting on January 1, 2019. This aligns with the required reporting timeframe for the CY 2020 HH QRP. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We seek comment on this proposal.

b. Cognitive Function and Mental Status Data

Cognitive function and mental status in PAC patient and resident populations can be affected by a number of underlying conditions, including dementia, stroke, traumatic brain injury, side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression.[185] The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,[186] and to improve quality of care. Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[187] [188] [189] and promising treatments for severe traumatic brain injury are currently being tested.[190] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[191] [192] [193] [194] and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[195]

Accurate assessment of cognitive function and mental status of patients and residents in PAC would be expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of health care resources. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying changes in cognitive function and mental status (for example, delirium), anticipating the patient or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. Standardized assessment data elements will enable or support clinical decision-making, early clinical intervention, as well as person-centered, high quality care through: Facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing cognitive impairment and mental status are needed to initiate a care plan that can best manage a patient or resident's prognosis and reduce the possibility of adverse events.

i. Brief Interview for Mental Status (BIMS)

We are proposing that the data elements that comprise the Brief Interview for Mental Status meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of seven BIMS questions that result in a cognitive function score. For more information on the BIMS, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

The BIMS is a performance-based cognitive assessment that assesses repetition, recall with and without prompting, and temporal orientation. It was developed to be a brief screener to assess cognition, with a focus on learning and memory. Dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life, increased health care costs, and mortality.[196] This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than for those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC providers.[197]

The BIMS data elements are currently in use in two of the PAC assessments: The MDS 3.0 in SNFs and the IRF–PAI in IRFs. The BIMS was tested in the PAC PRD where it was found to have substantial to almost perfect agreement for inter-rater reliability (kappa range of 0.71 to 0.91) when tested in all four PAC settings.[198] Clinical and subject matter expert advisors working with our data element contractor agreed that the BIMS is feasible for use by PAC providers. Additionally, discussions during a TEP convened on April 6 and 7, 2016, demonstrated support for the BIMS. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at *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.*

To solicit additional feedback on the BIMS, we requested public comment from August 12 to September 12, 2016. Many commenters expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. These comments noted that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning

[185] National Institute on Aging. (2014). Assessing Cognitive Impairment in Older Patients. A Quick Guide for Primary Care Physicians. Retrieved from *https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients.*

[186] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4). Research Triangle Park, NC: RTI International.

[187] Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics,* 35, 208–11.

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[189] Bherer L., Erickson K.I., Liu-Ambrose T. (2013). A Review of the Effects of Physical Activity and Exercise on Cognitive and Brain Functions in Older Adults. Journal of Aging Research, 657508.

[190] Giacino J.T., Whyte J., Bagiella E., et al. (2012). Placebo-controlled trial of amantadine for severe traumatic brain injury. New England Journal of Medicine, 366(9), 819–826.

[191] Alexopoulos G.S., Katz I.R., Reynolds C.F. 3rd, Carpenter D., Docherty J.P., Ross R.W. (2001). Pharmacotherapy of depression in older patients: a summary of the expert consensus guidelines. *Journal of Psychiatric Practice,* 7(6), 361–376.

[192] Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. Biological Psychiatry, 52(3), 293–303.

[193] Hollon S.D., Jarrett R.B., Nierenberg A.A., Thase M.E., Trivedi M., Rush A.J. (2005). Psychotherapy and medication in the treatment of adult and geriatric depression: which monotherapy or combined treatment? *Journal of Clinical Psychiatry,* 66(4), 455–468.

[194] Wagenaar D., Colenda C.C., Kreft M., Sawade J., Gardiner J., Poverejan E. (2003). Treating depression in nursing homes: practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465–469.

[195] Crespy S.D., Van Haitsma K., Kleban M., Hann C.J. Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative Quality Improvement Program. J Healthc Qual. 2016. Vol. 38, No. 6, pp. e76–e88.

[196] Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). ''Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study.'' Am J of Public Health 88(10): 1452–1456.

[197] RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM. Research Triangle Park, NC. 2016.

[198] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

process, and be useful during care transitions and when coordinating across providers. A full report of the comments is available at *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.*

Therefore, we are proposing to adopt the BIMS for use in the HH QRP. We are proposing to add the data elements that comprise the BIMS to the OASIS, and that HHAs would be required to report these data at SOC/ROC between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP. The BIMS data elements would be assessed at SOC/ROC only due to the relatively stable nature of the types of cognitive function assessed by the BIMS, making it unlikely that a patient's score on this assessment would change between the start and end of care. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe it is unnecessary.

We are inviting public comment on these proposals.

ii. Confusion Assessment Method (CAM)

We are proposing that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The CAM is a six-question instrument that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. For more information on the CAM, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemakings,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

The CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests whether the patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, as it is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults with dementia.[199] Assessing for signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is currently in use in two of the PAC assessments: The MDS 3.0 in SNFs and the LCDS in LTCHs. The CAM was tested in the PAC PRD where it was found to have substantial agreement for inter-rater reliability for the ''Inattention and Disorganized Thinking'' questions (kappa range of 0.70 to 0.73); and moderate agreement for the ''Altered Level of Consciousness'' question (kappa of 0.58).[200]

Clinical and subject matter expert advisors working with our data element contractor agreed that the CAM is feasible for use by PAC providers, that it assesses key aspects of cognition, and that this information about patient or resident cognition would be clinically useful both within and across PAC provider types. The CAM was also supported by a TEP that discussed and rated candidate data elements during a meeting on April 6 and 7, 2016. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at *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.* We requested public comment on the CAM from August 12 to September 12, 2016. Many commenters expressed support for use of the CAM, noting that it would provide important information for care planning and care coordination, and therefore, contribute to quality improvement. The commenters noted it is particularly helpful in distinguishing delirium and reversible confusion from other types of cognitive impairment. A full report of the comments is available at *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.*

Therefore, we are proposing to add the CAM data elements to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

iii. Behavioral Signs and Symptoms

We are proposing that the Behavioral Signs and Symptoms data elements meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of three Behavioral Signs and Symptoms questions and result in three scores that categorize patients as having or not having certain types of behavioral signs and symptoms. For more information on the Behavioral Signs and Symptoms data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

The questions included in the Behavioral Signs and Symptoms group assess whether the patient or resident has exhibited any behavioral symptoms that may indicate cognitive impairment or other mental health issues during the assessment period, including physical, verbal, and other disruptive or dangerous behavioral symptoms, but excluding patient wandering. Such behaviors can indicate unrecognized needs and care preferences and are associated most commonly with dementia and other cognitive impairment, and less commonly with adverse drug events, mood disorders, and other conditions.[201] Assessing behavioral disturbances can lead to early intervention, patient- and resident-centered care planning, clinical decision support, and improved staff and patient or resident safety. Assessment and documentation of these behaviors can help inform care planning and patient transitions, and provide important information about resource use.

Data elements that capture behavioral symptoms are currently included in two

[199] Fick, D.M., Steis, M.R., Waller, J.L., & Inouye, S.K. (2013). ''Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults.'' J of Hospital Med 8(9): 500–505.

[200] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

[201] Desai A, Grossbert G. Recognition and management of behavioral disturbances in dementia. The Primary Care Companion to the Journal of Clinical Psychiatry. 2001; 3(3):93–109.

of the PAC assessments: The MDS 3.0 in SNFs and the OASIS–C2 in HHAs. In the MDS, each question includes four response options ranging from ''behavior not exhibited'' (0) to behavior ''occurred daily'' (3). The OASIS–C2 includes some similar data elements which record the frequency of disruptive behaviors on a 6-point scale ranging from ''never'' (0) to ''at least daily'' (5). Data elements that mirror those used in the MDS and serve the same assessment purpose were tested in post-acute providers in the PAC PRD and found to be clinically relevant, meaningful for care planning, and feasible for use in each of the four PAC settings.[202]

The proposed data elements were supported by comments from the Standardized Patient Assessment Data TEP held by our data element contractor. The TEP identified patient and resident behaviors as an important consideration for resource intensity and care planning, and affirmed the importance of the standardized assessment of patient behaviors through data elements such as those in use in the MDS. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at *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*.

Because the PAC PRD version of the Behavioral Signs and Symptoms data elements were previously tested across PAC providers, we solicited additional feedback on this version of the data elements by including these data elements in a call for public comment that was open from August 12 to September 12, 2016. Consistent with the TEP discussion on the importance of patient and resident behaviors, many commenters expressed support for use of the Behavioral Signs and Symptoms data elements, noting that they would provide useful information about patient and resident behavior at both admission and discharge, and contribute to care planning regarding the most appropriate treatment and resource use for the patient or resident. Public comment also supported the use of a highly similar MDS version of the data elements to provide continuity with existing assessment processes in SNFs. A full report of the comments is available at *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*.

Therefore, we are proposing the MDS version of the Behavioral Signs and Symptoms data elements because they focus more closely on behavioral symptoms than the OASIS data elements, and include more detailed response categories than those used in the PAC PRD version, capturing more information about the frequency of behaviors. We are proposing that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

iv. Patient Health Questionnaire-2 (PHQ–2)

We are proposing that the PHQ–2 data elements meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of the PHQ–2 two-item questionnaire that assesses the cardinal criteria for depression: depressed mood and anhedonia (inability to feel pleasure). For more information on the PHQ–2, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

Depression is a common mental health condition that is often missed and under-recognized. Assessing depression helps PAC providers better understand the needs of their patients and residents by: Prompting further evaluation (that is, to establish a diagnosis of depression); elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge. A PHQ–2 score beyond a predetermined threshold signals the need for additional clinical assessment to determine a depression diagnosis.

The proposed data elements that comprise the PHQ–2 are currently used in the OASIS–C2 for HHAs and the MDS 3.0 for SNFs (as part of the PHQ–9). The PHQ–2 data elements were tested in the PAC PRD, where they were found to have almost perfect agreement for inter-rater reliability (kappa range of 0.84 to 0.91) when tested by all four PAC providers.[203]

Clinical and subject matter expert advisors working with our data element contractor agreed that the PHQ–2 is feasible for use in PAC, that it assesses key aspects of mental status, and that this information about patient or resident mood would be clinically useful both within and across PAC settings. We note that both the PHQ–9 and the PHQ–2 were supported by TEP members who discussed and rated candidate data elements during a meeting on April 6 and 7, 2016. They particularly noted that the brevity of the PHQ–2 made it feasible with low burden for both assessors and PAC patients or residents. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at *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*.

To solicit additional feedback on the PHQ–2, we requested public comment from August 12 to September 12, 2016. Many commenters provided feedback on using the PHQ–2 for the assessment of mood. Overall, commenters believed that collecting these data elements across PAC settings was appropriate, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ–2 as a gateway to the longer PHQ–9 and would maintain the reduced burden on most patients and residents, as well as test administrators, which is a benefit of the PHQ–2, while ensuring that the PHQ–9, which exhibits higher specificity,[204] would be administered for patients and residents who showed signs and symptoms of depression on the PHQ–2. Specific

[202] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

[203] Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

[204] Arroll B, Goodyear-Smith F, Crengle S, Gunn J, Kerse N, Fishman T, et al. Validation of PHQ–2 and PHQ–9 to screen for major depression in the primary care population. *Annals of family medicine.* 2010;8(4):348–53. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

comments are described in a full report available at *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*.

Therefore, we are proposing to adopt the PHQ–2 data elements for use in the HH QRP as standardized patient assessment data. As noted above in this section, the PHQ–2 is already included on the OASIS. HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

c. Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC setting to another, an acute care hospital, or discharge. Accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers are expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of healthcare resources.

For example, standardized assessment of special services, treatments, and interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central intravenous access), and identifying life-sustaining treatments that must be continued, such as mechanical ventilation, dialysis, suctioning, and chemotherapy, at the time of discharge or transfer. Standardized assessment of these data elements will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through, for example, facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing special services, treatments, and interventions are needed to initiate a care plan that can improve, maintain, or best manage a patient or resident's condition and reduce the possibility of adverse events.

We are proposing 15 special services, treatments, and interventions as presented below in this section grouped by cancer treatments, respiratory treatments, other treatments, and nutritional approaches. A TEP convened by our data element contractor provided input on the 15 data elements for Special Services, Treatments, and Interventions. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform with common workflow for PAC providers. A full report of the TEP discussion is available at *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*.

i. Cancer Treatment: Chemotherapy (IV, Oral, Other)

We are proposing that the Chemotherapy (IV, Oral, Other) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Chemotherapy data element and three sub-elements: IV Chemotherapy, Oral Chemotherapy, and Other. For more information on the Chemotherapy (IV, Oral, Other) data elements, we refer readers to the document titled, *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

Chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is typically used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy can have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can have as many side effects as IV chemotherapy, but can also be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling and transporting chemotherapy drugs. IV chemotherapy may be given by peripheral IV, but is more commonly given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use.

The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) require significant resources.

The Chemotherapy (IV, Oral, Other) data elements consist of a principal data element and three sub-elements: IV chemotherapy, which is generally resource-intensive; oral chemotherapy, which is less invasive and generally less intensive with regard to administration protocols; and a third category provided to enable the capture of other less common chemotherapeutic approaches. This third category is potentially associated with higher risks and is more resource intensive due to delivery by other routes (for example, intraventricular or intrathecal).

The principal Chemotherapy data element is currently in use in the MDS 3.0. One proposed sub-element, IV Chemotherapy, was tested in the PAC PRD and found feasible for use in each of the four PAC settings. We solicited public comment on IV Chemotherapy from August 12 to September 12, 2016. Several commenters provided support for the data element and suggested it be included as standardized patient assessment data. Commenters stated that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element.

Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A full report of the comments is available at *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*.

Therefore, we are proposing that the Chemotherapy (IV, Oral, Other) data elements with a principal data element and three sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Chemotherapy (IV, Oral, Other) data elements to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

ii. Cancer Treatment: Radiation

We are proposing that the Radiation data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Radiation data element. For more information on the Radiation data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

Radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource utilization, as PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The Radiation data element is currently in use in the MDS 3.0. This data element was not tested in the PAC PRD. However, public comment and other expert input on the Radiation data element supported its importance and clinical usefulness for patients in PAC settings, due to the side effects and consequences of radiation treatment on patients that need to be considered in care planning and care transitions. To solicit additional feedback on the Radiation data element we are proposing, we requested public comment from August 12 to September 12, 2016. Several commenters provided support for the data element, noting the relevance of this data element in facilitating care coordination and supporting care transitions, the feasibility of the item, and the potential for quality improvement. A full report of the comments is available at *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*.

The proposed data element was presented to and supported by the TEP held by our data element contractor on January 5 and 6, 2017, which opined that Radiation provided important corollary information about cancer treatment in addition to Chemotherapy (IV, Oral, Other), and that, because capturing this information is a customary part of clinical practice, the proposed data element would be feasible, reliable, and easily incorporated into existing workflow.

Therefore, we are proposing that the Radiation data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Radiation data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

iii. Respiratory Treatment: Oxygen Therapy (Continuous, Intermittent)

We are proposing that the Oxygen Therapy (Continuous, Intermittent) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Oxygen data element and two sub-elements, ''Continuous'' (whether the oxygen was delivered continuously, typically defined as >=14 hours per day), or ''Intermittent.'' For more information on the Oxygen Therapy (Continuous, Intermittent) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from room air. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as the source of oxygen, delivery systems (for example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). These data elements capture patient or resident use of two types of oxygen therapy (continuous and intermittent) which are reflective of intensity of care needs, including the level of monitoring and direct patient care required. Assessing the receipt of this service is important for care planning and resource use for PAC providers.

The proposed data elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS 3.0 (''Oxygen Therapy'') and OASIS–C2 (''Oxygen (intermittent or continuous)''), and a data element tested in the PAC PRD that focused on intensive oxygen therapy (''High O2 Concentration Delivery System with FiO2 > 40%'').

As a result of input from expert advisors, we solicited public comment on the single data element, Oxygen

(inclusive of intermittent and continuous oxygen use), from August 12 to September 12, 2016. Several commenters supported the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance in facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A full report of the comments is available at *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.*

As a result of public comment and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we expanded the single data element to include two sub-elements, intermittent and continuous.

Therefore, we are proposing that the Oxygen Therapy (Continuous, Intermittent) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to expand the existing Oxygen (intermittent or continuous)-data element in the OASIS to include sub-elements for Continuous and Intermittent, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

iv. Respiratory Treatment: Suctioning (Scheduled, As needed)

We are proposing that the Suctioning (Scheduled, As needed) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Suctioning data element, and two sub-elements, ''Scheduled'' and ''As needed.'' These sub-elements capture two types of suctioning. ''Scheduled'' indicates suctioning based on a specific frequency, such as every hour. ''As needed'' means suctioning only when indicated. For more information on the Suctioning (Scheduled, As needed) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Suctioning is an intervention used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' care plans, both to prevent the accumulation of secretions that can lead to aspiration pneumonia (a common condition in patients with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which can often lead to desaturation and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions; or can be done as needed, such as when secretions become so copious that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource-intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which, if left, can inhibit successful oxygenation of the individual and/or lead to infection. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death, or complications associated with hypoxia.

The proposed data elements are based on an item currently in use in the MDS 3.0 (''Suctioning'' without the two sub-elements), and data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients with tracheostomies (''Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every ____ hours]'').

Clinical and subject matter expert advisors working with our data element contractor agreed that the proposed Suctioning (Scheduled, As needed) data elements are feasible for use in PAC, and that they indicate important treatment that would be clinically useful to capture both within and across PAC providers. We solicited public comment on the suctioning data element currently included in the MDS 3.0 from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. We also received comments suggesting that we examine the frequency of suctioning to better understand the use of staff time, the impact on a patient or resident's capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (scheduled and as needed) to the suctioning element. The proposed data elements, Suctioning (Scheduled, As needed) includes both the principal suctioning data element that is included on the MDS 3.0 and two sub-elements, ''scheduled'' and ''as needed.'' A full report of the comments is available at *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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at *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.*

Therefore, we are proposing that the Suctioning (Scheduled, As needed) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Suctioning (Scheduled, As needed) data elements to the OASIS, and that HHAs would be

required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019, and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

v. Respiratory Treatment: Tracheostomy Care

We are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Tracheostomy Care data element. For more information on the Tracheostomy Care data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

A tracheostomy provides an airway to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy tube is clear of secretions which can inhibit successful oxygenation of the individual, or accumulate and cause infection. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, whether permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy tube becomes occluded or dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient), in general the presence of such a device is associated with increased patient risk and resource use. Tracheostomy care should include close monitoring to prevent occlusion or decannulation, skin infection or necrosis, and other complications to ensure adequate air flow and oxygenation. In addition to suctioning, skin care, dressing changes, and replacement or cleaning of the tracheostomy cannula (tube), is also a critical part of the tracheostomy care plan. Regular cleaning and suctioning is important in preventing infections such as pneumonia, preventing skin breakdown, and preventing any occlusions leading to inadequate oxygenation.

The proposed data element is currently in use in the MDS 3.0 (''Tracheostomy care''). Data elements (''Trach Tube with Suctioning'') that were tested in the PAC PRD included an equivalent principal data element on the presence of a tracheostomy. This data element was found feasible for use in each of the four PAC settings as the data collection aligned with usual work flow.

Clinical and subject matter expert advisors working with our data element contractor agreed that the Tracheostomy Care data element is feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC provider types.

We solicited public comment on this data element from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A full report of the comments is available at *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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at *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.*

Therefore, we are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Tracheostomy Care data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

vi. Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

We are proposing that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Non-invasive Mechanical Ventilator data element and two sub-elements, BiPAP and CPAP. For more information on the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (Bilevel Positive Airway Pressure, referred to as BiPAP) or through a mask continuously (Continuous PAP, referred to as CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify a more complex or underlying medical condition. Particularly when used in the context of acute illness or progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings. Additionally the patient or resident may require more nursing assessment, education, and interventions, such as pulse oximetry or venipuncture for blood gas evaluation.

Data elements that assess BiPAP and CPAP are currently included on the OASIS–C2 for HHAs (''Continuous/Bi-level positive airway pressure''), LCDS for the LTCH setting (''Non-invasive Ventilator (BIPAP, CPAP)''), and the MDS 3.0 for the SNF setting (''BiPAP/

CPAP''). A data element that focused on CPAP was tested across the four PAC providers in the PAC PRD study and found to be feasible for standardization. All of these data elements assess BiPAP or CPAP with a single check box, not separately.

Clinical and subject matter expert advisors working with our data element contractor agreed that the standardized assessment of Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements would be feasible for use in PAC, and assess an important treatment that would be clinically useful both within and across PAC provider types.

To solicit additional feedback on the form of the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements best suited for standardization, we requested public comment on a single data element, BiPAP/CPAP, equivalent (but for labeling) to what is currently in use on the MDS, OASIS, and LCDS, from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting the feasibility of these items in PAC, and the relevance of these data elements for facilitating care coordination and supporting care transitions. In addition, there was support in the public comment responses for separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A full report of the comments is available at *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*.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at *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*.

Therefore, we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing that the existing ''Continuous/Bi-level positive airway pressure'' data element in the OASIS be expanded and relabeled as the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

vii. Respiratory Treatment: Invasive Mechanical Ventilator

We are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of a single Invasive Mechanical Ventilator data element. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

Invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region (intubation), or through a surgical opening directly into the trachea (tracheostomy). Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical or surgical condition. Of note, invasive mechanical ventilation is associated with high daily and aggregate costs.[205]

Data elements that capture invasive mechanical ventilation, but vary in their level of specificity, are currently in use in the MDS 3.0 (''Ventilator or respirator''), LCDS (''Invasive Mechanical Ventilator: weaning'' and ''Invasive Mechanical Ventilator: non-weaning''), and related data elements that assess invasive ventilator use and weaning status were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning'') and found feasible for use in each of the four PAC settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing Invasive Mechanical Ventilator use is feasible in PAC, and would be clinically useful both within and across PAC providers.

To solicit additional feedback on the form of a data element on this topic that would be appropriate for standardization, data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning'') were included in a call for public comment that was open from August 12 to September 12, 2016 because they were being considered for standardization. Several commenters wrote in support of these data elements, highlighting the importance of this information in supporting care coordination and care transitions. Some commenters expressed concern about the appropriateness for standardization, given the prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how weaning status in particular relates to quality of care. These comments guided the decision to propose a single data element focused on current use of invasive mechanical ventilation only, and does not attempt to capture weaning status. A full report of the comments is available at *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*.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would

[205] Wunsch, H., Linde-Zwirble, W.T., Angus, D. C., Hartman, M.E., Milbrandt, E.B., & Kahn, J.M. (2010). ''The epidemiology of mechanical ventilation use in the United States.'' Critical Care Med 38(10): 1947–1953.

provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at *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*.

Therefore, we are proposing that the Invasive Mechanical Ventilator data element that assesses the use of an invasive mechanical ventilator, but does not assess weaning status, meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Invasive Mechanical Ventilator data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

viii. Other Treatment: Intravenous (IV) Medications (Antibiotics, Anticoagulation, Other)

We are proposing that the IV Medications (Antibiotics, Anticoagulation, Other) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal IV Medications data element and three sub-elements, Antibiotics, Anticoagulation, and Other. For more information on the IV Medications (Antibiotics, Anticoagulation, Other) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

IV medications are solutions of a specific medication (for example, antibiotics, anticoagulants) administered directly into the venous circulation via a port or intravenous tubing. IV medications are administered via intravenous push (bolus), single, intermittent, or continuous infusion through a catheter placed into the vein (for example, through central, midline, or peripheral ports). Further, IV medications are more resource intensive to administer than oral medications, and signify a higher patient complexity (and often higher severity of illness).

The clinical indications for each of the sub-elements of the IV Medication data element (Antibiotics, Anticoagulants, and Other) are very different. IV antibiotics are used for severe infections when: (1) The bioavailability of the oral form of the medication would be inadequate to kill the pathogen; (2) an oral form of the medication does not exist; or (3) the patient is unable to take the medication by mouth. IV anticoagulants refer to anti-clotting medications (that is, ''blood thinners''), often used for the prevention and treatment of deep vein thrombosis and other thromboembolic complications. IV anticoagulants are commonly used in patients with limited mobility (either chronically or acutely, in the post-operative setting), who are at risk of deep vein thrombosis, or patients with certain cardiac arrhythmias such as atrial fibrillation. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess and monitor each separately in PAC. Knowing whether or not patients are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The principal IV Medication data element is currently in use on the MDS 3.0 and there is a related data element in OASIS–C2 that collects information on Intravenous and Infusion Therapies. One sub-element of the proposed data elements, IV Anti-coagulants, and two other data elements related to IV therapy (IV Vasoactive Medications and IV Chemotherapy), were tested in the PAC PRD and found feasible for use in that the data collection aligned with usual work flow in each of the four PAC settings, demonstrating the feasibility of collecting IV medication information, including type of IV medication, through similar data elements in these settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that standardized collection of information on medications, including IV medications, would be feasible in PAC, and assess an important treatment that would be clinically useful both within and across PAC provider types.

We solicited public comment on a related data element, Vasoactive Medications, from August 12 to September 12, 2016. While commenters supported this data element with one noting the importance of this data element in supporting care transitions, others criticized the need for collecting specifically on Vasoactive Medications, giving feedback that the data element was too narrowly focused. Additionally, comments received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use.

Overall, public comment indicated the importance of including the additional check box data elements to distinguish particular classes of medications. A full report of the comments is available at *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*.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at *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*.

Therefore, we are proposing that the IV Medications (Antibiotics, Anticoagulation, Other) data elements with a principal data element and three sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the IV Medications (Antibiotics, Anticoagulation, Other) data elements to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12

months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

ix. Other Treatment: Transfusions

We are proposing that the Transfusions data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Transfusions data element. For more information on the Transfusions data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Transfusion refers to introducing blood, blood products, or other fluid into the circulatory system of a person. Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required before, during, and after the infusion to prevent errors and adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

The proposed data element was selected from three existing assessment items on transfusions and related services, currently in use in the MDS 3.0 (''Transfusions'') and OASIS–C2 (''Intravenous or Infusion Therapy''), and a data element tested in the PAC PRD (''Blood Transfusions''), that was found feasible for use in each of the four PAC settings. We chose to propose the MDS version because of its greater level of specificity over the OASIS–C2 data element. This selection was informed by expert advisors and reviewed and supported in the proposed form by the Standardized Patient Assessment Data TEP held by our data element contractor on January 5 and 6, 2017. A full report of the TEP discussion is available at *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.*

Therefore, we are proposing that the Transfusions data element that is currently in use in the MDS meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Transfusions data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

x. Other Treatment: Dialysis (Hemodialysis, Peritoneal Dialysis)

We are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal dialysis. For more information on the Dialysis (Hemodialysis, Peritoneal dialysis) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during, and after treatment. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances, as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to, during and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The principal Dialysis data element is currently included on the MDS 3.0 and the LCDS v3.0 and assesses the overall use of dialysis. The sub-elements for Hemodialysis and Peritoneal dialysis were tested across the four PAC providers in the PAC PRD study, and found to be feasible for standardization. Clinical and subject matter expert advisors working with our data element contractor opined that the standardized assessment of dialysis is feasible in PAC, and that it assesses an important treatment that would be clinically useful both within and across PAC providers. As the result of expert and public feedback, described below, we decided to propose data elements that include both the principal Dialysis data element and the two sub-elements (hemodialysis and peritoneal dialysis).

The Hemodialysis data element, which was tested in the PAC PRD, was included in a call for public comment that was open from August 12 to September 12, 2016. Commenters supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. Several commenters supported the Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. Several commenters also stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, hemodialysis and peritoneal dialysis; these are the same two data elements that were tested in the PAC PRD. This expanded version, Dialysis (Hemodialysis, Peritoneal dialysis), are the data elements being proposed. A full report of the comments

is available at *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*.

We note that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements were also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion is available at *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*.

Therefore, we are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Dialysis (Hemodialysis, Peritoneal dialysis) data elements to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xi. Other Treatment: Intravenous (IV) Access (Peripheral IV, Midline, Central Line, Other)

We are proposing that the IV Access (Peripheral IV, Midline, Central line, Other) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal IV Access data element and four sub-elements, Peripheral IV, Midline, Central line, and Other. For more information on the IV Access (Peripheral IV, Midline, Central line, Other) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Patients or residents with central lines, including those peripherally inserted or who have subcutaneous central line ''port'' access, always require vigilant nursing care to ensure patency of the lines and prevent any potentially life-threatening events such as infection, air embolism, or bleeding from an open lumen. Clinically complex patients and residents are likely to be receiving medications or nutrition intravenously. The sub-elements included in the IV Access data elements distinguish between peripheral access and different types of central access. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life-threatening events such as pulmonary embolism, infection, and bleeding.

The proposed IV Access (Peripheral IV, Midline, Central line, Other) data elements are not currently included on any of the mandated PAC assessment instruments. However, related data elements (for example, IV Medication in MDS 3.0 for SNF, Intravenous or infusion therapy in OASIS–C2 for HHAs) currently assess types of IV infusions or service. Several related data elements that describe types of IV infusions and services (for example, Central Line Management, IV Vasoactive Medications) were tested across the four PAC providers in the PAC PRD study, and found to be feasible for standardization.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing type of IV access would be feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC provider types.

We requested public comment on one of the PAC PRD data elements, Central Line Management, from August 12 to September 12, 2016. A central line is one type of IV access. Commenters supported the assessment of central line management and recommended that the data element be broadened to also include other types of IV access. Several commenters supported the data element, noting feasibility and importance for facilitating care coordination and care transitions. However, a few commenters recommended that the definition of this data element be broadened to include peripherally inserted central catheters (''PICC lines'') and midline IVs. Based on public comment feedback and in consultation with clinical and subject matter experts, we expanded the Central Line Management data element to include more types of IV access (Peripheral IV, Midline, Central line, Other). This expanded version, IV Access (Peripheral IV, Midline, Central line, Other), are the data elements being proposed. A full report of the comments is available at *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*.

We note that the IV Access (Peripheral IV, Midline, Central line, Other) data elements were supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion is available at *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*.

Therefore, we are proposing that the IV access (Peripheral IV, Midline, Central line, Other) data elements with a principal data element and four sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the IV Access (Peripheral IV, Midline, Central line, Other) data elements to the OASIS and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xii. Nutritional Approach: Parenteral/IV Feeding

We are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Parenteral/IV Feeding data element. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed*

Rulemaking, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Parenteral/IV Feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for IV/parenteral feeding indicates a clinical complexity that prevents the patient or resident from meeting his/her nutritional needs enterally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries, and maintenance of a central line. Therefore, assessing a patient or resident's need for parenteral feeding is important for care planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks such as embolism, sepsis, and glucose abnormalities.

The Parenteral/IV Feeding data element is currently in use in the MDS 3.0, and equivalent or related data elements are in use in the LCDS, IRF–PAI, and the OASIS–C2. An equivalent data element was tested in the PAC PRD (''Total Parenteral Nutrition'') and found feasible for use in each of the four PAC settings, demonstrating the feasibility of collecting information about this nutritional service in these settings.

Total Parenteral Nutrition (an item with the same meaning as the proposed data element, but with the label used in the PAC PRD) was included in a call for public comment that was open from August 12 to September 12, 2016. Several commenters supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public comment period, the Total Parenteral Nutrition data element was re-named Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS. A full report of the comments is available at *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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at *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.*

Therefore, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to rename the existing ''Parenteral nutrition (TPN or lipids)'' data element in the OASIS to the Parenteral/IV Feeding data element, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019, and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xiv. Nutritional Approach: Feeding Tube

We are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Feeding Tube data element. For more information on the Feeding Tube data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

The majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding, if unable to eat orally, very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive and are therefore important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a variety of complications.[206] In PAC settings, there are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The Feeding Tube data element is currently included in the MDS 3.0 for SNFs, and in the OASIS–C2 for HHAs, where it is labeled Enteral Nutrition. A related data element is collected in the IRF–PAI for IRFs (Tube/Parenteral Feeding). The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of feeding tubes and related nutritional services and devices, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor opined that the Feeding Tube data element is feasible for use in PAC, and supported its importance and clinical usefulness for patients in PAC settings, due to the increased level of nursing care and patient monitoring required for patients who received enteral nutrition with this device.

We solicited additional feedback on an Enteral Nutrition data element (an item with the same meaning as the proposed data element, but with the label used in the OASIS) in a call for public comment that was open from August 12 to September 12, 2016. Several commenters supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was re-named Feeding Tube, indicating the presence of an assistive device. A full report of the comments is available at *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.*

We note that the Feeding Tube data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/*

[206] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' Am J of Clinical Nutrition 47(2): 352–356.

IMPACT-Act-Downloads-and-Videos.html.

Therefore, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to rename the existing ''Enteral nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)'' data element in the OASIS to the Feeding Tube data element and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019, and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xv. Nutritional Approach: Mechanically Altered Diet

We are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Mechanically Altered Diet data element. For more information on the Mechanically Altered Diet data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

The Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.[207] In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree, which will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients on mechanically altered diets also require additional nursing supports such as individual feeding, or direct observation, to ensure the safe consumption of the food product. Assessing whether a patient or resident requires a mechanically altered diet is therefore important for care planning and resource identification.

The proposed data element for a mechanically altered diet is currently included on the MDS 3.0 for SNFs. A related data element for modified food consistency/supervision is currently included on the IRF–PAI for IRFs. A related data element is included in the OASIS–C2 for HHAs that collects information about independent eating that requires ''a liquid, pureed or ground meat diet.'' The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of various nutritional services across the four PAC settings, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that the proposed Mechanically Altered Diet data element is feasible for use in PAC, and it assesses an important treatment that would be clinically useful both within and across PAC settings. Expert input on the Mechanically Altered Diet data element highlighted its importance and clinical usefulness for patients in PAC settings, due to the increased monitoring and resource use required for patients on special diets. We note that the Mechanically Altered Diet data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion is available at *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.*

Therefore, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Mechanically Altered Diet data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xvi. Nutritional Approach: Therapeutic Diet

We are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Therapeutic Diet data element. For more information on the Therapeutic Diet data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Therapeutic Diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient or resident's diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients in PAC provides insight on the clinical complexity of these patients and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but can signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. They also often require more education and lifestyle modification training. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

The Therapeutic Diet data element is currently in use in the MDS 3.0. The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of various nutritional services across the four PAC settings, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor supported the importance

[207] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' Am J of Clinical Nutrition 47(2): 352–356.

and clinical usefulness of the proposed Therapeutic Diet data element for patients in PAC settings, due to the increased monitoring and resource use required for patients on special diets, and agreed that it is feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC settings. We note that the Therapeutic Diet data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017.

Therefore, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Therapeutic Diet data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

d. Medical Condition and Comorbidity Data

We are proposing that the data elements needed to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and that the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act.

''Medical conditions and co-morbidities'' and the conditions addressed in the standardized data elements used in the calculation and risk adjustment of these measures, that is, the presence of pressure ulcers, diabetes, incontinence, peripheral vascular disease or peripheral arterial disease, mobility, as well as low body mass index (BMI), are all health-related conditions that indicate medical complexity that can be indicative of underlying disease severity and other comorbidities.

Specifically, the data elements used in the measure are important for care planning and provide information pertaining to medical complexity. Pressure ulcers are serious wounds representing poor outcomes, and can result in sepsis and death. Assessing skin condition, care planning for pressure ulcer prevention and healing, and informing providers about their presence in patient transitions of care is imperative a customary and best practice. Venous and arterial disease and diabetes are associated with insufficient low blood flow, which may increase the risk of tissue damage. These diseases commonly are indicators of factors that may place individuals at risk for pressure ulcer development and are therefore important for care planning. Low BMI, which may be an indicator of underlying disease severity, may be associated with loss of fat and muscle, resulting in potential risk for pressure ulcers due to shearing. Bowel incontinence, and the possible maceration to the skin associated, can lead to higher risk for pressure ulcers. In addition, the bacteria associated with bowel incontinence can complicate current wounds and cause local infection. Mobility is an indicator of impairment or reduction in mobility and movement which is a major risk factor for the development of pressure ulcers. Taken separately and together, these data elements are important for care planning, transitions in services and identifying medical complexities.

e. Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients will require more intensive and prolonged treatment. Onset of these conditions can be gradual, so individualized assessment with accurate screening tools and regular follow-up evaluations are essential to determining which patients need hearing- or vision-specific medical attention or assistive devices, and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a patient's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and vision impairment would be expected to lead to appropriate treatment, accommodations, including the provision of auxiliary aids and services during the stay, and ensure that patients continue to have their vision and hearing needs met when they leave the facility.

Accurate individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC would be expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of healthcare resources. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls) identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

i. Hearing

We are proposing that the Hearing data element meets the definition of standardized patient assessment data for impairments under section 1899B(b)(1)(B)(v) of the Act. The proposed data element consists of the single Hearing data element. This data element assesses level of hearing impairment, and consists of one question. For more information on the Hearing data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, and social functioning, and emotional health.[208] [209] Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to increased quality of life.[210] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[211] [212] [213] higher rates of incident cognitive impairment and cognitive decline,[214] and less time in occupational therapy.[215] Accurate assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element was selected from two forms of the Hearing data element based on expert and stakeholder feedback. We considered the two forms of the Hearing data element, one of which is currently in use in the MDS 3.0 (Hearing) and another data element with different wording and fewer response option categories that is currently in use in the OASIS–C2 (Ability to Hear). Ability to Hear was also tested in the PAC PRD and found to have substantial agreement for inter-rater reliability across PAC settings (kappa of 0.78).[216]

Several data elements that assess hearing impairment were presented to the Standardized Patient Assessment Data TEP held by our data element contractor. The TEP did not reach consensus on the ideal number of response categories or phrasing of response options, which are the primary differences between the current MDS (Hearing) and OASIS (Ability to Hear) items. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at *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.*

The PAC PRD form of the data element (Ability to Hear) was included in a call for public comment that was open from August 12 to September 12, 2016. This data element includes three response choices, in contrast to the Hearing data element (in use in the MDS 3.0 and being proposed for standardization), which includes four response choices. Several commenters supported the use of the Ability to Hear data element, although some commenters raised concerns that the three-level response choice was not compatible with the current, four-level response used in the MDS, and favored the use of the MDS version of the Hearing data element. In addition, we received comments stating that standardized assessment related to hearing impairment has the ability to improve quality of care if information on hearing is included in medical records of patients and residents, which would improve care coordination and facilitate the development of patient- and resident-centered treatment plans. Based on comments that the three-level response choice (Ability to Hear) was not congruent with the current, four-level response used in the MDS (Hearing), and support for the use of the MDS version of the Hearing data element received in the public comment, we are proposing the Hearing data element from the MDS. A full report of the comments is available at *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.*

Therefore, we are proposing the Hearing data element currently in use in the MDS. We are proposing to add the Hearing data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP. The Hearing data element would be assessed at SOC/ROC only due to the relatively stable nature of hearing impairment, making it unlikely that this assessment would change between the start and end of care. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe it is unnecessary.

We are inviting public comment on these proposals.

ii. Vision

We are proposing that the Vision data element meets the definition of standardized patient assessment data for impairments under section 1899B(b)(1)(B)(v) of the Act. The proposed data element consists of the single Vision (Ability To See in Adequate Light) data element that consists of one question with five response categories. For more information on the Vision data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Evaluation of an individual's ability to see is important for assessing for risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment are more likely to experience falls and hip fracture, have less mobility, and report depressive symptoms.[217] [218] [219] [220] [221] [222] [223]

[208] Dalton DS, Cruickshanks KJ, Klein BE, Klein R, Wiley TL, Nondahl DM. The impact of hearing loss on quality of life in older adults. *Gerontologist.* 2003;43(5):661–668.

[209] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[210] Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S. Functional use of the Nucleus 22-channel cochlear implant in the elderly. *The Laryngoscope.* 1991;101(3):284–288.

[211] Sprinzl GM, Riechelmann H. Current trends in treating hearing loss in elderly people: a review of the technology and treatment options—a mini-review. *Gerontology.* 2010;56(3):351–358.

[212] Lin FR, Thorpe R, Gordon-Salant S, Ferrucci L. Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 2011;66A(5):582–590.

[213] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[214] Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing Loss and Incident Dementia. *Arch Neurol.* 2011;68(2):214–220.

[215] Cimarolli VR, Jung S. Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc.* 2016;17(10):939–942.

[216] Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

[217] Colon-Emeric CS, Biggs DP, Schenck AP, Lyles KW. Risk factors for hip fracture in skilled nursing facilities: who should be evaluated? *Osteoporos Int.* 2003;14(6):484–489.

[218] Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older

Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. For patients with some types of visual impairment, use of glasses and contact lenses can be effective in restoring vision.[224] Other conditions, including glaucoma[225] and age-related macular degeneration,[226] [227] have responded well to treatment. Accurate assessment of vision impairment is important in the PAC setting for care planning and defining resource use.

The Vision data element that we are proposing for standardization was tested as part of the development of the MDS 3.0 and is currently in use in that assessment. Similar data elements, but with different wording and fewer response option categories, are in use in the OASIS–C2 and were tested in post-acute providers in the PAC PRD and found to be clinically relevant, meaningful for care planning, reliable (kappa of 0.74),[228] and feasible for use in each of the four PAC settings.

Several data elements that assess vision were presented to the TEP held by our data element contractor. The TEP did not reach consensus on the ideal number of response categories or phrasing of response options, which are the primary differences between the current MDS and OASIS items; some members preferring more granular response options (for example, mild impairment and moderate impairment) while others were comfortable with collapsed response options (that is, mild/moderate impairment). The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at *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*.

We solicited public comment from August 12 to September 12, 2016, on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories). The data element in public comment differed from the proposed data element, but the comments supported the assessment of vision in PAC settings and the useful information a vision data element would provide. The commenters stated that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element over the form put forward in public comment, citing the widespread use of this data element. A full report of the comments is available at *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*.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing vision impairment of patients and residents with a standardized data element is feasible in PAC, that it can reliably and accurately identify adults with objective impaired vision, and that this information about impaired vision would be clinically useful to identify needed accommodations and/or treatment both within and across PAC settings.

Therefore, we are proposing the Vision data element from the MDS. We are proposing to add the Vision data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at the start of care between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP. The Vision data element would be assessed at start of care only due to the relatively stable nature of vision impairment, making it unlikely that this assessment would change between the start and end of care. Assessment at the end of care would introduce additional burden without improving the quality or usefulness of the data, and we believe it is unnecessary.

We are inviting public comment on these proposals.

I. Proposals Relating to the Form, Manner, and Timing of Data Submission Under the HH QRP

1. Proposed Start Date for Reporting Standardized Patient Assessment Data by New HHAs

In the CY 2016 HH PPS final rule (80 FR 68624), we adopted timing for new HHAs to begin reporting standardized quality data under the HH QRP. We are proposing in this proposed rule that new HHAs will be required to begin reporting standardized patient assessment data on the same schedule. We are inviting public comment on this proposal.

2. Proposed Mechanism for Reporting Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

Under our current policy, HHAs report data by completing applicable sections of the OASIS, and submitting the OASIS to CMS through the QIES, ASAP system. For more information on HH QRP reporting through the QIES ASAP system, refer to *https://www.qtso.com/index.php*. In addition to the data currently submitted on quality measures as previously finalized and described in Table 49 of this proposed

adults: the Salisbury eye evaluation. *Invest Ophthalmol Vis Sci.* 2007;48(10):4445–4450.

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[223] Tinetti ME, Ginter SF. The nursing home life-space diameter. A measure of extent and frequency of mobility among nursing home residents. *J Am Geriatr Soc.* 1990;38(12):1311–1315.

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[226] Age-Related Eye Disease Study Research G. A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins c and e, beta carotene, and zinc for age-related macular degeneration and vision loss: AREDS report no. 8. *Archives of Ophthalmology.* 2001;119(10):1417–1436.

[227] Takeda AL, Colquitt J, Clegg AJ, Jones J. Pegaptanib and ranibizumab for neovascular age-related macular degeneration: a systematic review. *The British Journal of Ophthalmology.* 2007;91(9):1177–1182.

[228] Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

rule, we are proposing that HHAs would be required to begin submitting the proposed standardized patient assessment data for HHA Medicare and Medicaid quality episodes that begin or end on or after January 1, 2019 using the OASIS, as described here.

Further, the proposed standardized patient assessment data elements described above would be added to the OASIS, so the new reporting requirements regarding those elements would result in no changes to the mechanism by which HHAs report data under the HH QRP. All standardized patient assessment data elements would be collected at SOC/ROC using the OASIS item set, and all except the Brief Interview for Mental Status (BIMS), Hearing, and Vision data elements are or would be collected at discharge using the OASIS item set. Details on the modifications and assessment collection for the OASIS for the proposed standardized data are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

We are inviting public comments on these proposals.

3. Proposed Schedule for Reporting Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

Starting with the CY 2019 HH QRP, we are proposing to apply our current schedule for the reporting of measure data to the reporting of standardized patient assessment data. Under that policy, except for the first program year for which a measure is adopted, HHAs must report data on measures for HHA Medicare and Medicaid quality episodes that occur during the 12-month period (between July 1 and June 30) that applies to the program year. For the first program year for which a measure is adopted, HHAs are only required to report data on HHA Medicare and Medicaid quality episodes that begin on or after January 1 and end up to and including June 30 of the calendar year that applies to that program year. For example, for the CY 2019 HH QRP, data on measures adopted for earlier program years must be reported for all HHA Medicare and Medicaid quality episodes that begin on or after July 1, 2017 and end on or before June 30, 2018. However, data on new measures adopted for the first time for the CY 2019 HH QRP program year must only be reported for HHA Medicare and Medicaid quality episodes that begin or end during the first two quarters of CY 2018. Tables 49 and 50 illustrate this policy.

TABLE 49—SUMMARY ILLUSTRATION OF INITIAL REPORTING FOR NEWLY ADOPTED MEASURES AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING USING CY Q1 AND Q2 DATA FOR THE HH QRP*:

Proposed data collection/submission reporting period*	Proposed data submission deadlines beginning with CY 2019 HH QRP*
January 1, 2018–June 30, 2018	July 31, 2018.

*We note that submission of the OASIS must also adhere to the HH PPS deadlines.

^ The term ''CY 2019 HH QRP'' means the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for a HHA to avoid a two percentage point reduction to its market basket percentage when calculating the payment rates applicable to it for that calendar year.

TABLE 50—SUMMARY ILLUSTRATION OF OASIS 12 MONTH DATA REPORTING FOR MEASURES AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING FOR THE HH QRP*

Proposed data collection/submission reporting period*	Proposed data submission deadlines beginning with CY 2020 HH QRP* ^
July 1, 2018—June 30, 2019	July 31, 2019.

* We note that submission of the OASIS must also adhere to the HH PPS deadlines.

^ The term ''CY 2020 HH QRP'' means the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for a HHA to avoid a two percentage point reduction to its market basket percentage when calculating the payment rates applicable to it for that calendar year.

We are inviting comment on our proposal to extend our current policy governing the schedule for reporting the quality measure data to the reporting of standardized patient assessment data for the HH QRP beginning with the CY 2019 HH QRP.

4. Proposed Schedule for Reporting the Proposed Quality Measures Beginning With the CY 2020 HH QRP

As discussed in section V.I. of this proposed rule, we are proposing to adopt three quality measures beginning with the CY 2020 HH QRP: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury; Application of The Percent of Residents Experiencing One or More Falls with Major Injury (NQF # 0674); and Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631). We are proposing that HHAs would report data on these measures using OASIS reporting that is submitted through the QIES ASAP system. More information on OASIS reporting using the QIES ASAP system is located at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/DataSpecifications.html*.

For the CY 2020 HH QRP, HHAs would be required to report these data for HHA Medicare and Medicaid quality episodes that begin or end during the period from January 1, 2019 to June 30, 2019. Beginning with the CY 2021 HH QRP, HHAs would be required to submit data for the entire 12-month period from July 1 to June 30. Further, for the purposes of measure calculation, our policy was established in the CY 2017 HH PPS final rule (81 FR 76702) that data are utilized using calendar year timeframes with review and correction periods.

We are inviting public comment on this proposal.

5. Input Sought for Data Reporting Related to Assessment Based Measures

Through various means of public input, including through previous rules, public comment on measures, and the MAP, we have received input suggesting that we expand the population for quality measurement to include all patients regardless of payer. Approximately 75 percent of home health expenditures in 2014 were made

by either Medicare or Medicaid and currently both Medicare and Medicaid collect and report data for OASIS. We believe that expanding the patient population for which OASIS collects data will allow us to ensure data that is representative of quality provided to all patients in the HHA setting and therefore allow us to better determine whether HH Medicare beneficiaries receive the same quality of care that other patients receive. We also appreciate that collecting quality data on all patients regardless of payer source may create additional burden. However, we also received input that the effort to separate out Medicare and Medicaid beneficiaries, who are currently reported through OASIS, from other patients creates clinical and work flow implications with an associated burden too, and we further appreciate that it is common practice for HHAs to collect OASIS data on all patients, regardless of payer source. Thus, we are seeking input on whether we should require quality data reporting on all HH patients, regardless of payer, where feasible—noting that because Medicare Part A claims data are submitted only with respect to Medicare beneficiaries, claims-based measures rates would continue to be calculated only for Medicare beneficiaries.

We are inviting public comments on this topic.

J. Other Proposals for the CY 2019 HH QRP and Subsequent Years

1. Proposal To Apply the HH QRP Data Completion Thresholds to the Submission of Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

In the CY 2016 HH PPS final rule (80 FR 68703 through 68705), we defined the pay-for-reporting performance system model that could accurately measure the level of an HHA's submission of OASIS data based on the principle that each HHA is expected to submit a minimum set of two matching assessments for each patient admitted to their agency. These matching assessments together create what is considered a quality episode of care, consisting ideally of a Start of Care (SOC) or Resumption of Care (ROC) assessment and a matching End of Care (EOC) assessment. EOC assessments comprise the Discharge from Agency, Death at Home and Transfer to an Inpatient Facility time points. For further information on successful submission of OASIS assessments, types of assessments submitted by an HHA that fit the definition of a quality assessment, defining the ''Quality Assessments Only'' (QAO) formula, and implementing a pay-for-reporting performance requirement over a 3-year period, please see the CY 2016 HH PPS final rule (80 FR 68704 to 68705).

Additionally, we finalized the pay-for-reporting threshold requirements in the CY 2016 HH PPS rule. We finalized a policy through which HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance requirement for CY 2017 (reporting period July 1, 2015 to June 30, 2016), 80 percent for CY 2018 (reporting period July 1, 2016 to June 30, 2017) and 90 percent for CY 2019 (reporting period July 1, 2017 to June 30, 2018). An HHA that does not meet this requirement for a calendar year will be subject to a two percentage point reduction to the market basket percentage increase that would otherwise apply for that calendar year. We are now proposing to apply the threshold requirements established in the CY 2016 HH PPS rule to the submission of standardized patient assessment data beginning with the CY 2019 HH QRP.

We are inviting public comment on our proposal to extend our current HH QRP data completion requirements to the submission of standardized patient assessment data.

2. Proposal for the HH QRP Submission Exception and Extension Requirements

Our experience with other QRPs has shown that there are times when providers are unable to submit quality data due to extraordinary circumstances beyond their control (for example, natural, or man-made disasters). Other extenuating circumstances are reviewed on a case-by-case basis. We propose to define a ''disaster'' as any natural or man-made catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation. Natural disasters could include events such as hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis. Man-made disasters could include such events as terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions. A disaster may be widespread and impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, an HHA may have the ability to conduct a full patient assessment, and record and save the associated data either during or before the occurrence of the extraordinary event. In this case, the extraordinary event has not caused the agency's data files to be destroyed, but it could hinder the HHA's ability to meet the QRP's data submission deadlines. In this scenario, the HHA would potentially have the ability to report the data at a later date, after the emergency has passed. In such cases, a temporary extension of the deadlines for reporting might be appropriate.

In other circumstances of natural or man-made disaster, an HHA may not have had the ability to conduct a full patient assessment, or to record and save the associated data before the occurrence of the extraordinary event. In such a scenario, the agency may not have complete data to submit to CMS. We believe that it may be appropriate, in these situations, to grant a full exception to the reporting requirements for a specific period of time.

We do not wish to penalize HHAs in these circumstances or to unduly increase their burden during these times. Therefore, we propose a process for HHAs to request and for us to grant exceptions and extensions for the reporting requirements of the HH QRP for one or more quarters, beginning with the CY 2019 HH QRP, when there are certain extraordinary circumstances beyond the control of the HHA. When an exception or extension is granted, we would not reduce the HHA's PPS payment for failure to comply with the requirements of the HH QRP.

We propose that if an HHA seeks to request an exception or extension for the HH QRP, the HHA should request an exception or extension within 90 days of the date that the extraordinary circumstances occurred. The HHA may request an exception or extension for one or more quarters by submitting a written request to CMS that contains the information noted below, via email to the HHA Exception and Extension mailbox at *HHAPureConsiderations@cms.hhs.gov*. Requests sent to CMS through any other channel would not be considered as valid requests for an exception or extension from the HH QRP's reporting requirements for any payment determination.

The subject of the email must read ''HH QRP Exception or Extension Request'' and the email must contain the following information:

- HHA CCN;
- HHA name;
- CEO or CEO-designated personnel contact information including name, telephone number, email address, and mailing address (the address must be a physical address, not a post office box);
- HHA's reason for requesting an exception or extension;
- Evidence of the impact of extraordinary circumstances, including

but not limited to photographs, newspaper and other media articles; and

• A date when the HHA believes it will be able to again submit HH QRP data and a justification for the proposed date.

We propose that exception and extension requests be signed by the HHA's CEO or CEO-designated personnel, and that if the CEO designates an individual to sign the request, the CEO-designated individual has the appropriate authority to submit such a request on behalf of the HHA. Following receipt of the email, we would: (1) Provide a written acknowledgement, using the contact information provided in the email, to the CEO or CEO-designated contact notifying them that the request has been received; and (2) provide a formal response to the CEO or any CEO-designated HHA personnel, using the contact information provided in the email, indicating our decision.

This proposal does not preclude us from granting exceptions or extensions to HHAs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. If we make the determination to grant an exception or extension to all HHAs in a region or locale, we propose to communicate this decision through routine communication channels to HHAs and vendors, including, but not limited to, issuing memos, emails, and notices on our HH QRP Web site once it is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html*.

We also propose that we may grant an exception or extension to HHAs if we determine that a systemic problem with one of our data collection systems directly affected the ability of the HHA to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting an exception or extension on this basis frequently.

If an HHA is granted an exception, we would not require that the HHA submit any measure data for the period of time specified in the exception request decision. If we grant an extension to the original submission deadline, the HHA would still remain responsible for submitting quality data collected during the timeframe in question, although we would specify a revised deadline by which the HHA must submit this quality data.

We also propose that any exception or extension requests submitted for purposes of the HH QRP would apply to that program only, and not to any other program we administer for HHAs such as survey and certification. OASIS requirements, including electronic submission, during Declared Public Health Emergencies can be found at FAQs I–5, I–6, I–7, I–8 at *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/downloads/AllHazardsFAQs.pdf*.

We intend to provide additional information pertaining to exceptions and extensions for the HH QRP, including any additional guidance, on the HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html*.

We propose to add the HH QRP Submission Exception and Extension Requirements at § 484.250(d). We welcome comment on these proposals.

3. Proposed HH QRP Submission Reconsideration and Appeals Procedures

The HH QRP reconsiderations and appeals process was finalized in the CY 2013 HH PPS final rule (77 FR 67096) and has been used for prior all periods cited in the previous rules, and utilized in the CY 2012 to CY 2017 APU determinations. At the conclusion of the required quality data reporting and submission period, we review the data received from each HHA during that reporting period to determine if the HHA met the HH QRP reporting requirements. HHAs that are found to be noncompliant with the HH QRP reporting requirements for the applicable calendar year will receive a 2 percentage point reduction to its market basket percentage update for that calendar year.

Similar to our other quality reporting programs, such as the SNF QRP, the LTCH QRP, and the IRF QRP, we include an opportunity for the providers to request a reconsideration of our initial noncompliance determination. To be consistent with other established quality reporting programs and to provide an opportunity for HHAs to seek reconsideration of our initial noncompliance decision, we are proposing a process that enables an HHA to request reconsideration of our initial non-compliance decision in the event that it believes that it was incorrectly identified as being non-compliant with the HH QRP reporting requirements for a particular calendar year. These proposals clarify the HH QRP reconsiderations and appeals process that we have finalized in previous rules.

For the CY 2019 HH QRP, and subsequent years, we are proposing that a HHA would receive a notification of noncompliance if we determine that the HHA did not submit data in accordance with the HH QRP reporting requirements for the applicable CY. The purpose of this notification is to put the HHA on notice that the HHA: (1) Has been identified as being non-compliant with the HH QRP's reporting requirements for the applicable calendar year; (2) will be scheduled to receive a reduction in the amount of two percentage points to its market basket percentage update for the applicable calendar year; (3) may file a request for reconsideration if it believes that the finding of noncompliance is erroneous, has submitted a request for an extension or exception that has not yet been decided, or has been granted an extension or exception; and (4) must follow a defined process on how to file a request for reconsideration, which will be described in the notification. We would only consider requests for reconsideration after an HHA has been found to be noncompliant.

Notifications of noncompliance and any subsequent notifications from CMS would be sent via a traceable delivery method, such as certified U.S. mail or registered U.S. mail, or through other practicable notification processes, such as a report from CMS to the provider as a Certification and Survey Provider Enhanced Reports (CASPER) report, that will provide information pertaining to their compliance with the reporting requirements for the given reporting cycle or from the Medicare Administrative Contractors assigned to process the provider's claims. To obtain the compliance reports, providers should access the CASPER Reporting Application. HHA providers access the CASPER Reporting application via their CMS OASIS System Welcome page by selecting the CASPER Reporting link. The ''CASPER Reports'' link will connect an HHA to the QIES National System Login page for CASPER Reporting.

We propose to disseminate communications regarding the availability of compliance reports through routine channels to HHAs and vendors, including, but not limited to issuing memos, emails, Medicare Learning Network (MLN) announcements, and notices on our HH QRP Web site once it is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/*

HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html.

An HHA would have 30 days from the date of the letter of noncompliance to submit to us a request for reconsideration. This proposed time frame allows us to balance our desire to ensure that HHA s have the opportunity to request reconsideration with our need to complete the process and provide HHAs with our reconsideration decision in a timely manner. We are proposing that an HHA may withdraw its request at any time and may file an updated request within the proposed 30-day deadline. We are also proposing that, in very limited circumstances, we may grant a request by an HHA to extend the proposed deadline for reconsideration requests. It would be the responsibility of an HHA to request an extension and demonstrate that extenuating circumstances existed that prevented the filing of the reconsideration request by the proposed deadline.

We also are proposing that as part of the HHA's request for reconsideration, the HHA would be required to submit all supporting documentation and evidence demonstrating full compliance with all HH QRP reporting requirements for the applicable calendar year, that the HHA has requested an extension or exception for which a decision has not yet been made, that the HHA has been granted an extension or exception, or has experienced an extenuating circumstance as defined in section V.I.2 of this rule but failed to file a timely request of exception. We propose that we would not review any reconsideration request that fails to provide the necessary documentation and evidence along with the request.

The documentation and evidence may include copies of any communications that demonstrate the HHA's compliance with the HH QRP, as well as any other records that support the HHA's rationale for seeking reconsideration, but should not include any protected health information (PHI). We intend to provide a sample list of acceptable supporting documentation and evidence, as well as instructions for HHAs on how to retrieve copies of the data submitted to CMS for the appropriate program year in the future on our HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html*.

We are proposing that an HHA wishing to request a reconsideration of our initial noncompliance determination would be required to do so by submitting an email to the following email address: *HHAPureConsiderations@cms.hhs.gov*. Any request for reconsideration submitted to us by an HHA would be required to follow the guidelines outlined on our HH QRP Web site once it is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html*.

All emails must contain a subject line that reads ''HH QRP Reconsideration Request.'' Electronic email submission is the only form of reconsideration request submission that will be accepted by us. Any reconsideration requests communicated through another channel including, but not limited to, U.S. Postal Service or phone, will not be considered as a valid reconsideration request.

We are proposing that a reconsideration request include the following information:

- HHA CMS Certification Number (CCN);
- HHA Business Name;
- HHA Business Address;
- The CEO contact information including name, email address, telephone number and physical mailing address; or The CEO-designated representative contact information including name, title, email address, telephone number and physical mailing address; and
- CMS identified reason(s) for noncompliance from the non-compliance notification; and
- The reason(s) for requesting reconsideration.

The request for reconsideration must be accompanied by supporting documentation demonstrating compliance. Following receipt of a request for reconsideration, we would provide an email acknowledgment, using the contact information provided in the reconsideration request, to the CEO or CEO-designated representative that the request has been received. Once we have reached a decision regarding the reconsideration request, an email would be sent to the HHA CEO or CEO designated representative, using the contact information provided in the reconsideration request, notifying the HHA of our decision.

We also propose that the notifications of our decision regarding reconsideration requests may be made available through a traceable delivery method, such as certified U.S. mail or registered U.S. mail or through the use of CASPER reports. If the HHA is dissatisfied with the decision rendered at the reconsideration level, the HHA may appeal the decision to the PRRB under 42 CFR 405.1835. We believe this proposed process is more efficient and less costly for CMS and for HHAs because it decreases the number of PRRB appeals by resolving issues earlier in the process. Additional information about the reconsideration process including details for submitting a reconsideration request will be posted in the future to our HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html*.

We propose to add the HH QRP Submission Reconsideration and Appeals Procedures at § 484.250(e) and (f). We welcome comment on these proposals.

K. Proposals and Policies Regarding Public Display of Quality Measure Data for the HH QRP

Our home health regulations, 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. Section 1899B(g) of the Act requires that data and information of provider performance on quality measures and resource use and other measures be made publicly available beginning not later than two years after the applicable specified ''application date''. In addition, sections 1895(b)(3)(B)(v)(III) requires the Secretary to establish procedures for making data submitted under section 1895(b)(3)(B)(v)(II) available to the public, and section 1899B(g)(1) of the Act requires the Secretary to do the same with respect to HHA performance on measures specified under sections 1899B(c)(1) and (d)(1) of the Act. Section 1895(b)(3)(B)(v)(III) of the Act requires that the public reporting procedures for data submitted under subclause (II) ensure that a HHA has the opportunity to review the data that is to be made public with respect to it prior to such data being made public. Under section 1899B(g)(2) of the Act, the public reporting procedures for performance on measures under sections 1899B(c)(1) and (d)(1) of the Act must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, (which refers to public display and review requirements in the Hospital Inpatient Quality Reporting (Hospital IQR) Program), that a HHA has the

opportunity to review and submit corrections to its data and information that are to be made public for the agency prior to such data being made public. We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to ensuring that the data made available to the public are meaningful. Further, we agree that measures for comparing performance across home health agencies should be constructed from data collected in a standardized and uniform manner.

In the CY 2017 HH PPS final rule (81 FR 76785 through 76786), we finalized procedures that allow individual HHAs to review and correct their data and information on IMPACT Act measures that are to be made public before those measure data are made public. Information on how to review and correct data on IMPACT Act measures that are to be made public before those measure data are made public can be found on the HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html*. We are not proposing any changes to these policies.

In this CY 2018 HH PPS proposed rule, pending the availability of data, we are proposing to publicly report data beginning in CY 2019 for the following two assessment-based measures: (1) Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (NQF #0678); and (2) Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP. Data collection for these two assessment-based measures began on OASIS on January 1, 2017. We propose to publicly report data beginning in CY 2019 for these assessment-based measures based on four rolling quarters of data, beginning with data collected for discharges in 2017.

In addition, we are proposing to publicly report data beginning in CY 2019 for the following 3 claims-based measures: (1) Medicare Spending Per Beneficiary-PAC HH QRP; (2) Discharge to Community-PAC HH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP. As adopted in the CY 2017 HH PPS final rule (81 FR 43773), for the MSPB–PAC HH QRP measure, we will use one year of claims data beginning with CY 2016 claims data to inform confidential feedback reports for HHAs, and CY 2017 claims data for public reporting for the HH QRP. For the Discharge to Community—PAC HH QRP measure we will use 2 years of claims data, beginning with CYs 2015 and 2016 claims data to inform confidential feedback and CYs 2016 and 2017 claims data for public reporting. For the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, we will use 3 years of claims data, beginning with CY 2014, 2015 and 2016 claims data to inform confidential feedback reports for HHAs, and CY 2015, 2016 and 2017 claims data for public reporting.

Finally, we are proposing to assign HHAs with fewer than 20 eligible cases during a performance period to a separate category: ''The number of patient episodes for this measure is too small to report,'' [229] to ensure the statistical reliability of the measures. If a HHA had fewer than 20 eligible cases, the HHA's performance would not be publicly reported for the measure for that performance period.

TABLE 51—SUMMARY OF PROPOSED NEW HH QRP MEASURES FOR CY 2019 PUBLIC DISPLAY

Proposed Measures:
Percent of Residents or Patients with Pressure Ulcers that Are New or Worsened (Short Stay) (NQF #0678).
Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP.
Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP.
Discharge to Community—(PAC) HH QRP.
Medicare Spending Per Beneficiary (PAC) HH QRP.

We are inviting public comment on these proposals for the public display of quality data, as described in this proposed rule.

L. Proposed Mechanism for Providing Confidential Feedback Reports to HHAs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care (PAC) providers on their performance on the measures specified under subsections (c)(1) and (d)(1) of section 1899B of the Act, beginning one year after the specified application date that applies to such measures and PAC providers. In the CY 2017 HH PPS final rule (81 FR 76702), we finalized processes to allow HH providers the opportunity to review their data and information using confidential feedback reports that will enable HHAs to review their performance on the measures required under the HH QRP. Information on how to obtain these and other reports available to the HH QRP can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html*. We are not proposing any changes to this policy.

M. Home Health Care CAHPS® Survey (HHCAHPS)

In the CY 2017 HH PPS final rule (81 FR 76787), we stated that the home health quality measures reporting requirements for Medicare-certified agencies includes the Home Health Care CAHPS® (HHCAHPS) Survey for the Home Health Quality Reporting Program and along with OASIS measures, HHCAHPS participation is required for the Annual Payment Update (APU). In the CY 2017 HH PPS final rule, we finalized the reporting requirements and the data submission dates for the CY 2017–CY 2020 APU periods. We proposed to continue the HHCAHPS requirements in future years for the continuous monthly data collection and quarterly data submission of HHCAHPS data.

1. Background and Description of HHCAHPS

The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. For more details about the HH CAHPS Survey please see 81 FR 76787 through 76788.

We stated in previous rules that Medicare-certified HHAs are required to contract with an approved HHCAHPS survey vendor. This requirement continues, and Medicare-certified agencies are required to provide a monthly list of their HHCAHPS-eligible patients to their respective HHCAHPS

[229] This language is currently available as Footnote #4 on Home Health Compare (*https://www.medicare.gov/HomeHealthCompare/Data/Footnotes.html*).

survey vendors. Home health agencies are not allowed to influence their patients about how the HHCAHPS survey.

As previously required, new HHCAHPS survey vendors are required to attend Introduction training, and current HHCAHPS vendors are required to attend Update training conducted by CMS and the HHCAHPS Survey Coordination Team. New HHCAHPS vendors need to pass a post-training certification test. We have approximately 30 approved HHCAHPS survey vendors. The list of approved HHCAHPS survey vendors is available at *https://homehealthcahps.org*.

2. HHCAHPS Oversight Activities

We stated in prior final rules that all approved HHCAHPS survey vendors are required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. The purpose of the oversight activities is to ensure that approved HHCAHPS survey vendors follow the *HHCAHPS Protocols and Guidelines Manual*.

In the CY 2013 HH PPS final rule (77 FR 67094, 67164), we codified the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

For the sake of continuity with this proposed rule, we are reiterating the HHCAHPS requirements for CY 2019, because participation occurs in the period of the publication of the proposed and final rules for CY 2018. We are additionally presenting the HHCAHPS requirements for CY 2020 for the sake of continuity. We are proposing the HHCAHPS requirements for the CY 2021 Annual Payment Update.

3. HHCAHPS Requirements for the CY 2019 HH QRP

In the CY 2017 HH PPS final rule, we finalized the requirements for the CY 2019 HH QRP. For the CY 2019 HH QRP, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2018 HH QRP includes the second quarter 2017 through the first quarter 2018 (the months of April 2017 through March 2018). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2017 by 11:59 p.m., eastern daylight time (e.d.t.) on October 19, 2017; for the third quarter 2017 by 11:59 p.m., eastern standard time (e.s.t.) on January 18, 2018; for the fourth quarter 2017 by 11:59 p.m., e.d.t. on April 19, 2018; and for the first quarter 2018 by 11:59 p.m., e.d.t. on July 19, 2018. These deadlines are firm; no exceptions will be permitted.

For more details on the CY 2019 HH QRP, we refer readers to 81 FR 76789.

4. HHCAHPS Requirements for the CY 2020 HH QRP

In the CY 2017 HH PPS final rule, we finalized the requirements for the CY 2020 HH QRP. For the CY 2020 HH QRP, we require continued monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2020 HH QRP includes the second quarter 2018 through the first quarter 2019 (the months of April 2018 through March 2019). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2018 by 11:59 p.m., e.d.t. on October 18, 2018; for the third quarter 2018 by 11:59 p.m., e.s.t. on January 17, 2019; for the fourth quarter 2018 by 11:59 p.m., e.d.t. on April 18, 2019; and for the first quarter 2019 by 11:59 p.m., e.d.t. on July 18, 2019. These deadlines are firm; no exceptions will be permitted.

For more details about the CY 2020 HH QRP, we refer readers to 81 FR 76789.

5. HHCAHPS Requirements for the CY 2021 HH QRP

For the CY 2021 HH QRP, we propose to require the continued monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2021 HH QRP includes the second quarter 2019 through the first quarter 2020 (the months of April 2019 through March 2020). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2019 by 11:59 p.m., e.d.t. on October 17, 2019; for the third quarter 2019 by 11:59 p.m., e.s.t. on January 16, 2020; for the fourth quarter 2019 by 11:59 p.m., e.d.t. on April 16, 2020; and for the first quarter 2020 by 11:59 p.m., e.d.t. on July 16, 2020. These deadlines are firm; no exceptions will be permitted.

For the CY 2021 HH QRP, we propose to require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2018 through March 31, 2019 are exempt from the HHCAHPS data collection and submission requirements for the CY 2021 HH QRP, upon completion of the CY 2021 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2018 through March 31, 2019 are proposed to be required to submit their patient counts on the CY 2021 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2019 to 11:59 p.m., e.d.t. to March 31, 2020. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We propose to automatically exempt HHAs receiving Medicare certification on or after the start of the period in which HHAs do their patient count for a particular year's HHCAHPS data submission from the HHCAHPS reporting requirement for the year. We propose that HHAs receiving Medicare-certification on or after April 1, 2019 would be exempt from the HHCAHPS reporting requirement for the CY 2021 HH QRP. As we have finalized in previous years, we propose that these newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2021 HH QRP.

6. HHCAHPS Reconsiderations and Appeals Process

As finalized in previous rules, we propose that HHAs should monitor their respective HHCAHPS survey vendors to ensure that vendors submit their HHCAHPS data on time, by accessing their HHCAHPS Data Submission Reports on *https://homehealthcahps.org*. This helps HHAs ensure that their data are submitted in the proper format for data processing to the HHCAHPS Data Center.

We propose to continue HHCAHPS oversight activities as finalized in the previous rules. In the CY 2013 HH PPS final rule (77 FR 67068, 67164), we codified the current guideline that all approved HHCAHPS survey vendors must fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

For further information on the HH QRP reconsiderations and appeals process, please see Section V.J.3. of this proposed rule.

7. Summary

We are not proposing any changes to the participation requirements, or to the requirements pertaining to the implementation of the Home Health CAHPS® Survey (HHCAHPS). We only updated the information to reflect the dates for future HH QRP years. We again strongly encourage HHAs to keep up-to-date about the HHCAHPS by regularly viewing the official Web site for the

HHCAHPS at *https://homehealthcahps.org*. HHAs can also send an email to the HHCAHPS Survey Coordination Team at *hhcahps@rti.org* or to CMS at *homehealthcahps@cms.hhs.gov*, or telephone toll-free (1–866–354–0985) for more information about the HHCAHPS Survey.

VI. Request for Information on CMS Flexibilities and Efficiencies

CMS is committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek 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. These are the reasons we are including this Request for Information in this proposed rule.

As we work to maintain flexibility and efficiency throughout the Medicare program, we would like to start a national conversation 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. We aim to increase quality of care, lower costs improve program integrity, and make the health care system more effective, simple and accessible.

We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome for CMS' consideration. We are particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including reimbursement methodologies, care coordination, systems and services integration, use of paraprofessionals including community paramedics and other strategies. We are requesting commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise responses. This Request for Information is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this Request for Information and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Request for Information; all costs associated with responding to this Request for Information will be solely at the interested party's expense. We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the FY 2018 HH PPS final rule. Rather, CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Request for Information may be used by the Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This Request for Information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the public comments received, or a summary of those public comments.

VII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the OMB for review and approval. We note that we will submit a revised information collection request (OMB control number 0938–1279) to OMB for review. This will also extend the information collection request which expires December 30, 2019. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA 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.

This proposed rule makes reference to associated information collections that are not discussed in the regulation text contained in this document.

B. Collection of Information Requirements for the HH QRP

We believe that the burden associated with the HH QRP is the time and effort associated with data collection and reporting. As of April 1, 2017, there are approximately 12,149 HHAs currently reporting quality data to CMS. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2016 National Occupational

Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). To account for overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in Table 52.

TABLE 52—U.S. BUREAU OF LABOR STATISTICS' MAY 2016 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit (100%) ($/hr)	Adjusted hourly wage ($/hr)
Registered Nurse (RN)	29–1141	$34.70	$34.70	$69.40
Physical therapists HHAs	29–1123	46.42	46.42	92.84
Speech-Language Pathologists (SLP)	29–1127	37.60	37.60	75.20
Occupational Therapists (OT)	29–1122	40.25	40.25	80.50

The OASIS changes proposed in section V.D of this proposed rule will result in the removal of 75 data elements from the OASIS at the time point of Start of Care (SOC), 75 data elements at the time point of Resumption of Care (ROC), 20 data elements at the time point of Follow-up (FU), 42 data elements at the time point of Transfer to an Inpatient Facility (TOC), 1 data element at the time point of Death at Home (Death), and 34 data elements at the time point of Discharge from Agency (Discharge). These data items will not be used in the calculation of quality measures adopted in the HH QRP nor are they used for previously established purposes that are non-related to our HH QRP. More detail on these OASIS data elements proposed for removal can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html*.

Section V.F.1 of this rule proposes to adopt a new pressure ulcer measure to replace the current pressure ulcer measure that has been specified under section 1899B(c)(1)(B) of the Act beginning with the CY 2020 HH QRP. The proposed replacement measure is entitled, ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.'' The new measure will be calculated using data elements that are currently collected and reported using the OASIS–C2 (version effective January 1, 2017). Adoption of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure would result in the removal of item M1313, related to pressure ulcer assessment that we believe is duplicative and no longer necessary. Specifically, with adoption of Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure, we would remove 6 data elements at Discharge.

In sections V.F.2 of this proposed rule, we are proposing a new quality measure to meet requirements of the IMPACT Act under section 1899B(c)(1)(A) of the Act beginning with the CY 2020 HH QRP titled ''Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).'' Specifically, we are proposing to add 13 standardized patient assessment data elements at SOC, 13 data elements at ROC, 15 standardized patient assessment data elements at FU, and 13 standardized patient assessment data elements at Discharge.

In sections V.F.3 of this proposed rule, we are proposing a new quality measure to meet requirements of the IMPACT Act under section 1899B(c)(1)(D) of the Act beginning with the CY 2020 HH QRP titled ''Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF# 0674).'' The new measure will be calculated using new standardized data elements added to the OASIS. Specifically, we are proposing to add 4 data elements at TOC, 4 data elements at Death, and 4 data elements at Discharge.

In sections V.H.2 and V.H.3 of this proposed rule, we are proposing requirements related to the reporting of standardized patient assessment data beginning with the CY 2019 HH QRP. We are proposing to define the term ''standardized patient assessment data'' as patient assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. The standardized patient assessment data is intended to be shared electronically among PAC providers and will otherwise enable the data to be comparable for various purposes, including the development of cross-setting quality measures and to inform payment models that take into account patient characteristics rather than setting. Specifically, we are proposing to add 53 standardized patient assessment data elements at SOC, 53 standardized patient assessment data elements at ROC, and 36 standardized patient assessment data elements at Discharge.

The OASIS instrument is used for both the HH QRP and the HH PPS. As outlined in section III.E of this proposed rule, to calculate the case-mix adjusted payment amount (specifically the functional level assignment), we are proposing to add collection of two current OASIS–C2 items (10 data elements) at the FU time point:

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

As outlined in section III.E of this proposed rule, OASIS integumentary status items would not be needed in case-mix adjusting the period payment; therefore, we are proposing to remove collection of eight current OASIS–C2 items (19 data elements) at the FU time point:

- 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).

Therefore, we are proposing the net removal associated with the HHGM of 9 data elements at FU.

In summary, there is a net reduction of 9 data elements at SOC, 9 data elements at ROC,14 data elements at FU

and 38 data elements at TOC. There is a net increase of 3 data elements at Death and 13 data elements at Discharge.

Under section 1899B(m) of the Act, the Paperwork Reduction Act does not apply to section 1899B, or to the sections of the OASIS that require modification to achieve the standardization of patient assessment data. We are, however, setting out the burden as a courtesy to advise interested parties of the proposed actions' time and costs and for reference in the regulatory impact analysis (RIA) section IX. The requirement and burden will be submitted to OMB for review and approval when the modifications to the OASIS have achieved standardization and are no longer exempt from the requirements under section 1899B(m) of the Act.

We assume that each data element requires 0.3 minutes of clinician time to complete. Therefore, there is a reduction in clinician burden per OASIS assessment of 2.7 minutes at SOC, 2.7 minutes at ROC, 4.2 minutes at FU and 11.4 minutes at TOC. There is an increase in clinician burden per assessment of 0.9 minutes at Death and 3.9 minutes at Discharge.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2016 show that the SOC/ROC OASIS is completed by RNs (approximately 87 percent of the time), PTs (approximately 12.7 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). Based on this analysis we estimated a weighted clinician average hourly wage of $72.40, inclusive of fringe benefits, using the hourly wage data in Table 52. Individual providers determine the staffing resources necessary.

Table 53 shows the total number of assessments submitted in CY 2016 and estimated burden at each time point.

TABLE 53—CY 2016 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time point	CY 2016 assessments completed	Estimated burden ($)
Start of Care	6,261,934	−$20,401,380.97
Resumption of Care	1,049,247	−3,418,446.73
Follow-up	3,797,410	−19,245,273.88
Transfer to an inpatient facility	1,892,099	−26,027,713.84
Death at Home	41,128	44,665.01
Discharge from agency	5,120,124	24,095,303.54
Total	18,161,942	−44,952,846.87

*Estimated Burden ($) at each Time-Point = (# CY 2016 Assessments Completed) × (clinician burden [min]/60) × ($72.40 [weighted clinician average hourly wage]).

Based on the data in Table 53, for the 12,149 active Medicare-certified HHAs in April 2017, we estimate the total average decrease in cost associated with proposed changes to the HH QRP at $3,700,74 per HHA annually, or $44,952,846.87 for all HHAs annually. This decrease in burden will be accounted for in the information collection under OMB control number 0938–1279.

C. Submission of PRA-Related Comments

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

We invite public comments on these information collection requirements. If you wish to comment, please identify the rule (CMS–1672–P) and, where applicable, the ICR's CFR citation, CMS ID number, and OMB control number.

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

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

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

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

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

VIII. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. Regulatory Impact Analysis

A. Statement of Need

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH 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 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; (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 HH 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 was 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.

The HHVBP Model will apply a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and costs of care.

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 Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, 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 2018 is estimated to be −$80 million (−0.4 percent). The net transfer impact in CY 2019 related to the change in the unit of payment under the proposed HHGM is estimated to be −$950 million (−4.3 percent) if the HHGM is implemented in a fully non-budget neutral manner in CY 2019. The net transfer impact in CY 2019 related to the change in the unit of payment under the proposed HHGM is estimated to be −$480 million (−2.2 percent) if the HHGM is implemented in a partially budget-neutral manner in CY 2019 with the removal of the HHGM partial budget neutrality adjustment factor in CY 2020. The savings impacts related to the HHVBP model as a whole are estimated at a total projected 5-year gross savings of $378 million assuming a savings estimate of a 6 percent annual reduction in hospitalizations and a 1.0 percent annual reduction in SNF admissions; the portion attributable to this proposed rule is negligible. In the CY 2018 HH PPS proposed rule, we have identified a reduction in our regulatory reporting burden of $44,952,846.87. 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.

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

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This proposed rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $148 million or more.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/2016/may/naics4_621100.htm*). Assuming an average reading speed, we estimate that it would take approximately 3.8 hours for the staff to review half of this proposed rule. For each HHA that reviews the rule, the estimated cost is $399.61 (3.8 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $33,966.85 ($399.61 × 85 reviewers).

1. HH PPS for CY 2018

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2018. Accordingly, the following analysis describes the impact in CY 2018 only. We estimate that the net impact of the policies in this rule is approximately $80 million in decreased payments to HHAs in CY 2018. We applied a wage index budget neutrality factor and a case-mix weights budget neutrality factor to the rates as discussed in section III.C.3 of this proposed rule. Therefore, the estimated impact of the 2018 wage index and the recalibration of the case-mix weights for 2018 is zero. The −$80 million impact reflects the distributional effects of a 0.5 percent reduction in payments due to the sunset of the rural add-on provision ($100 million decrease), a 1 percent home health payment update percentage ($190 million increase), and a −0.97 percent adjustment to the national, standardized 60-day episode payment rate to account for nominal case-mix growth for an impact of −0.9 percent ($170 million decrease). The $80 million in decreased payments is reflected in the last column of the first row in Table 54 as a 0.4 percent decrease in expenditures when comparing CY 2017 payments to estimated CY 2018 payments.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare-paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS proposed rule would have a significant economic impact on a substantial number of small entities. Further detail is presented in Table 54, by HHA type and location.

With regards to options for regulatory relief, the sunset of rural add-on payments for CY 2018 is statutory and we do not have the authority to authorize rural add-on payments past December 31, 2017. We believe it is appropriate to reduce the national, standardized 60-day episode payment amount by 0.97 percent in CY 2018 to account for the estimated increase in nominal case-mix in order to move towards more accurate payment for the delivery of home health services where payments better align with the costs of providing such services.

2. HH PPS for CY 2019 (Proposed HHGM)

The net transfer impacts in CY 2019 related to the proposed change in the unit of payment under the HHGM are estimated to be −$950 million (−4.3 percent) if implemented in a fully non-budget neutral manner in CY 2019. The net transfer impact in CY 2019 related to the change in the unit of payment under the proposed HHGM is estimated to be −$480 million (−2.2 percent) if the HHGM is implemented in a partially budget-neutral manner in CY 2019 with the removal of the HHGM partial budget neutrality adjustment factor in CY 2020. Based on our analysis, we conclude that the implementation of the HHGM in CY 2019 would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs, and therefore, would have a significant economic impact on a substantial number of small entities. Further detail is presented in Table 55, by HHA type and location.

With regards to options for regulatory relief, changing the unit of payment from a 60-day episode to a 30-day period is not subject to the budget neutrality requirements under section 1895 of the Act and would result in an estimated 4.3 percent decrease (−$950 million) in total HH PPS payments in CY 2019. As outlined in section III.E.3, we are proposing to implement the change in the unit of payment from 60-day episodes of care to 30-day periods care in a non-budget neutral manner as doing so would better align home health payments with the costs of providing care. However, as noted in section III.E.3, we are considering potential alternative implementation approaches for the HHGM, including, but not limited to, a partially budget-neutral approach with a phase-out period. Specifically, we are considering applying a HHGM partial budget neutrality adjustment factor that would reduce the estimated impact of the HHGM from an estimated −4.3 percent to −2.2 percent in CY 2019, to be eliminated as soon as CY 2020. We invite comments on whether to implement the HHGM in a fully non-budget neutral manner beginning in CY 2019, as proposed; whether to implement the HHGM in CY 2019 with a HHGM partial budget neutrality adjustment factor applied and then subsequently removed in CY 2020; or whether a HHGM partial budget neutrality adjustment factor should be applied and then phased-out over a longer period of time.

HHAs that provide a larger percentage of overall visits as therapy visits compared to skilled nursing visits may experience larger decreases in payments under the HHGM. We do not believe it would be appropriate to offer regulatory relief, or otherwise mitigate the impact of the proposed HHGM, for HHAs that provide a preponderance of their visits as therapy visits compared to nursing visits. The HHGM would still provide adequate reimbursement for therapy services and was developed, in part, to eliminate the current therapy thresholds that encourage the provision of the most profitable number of therapy visits, even when patient need may not justify such services. We anticipate that HHAs currently providing excess therapy visits solely to maximize reimbursement, as outlined in section II.D of this proposed rule, will no longer do so under the HHGM. We note that therapy continues to be a valued home health service, as two of the six clinical groups (neuro/stroke rehabilitation and musculoskeletal rehabilitation) under the HHGM reflect instances where therapy would be the primary focus of home health care.

3. HHVBP Model

Under the HHVBP Model, the first payment adjustment will apply 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 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 proposed

changes in this rule would affect the prior estimates.

C. Detailed Economic Analysis

This rule proposes updates for CY 2018 to the HH PPS rates contained in the CY 2017 HH PPS final rule (81 FR 76702 through 76797). The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2016. 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.

1. HH PPS for CY 2018

Table 54 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2018. For this analysis, we used an analytic file with linked CY 2016 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2016. The first column of Table 54 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 2018 wage index. The fourth column shows the payment effects of the CY 2018 case-mix weights. The fifth column shows the effects the 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for nominal case-mix growth. The sixth column shows the payment effects from the sunset of the rural add-on payment provision in statute. The seventh column shows the effects of the CY 2018 home health payment update percentage.

The last column shows the combined effects of all the policies proposed in this rule. Overall, it is projected that aggregate payments in CY 2018 would decrease by 0.4 percent. As illustrated in Table 54, 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 2018 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2018 relative to CY 2017, 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. In addition, we clarify that there are negative estimated impacts attributed to the sunset of the rural add-on provision for HHAs located in urban areas as well as rural areas. This is due to the fact that HHAs located in urban areas provide services to patients located in rural areas and payments are based on the location of the beneficiary.

TABLE 54—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2018

	Number of agencies	CY 2018 wage index [1] (%)	CY 2018 case-mix weights [2] (%)	60-day episode rate nominal case-mix reduction [3] (%)	Sunset of rural add-on (%)	HH payment update percentage [4] (%)	Total (%)
All Agencies	10,930	0.0	0.0	−0.9	−0.5	1.0	−0.4
Facility Type and Control							
Free-Standing/Other Vol/NP	1,089	0.0	0.1	−0.8	−0.4	1.0	−0.1
Free-Standing/Other Proprietary	8,588	0.0	0.0	−0.9	−0.4	1.0	−0.3
Free-Standing/Other Government	322	−0.2	0.2	−0.9	−1.4	1.0	−1.3
Facility-Based Vol/NP	646	0.0	0.3	−0.8	−0.7	1.0	−0.2
Facility-Based Proprietary	92	−0.2	0.2	−0.9	−1.3	1.0	−1.2
Facility-Based Government	193	−0.2	0.2	−0.9	−1.4	1.0	−1.3
Subtotal: Freestanding	9,999	0.0	0.0	−0.9	−0.4	1.0	−0.3
Subtotal: Facility-based	931	−0.1	0.3	−0.8	−0.8	1.0	−0.4
Subtotal: Vol/NP	1,735	0.0	0.2	−0.8	−0.5	1.0	−0.1
Subtotal: Proprietary	8,680	0.0	0.0	−0.9	−0.5	1.0	−0.4
Subtotal: Government	515	−0.2	0.2	−0.9	−1.4	1.0	−1.3
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	267	0.2	0.2	−0.9	−2.5	1.0	−2.0
Free-Standing/Other Proprietary	814	−0.2	−0.1	−0.9	−2.3	1.0	−2.5
Free-Standing/Other Government	229	−0.4	0.1	−0.9	−2.6	1.0	−2.8
Facility-Based Vol/NP	291	−0.4	0.2	−0.9	−2.7	1.0	−2.8
Facility-Based Proprietary	47	−0.1	0.2	−0.9	−2.7	1.0	−2.5
Facility-Based Government	142	−0.2	0.2	−0.9	−2.6	1.0	−2.5
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	822	−1.0	0.1	−0.8	−0.1	1.0	−0.8

TABLE 54—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2018—Continued

	Number of agencies	CY 2018 wage index [1] (%)	CY 2018 case-mix weights [2] (%)	60-day episode rate nominal case-mix reduction [3] (%)	Sunset of rural add-on (%)	HH payment update percentage [4] (%)	Total (%)
Free-Standing/Other Proprietary	7,774	0.0	0.0	−0.9	−0.2	1.0	−0.1
Free-Standing/Other Government	93	0.0	0.2	−0.9	−0.1	1.0	0.2
Facility-Based Vol/NP	355	0.1	0.3	−0.8	−0.1	1.0	0.5
Facility-Based Proprietary	45	−0.3	0.2	−0.9	−0.2	1.0	−0.2
Facility-Based Government	51	−0.2	0.3	−0.9	−0.3	1.0	−0.1
Facility Location: Urban or Rural							
Rural	1,790	−0.1	0.0	−0.9	−2.4	1.0	−2.4
Urban	9,140	0.0	0.0	−0.9	−0.2	1.0	−0.1
Location: Region of the Country (Census Region)							
New England	346	0.1	0.1	−0.8	−0.3	1.0	0.1
Mid Atlantic	488	0.0	0.0	−0.8	−0.2	1.0	0.0
East North Central	2,216	0.0	0.2	−0.9	−0.4	1.0	−0.1
West North Central	706	0.3	0.2	−0.9	−0.8	1.0	−0.2
South Atlantic	1,721	−0.1	−0.1	−0.9	−0.3	1.0	−0.4
East South Central	423	−0.2	−0.2	−0.9	−1.3	1.0	−1.6
West South Central	2,972	0.2	−0.2	−0.9	−0.7	1.0	−0.6
Mountain	668	−0.3	0.1	−0.9	−0.4	1.0	−0.5
Pacific	1,343	0.1	0.5	−0.9	−0.1	1.0	0.6
Other	47	0.2	−1.0	−0.8	−0.6	1.0	−1.2
Facility Size (Number of 1st Episodes)							
<100 episodes	3,109	0.1	0.2	−0.9	−0.4	1.0	0.0
100 to 249	2,478	0.1	0.2	−0.9	−0.5	1.0	−0.1
250 to 499	2,203	0.1	0.2	−0.9	−0.5	1.0	−0.1
500 to 999	1,646	0.0	0.1	−0.9	−0.5	1.0	−0.3
1,000 or More	1,494	0.0	−0.1	−0.9	−0.5	1.0	−0.5

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 for which we had a linked OASIS assessment.

[1] The impact of the CY 2018 home health wage index is offset by the wage index budget neutrality factor described in section III.C.3 of this proposed rule.

[2] The impact of the CY 2018 home health case-mix weights reflects the recalibration of the case-mix weights offset by the case-mix weights budget neutrality factor described in section III.B of this proposed rule.

[3] The 0.97 percent reduction to the national, standardized 60-day episode payment amount in CY 2018 is estimated to have a 0.9 percent impact on overall HH PPS expenditures.

[4] The CY 2018 home health payment update percentage reflects the home health payment update of 1 percent as described in section III.C.1 of this proposed rule.

Region Key:

New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; *Middle Atlantic* = Pennsylvania, New Jersey, New York; *South Atlantic* = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; *East North Central* = Illinois, Indiana, Michigan, Ohio, Wisconsin; *East South Central* = Alabama, Kentucky, Mississippi, Tennessee; *West North Central* = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; *West South Central* = Arkansas, Louisiana, Oklahoma, Texas; *Mountain* = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; *Pacific* = Alaska, California, Hawaii, Oregon, Washington; *Other* = Guam, Puerto Rico, Virgin Islands.

2. HH PPS for CY 2019 (Proposed HHGM)

Table 55 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2019. For this analysis, we used an analytic file with linked CY 2016 OASIS assessments and CY 2016 HH claims data (as of March 17, 2017) for dates of service that ended on or before December 31, 2016. The first column of Table 55 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 and fourth columns shows the impact of the proposed HHGM as outlined in section III.E of this proposed rule. Overall, before application of the home health payment update percentage for CY 2019, it is projected that aggregate payments in CY 2019 would decrease by $950 million (−4.3 percent) if implemented in a fully non-budget neutral manner and by −$480 million (−2.2 percent) if the HHGM is implemented in a partially budget-neutral manner in CY 2019 with the removal of the HHGM partial budget neutrality adjustment factor in CY 2020. As illustrated in Table 55, the effect of the proposed HHGM varies 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. 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.

TABLE 55—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2019

	Number of agencies	Implementation of the HHGM (not budget neutral) (%)	Implementation of the HHGM (partially budget neutral) (%)
All Agencies	10,860	−4.3	−2.2
Facility Type and Control			
Free-Standing/Other Vol/NP	1,085	−1.3	0.9
Free-Standing/Other Proprietary	8,525	−5.7	−3.6
Free-Standing/Other Government	319	−2.9	−0.7
Facility-Based Vol/NP	646	−0.2	2.0
Facility-Based Proprietary	92	0.4	2.6
Facility-Based Government	193	1.3	3.6
Subtotal: Freestanding	9,929	−4.7	−2.6
Subtotal: Facility-based	931	0.0	2.2
Subtotal: Vol/NP	1,731	−1.0	1.2
Subtotal: Proprietary	8,617	−5.7	−3.6
Subtotal: Government	512	−0.7	1.5
Facility Type and Control: Rural			
Free-Standing/Other Vol/NP	267	0.2	2.5
Free-Standing/Other Proprietary	808	−0.6	1.7
Free-Standing/Other Government	226	−1.7	0.6
Facility-Based Vol/NP	291	0.3	2.5
Facility-Based Proprietary	47	5.0	7.3
Facility-Based Government	142	1.8	4.1
Facility Type and Control: Urban			
Free-Standing/Other Vol/NP	818	−1.5	0.7
Free-Standing/Other Proprietary	7,717	−6.3	−4.3
Free-Standing/Other Government	93	−4.2	−2.0
Facility-Based Vol/NP	355	−0.3	1.9
Facility-Based Proprietary	45	−3.1	−1.0
Facility-Based Government	51	0.9	3.1
Facility Location: Urban or Rural			
Rural	1,781	−0.2	2.1
Urban	9,079	−4.9	−2.8
Facility Location: Region of the Country (Census Region)			
New England	339	−2.3	−0.2
Mid Atlantic	485	−0.6	1.5
East North Central	2,199	−5.2	−3.1
West North Central	705	−7.9	−5.9
South Atlantic	1,713	−10.2	−8.2
East South Central	423	−3.2	−1.0
West South Central	2,947	−0.3	1.9
Mountain	662	−9.7	−7.8
Pacific	1,340	0.1	2.3
Other	47	6.0	8.4
Facility Size (Number of 1st Episodes)			
< 100 episodes	3,040	−2.9	−0.8
100 to 249	2,478	−3.8	−1.7
250 to 499	2,203	−3.9	−1.8
500 to 999	1,645	−4.6	−2.5
1,000 or More	1,494	−4.4	−2.3
Nursing/Therapy Visits Ratio			
1st Quartile (Lowest 25 Nursing)	2,715	−14.4	−12.6
2nd Quartile	2,715	−4.6	−2.5
3rd Quartile	2,715	2.6	4.9

TABLE 55—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2019—Continued

	Number of agencies	Implementation of the HHGM (not budget neutral) (%)	Implementation of the HHGM (partially budget neutral) (%)
4th Quartile (Top 25 Nursing)	2,715	12.9	15.5

Source: CY 2016 Medicare claims data (as of March 17, 2017) for episodes ending on or before December 31, 2016 for which we had a linked OASIS assessment.

Notes: This analysis includes assumptions on behavioral responses as a result of the new case-mix adjustment methodology and omits 360,683 individuals not grouped under the HHGM (either due to a missing 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 HHGM, a further 28 periods were excluded with missing wage index information, 17 periods with missing NRS weights, and 2,376 periods with a missing urban/rural indicator. These excluded episodes results overall in 70 fewer HHAs being represented than in Table 54.

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.

3. HHVBP Model

Table 57 displays our analysis of the distribution of possible payment adjustments at the 3-percent, 5-percent, 6-percent, 7-percent, and 8-percent rates that are being used in the Model using the 2015 and 2016 OASIS-based measures, claims-based hospitalization and Emergency Department (ED) measures, and HHCAHPS data. Full 2016 data are not yet available for claims-based and HHCAHPS-based measures. For these measures, we used the available data—12 months of episodes ending September 30, 2016 for claims-based measures and 12 months ending June 30, 2016 for HHCAHPS-based measures. The estimated impacts account for the minimum 40 HHCAHPS completed surveys proposal and the proposal to remove the OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care beginning in PY 3. We simulated the impacts based on nine (9) OASIS quality measures, two (2) claims-based measures in QIES, and the three (3) New Measures (using the October 2016 and January 2017 submission data), using the QIES Roll Up File data in the same manner as they will be in the Model. HHAs were classified as being in the smaller or larger volume cohort using the 2015 Quality Episode File, which is created using OASIS assessments. The basis of the payment adjustment was derived from complete 2015 claims data. We note that this impact analysis is based on the aggregate value of all nine (9) states.

Table 58 displays our analysis of the distribution of possible payment adjustments based on the same 2015–2016 data used to calculate Table 57, providing information on the estimated impact of the proposals in this rule. We note that this impact analysis is based on the aggregate value across all nine (9) 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. This analysis reflects that under our proposal, only HHAs that have data for at least five measures that meet the requirements of proposed § 484.305 would be included in the LEF and would have a payment adjustment calculated. Value-based incentive payment adjustments for the estimated 1,600 plus HHAs in the selected states that will 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 (8) 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 58, Maryland, North Carolina, Tennessee and Washington will only have one cohort while Arizona, Florida, Iowa, Massachusetts, and Nebraska will have both a smaller-volume cohort and a larger-volume cohort. For example, Iowa has 32 HHAs eligible to be exempt from being required to have their beneficiaries complete HHCAHPS surveys because they provided HHA services to less than 60 beneficiaries. Therefore, those 32 HHAs would be competing in Iowa's smaller-volume cohort for the 2016 performance year under the Model.

Using 2015–2016 data and the maximum payment adjustment for performance year 1 of 3-percent (as applied in CY 2018), based on the nine (9) OASIS quality measures, two (2) claims-based measures in QIES, the five (5) HHCAHPS measures, and the three (3) New Measures, the smaller-volume HHAs in Iowa would have a mean payment adjustment of 0.0 percent (Table 58). Only 10-percent of HHAs in the smaller-volume cohort would be subject to downward payment adjustments of more than minus 1.4 percent (-1.4 percent). The next columns provide the distribution of scores by percentile; we see that the cohort payment adjustment distribution for HHAs in Iowa in the smaller-volume cohort ranges from -1.4 percent at the 10th percentile to +1.3 percent at the 90th percentile, while the cohort payment adjustment distribution median is -0.2 percent.

Table 59 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 better performance.

The payment adjustment percentages were calculated at the state and size cohort level. Hence, the values of each separate analysis in the tables are representative of the baseline year of 2015 and the performance year of 2016 (though full 2016 data are not yet available for claims- and HHCAHPS-based measures). There were 1,674 HHAs in the nine selected states out of

1,894 HHAs that had a sufficient number of measures to receive a payment adjustment in the Model. It is expected that a certain number of HHAs will not have a payment adjustment because they may be servicing too small of a population to report on an adequate number of measures to calculate a TPS.

Additional analysis (see Table 60) was conducted to illustrate the effect of our proposal to require 40 or more completed HHCAHPS surveys versus 20 or more completed HHCAHPS surveys. The percentage difference in the average TPS across all larger-volume HHAs for each state ranged from −0.4 percent through 2.2 percent and the majority of states were close to zero. We include information on average statewide TPS (by size cohort) because this is what is used to determine payment adjustment amounts in HHVBP. The relative ranking of one HHA's TPS to the average TPS will directly affect the HHA's payment adjustment amount. The reporting of TPS also shows that this change has no impact on the TPS for the smaller volume cohort, for which the HHCAHPS measures are not used (regardless of the minimum sample size).

TABLE 57—ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES

[Percentage]

Payment adjustment distribution	Range (%)	10%	20%	30%	40%	Median (%)	60%	70%	80%	90%
3% Payment Adjustment For Performance Year 1 of the Model	3.0	−1.5	−1.0	−0.7	−0.4	−0.1	0.2	0.6	0.9	1.5
5% Payment Adjustment For Performance Year 2 of the Model	5.0	−2.5	−1.6	−1.1	−0.7	−0.1	0.4	0.9	1.5	2.6
6% Payment Adjustment For Performance Year 3 of the Model	6.0	−2.9	−2.0	−1.3	−0.8	−0.2	0.4	1.1	1.8	3.1
7% Payment Adjustment For Performance Year 4 of the Model	7.0	−3.4	−2.3	−1.5	−0.9	−0.2	0.5	1.3	2.1	3.6
8% Payment Adjustment For Performance Year 5 of the Model	8.0	−3.9	−2.6	−1.8	−1.1	−0.2	0.6	1.5	2.4	4.1

TABLE 58—HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT

[Based on a 3-percent payment adjustment]

Cohort	# of HHAs	Average payment adj. %	10%	20%	30%	40%	50%	60%	70%	80%	90%
HHA Cohort in States with no small cohorts (percent)											
MD	51	0.0	−1.0	−0.8	−0.6	−0.4	0.1	0.3	0.5	0.6	1.1
NC	167	−0.1	−1.3	−0.9	−0.6	−0.3	−0.1	0.1	0.4	0.7	0.9
TN	124	−0.2	−1.4	−0.9	−0.7	−0.5	−0.1	0.1	0.5	0.7	1.0
WA	57	−0.2	−1.1	−0.9	−0.6	−0.3	0.0	0.2	0.3	0.4	0.7
Smaller-volume HHA Cohort in states with small cohort (percent)											
AZ	8	−0.4	−2.4	−1.7	−1.3	−1.1	−1.0	−0.9	0.4	1.4	2.1
FL	103	0.2	−1.7	−1.3	−0.8	−0.5	−0.2	0.6	1.1	1.6	2.9
IA	32	0.0	−1.4	−1.0	−0.7	−0.5	−0.2	0.2	0.6	1.1	1.3
MA	23	−0.7	−2.6	−2.0	−1.7	−1.5	−1.3	−0.9	0.1	1.2	1.2
NE	16	0.4	−1.8	−1.3	−1.2	−0.7	0.5	1.0	1.8	2.4	3.1
Large-volume HHA Cohort in states with small cohorts (percent)											
AZ	105	−0.1	−1.5	−1.0	−0.7	−0.5	−0.3	0.2	0.6	0.7	1.2
FL	723	0.1	−1.4	−0.9	−0.6	−0.3	0.0	0.3	0.7	1.1	1.8
IA	94	−0.1	−1.5	−1.1	−0.7	−0.4	−0.2	0.1	0.5	0.9	1.4
MA	111	−0.2	−1.6	−1.2	−0.8	−0.5	−0.3	0.1	0.3	0.7	1.1
NE	44	0.1	−1.3	−0.9	−0.5	−0.1	0.2	0.3	0.7	0.9	1.1

TABLE 59—PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS

[Based on a 3-percent payment adjustment] [230] [231]

Cohort	# of HHAs	Average payment adj. %	10%	20%	30%	40%	50%	60%	70%	80%	90%
Small HHA (<60 patients in CY 2015)	189	0.1	−1.8	−1.4	−1.0	−0.6	−0.2	0.5	1.1	1.3	2.6
Large HHA (≥60 patients in CY 2015)	1,469	0.0	−1.4	−1.0	−0.6	−0.4	−0.1	0.2	0.5	0.8	1.5
Low % Dually—Eligible	414	0.1	−1.1	−0.8	−0.5	−0.2	0.1	0.4	0.6	0.9	1.4
Medium % Dually—Eligible	830	−0.1	−1.4	−1.0	−0.7	−0.4	−0.2	0.1	0.4	0.7	1.2
High % Dually—Eligible	414	0.1	−1.7	−1.3	−0.8	−0.5	0.0	0.4	0.9	1.5	2.3
Low Acuity	415	−0.3	−1.8	−1.4	−1.0	−0.7	−0.5	−0.1	0.2	0.6	1.2
Mid Acuity	828	0.0	−1.3	−0.9	−0.6	−0.4	−0.1	0.2	0.5	0.8	1.4
High Acuity	414	0.4	−1.1	−0.6	−0.3	0.0	0.3	0.6	0.9	1.3	2.2
All non-rural beneficiaries	989	0.1	−1.5	−1.0	−0.7	−0.4	0.0	0.3	0.7	1.1	1.9
Up to 35% rural beneficiaries	389	−0.1	−1.5	−1.0	−0.6	−0.4	−0.1	0.1	0.4	0.7	1.1
Over 35% rural beneficiaries	280	−0.1	−1.4	−1.0	−0.7	−0.5	−0.2	0.0	0.4	0.8	1.3
Non-Profit HHAs	304	0.1	−1.2	−0.8	−0.6	−0.3	0.0	0.3	0.6	0.9	1.4
For-Profit HHAs	1,238	0.0	−1.5	−1.0	−0.7	−0.4	−0.1	0.2	0.6	0.9	1.6
Government HHAs	116	−0.1	−1.3	−1.0	−0.7	−0.5	−0.3	0.0	0.3	0.6	1.2
Freestanding	1,494	0.0	−1.5	−1.0	−0.7	−0.4	−0.1	0.2	0.6	0.9	1.6
Facility-based	164	0.0	−1.2	−0.9	−0.5	−0.3	0.0	0.3	0.5	0.8	1.2

TABLE 60—IMPACT OF CHANGING MINIMUM REQUIRED SAMPLE SIZE FOR HHCAHPS PERFORMANCE MEASURES ON AVERAGE TPS AND PAYMENT ADJUSTMENT RANGE [232]

State	HHA count	Average TPS				Minimum payment adjustment		Maximum payment adjustment	
		20 Minimum	40 Minimum	Difference	% Difference	20 Minimum (%)	40 Minimum (%)	20 Minimum (%)	40 Minimum (%)
Larger-Volume HHAS									
AZ	105	38.393	39.254	0.86	2.2	−2.6	−2.6	3.0	3.0
FL	723	36.794	37.451	0.657	1.8	−2.6	−2.6	3.0	3.0
IA	94	41.079	41.049	−0.03	−0.1	−2.4	−2.4	2.0	3.0
MA	111	40.074	39.927	−0.147	−0.4	−2.8	−2.8	2.6	2.6
MD	50	47.287	47.517	0.23	0.5	−1.2	−1.2	2.0	2.4
NC	164	43.738	44.175	0.437	1.0	−2.0	−2.0	2.2	2.2
NE	44	39.714	40.581	0.867	2.1	−1.8	−1.8	2.9	2.7
TN	121	45.699	45.749	0.05	0.1	−2.8	−2.6	1.8	1.8
WA	57	49.888	49.685	−0.203	−0.4	−1.4	−1.8	1.2	1.2
Total	1,469								
Smaller-Volume HHAS									
AZ	8	31.474	31.474	0	0.0	−2.4	−2.4	2.1	2.1
FL	103	37.349	37.349	0	0.0	−2.6	−2.6	3.0	3.0
IA	32	37.741	37.741	0	0.0	−1.9	−1.9	2.0	2.0
MA	23	26.904	26.904	0	0.0	−2.7	−2.7	3.0	3.0
MD	1	55.841	55.841	0	0.0	0.6	0.6	0.6	0.6
NC	3	67.1	67.1	0	0.0	−0.2	−0.2	3.0	3.0
NE	16	37.076	37.076	0	0.0	−2.8	−2.8	3.0	3.0
TN	3	48.549	48.549	0	0.0	−1.4	−1.4	2.3	2.3
Total	189								
Total	*1,658*								

4. HH QRP

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act will result in the reduction of the annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any HHA that does not comply with the requirements established by the Secretary. At the time that this analysis was prepared, 513, or approximately 4.3 percent, of the 12,149 active Medicare-certified HHAs, did not receive the full annual percentage increase for the CY 2017 annual payment update determination. Information is not available to determine the precise number of HHAs that will not meet the requirements to receive the full annual percentage increase for the CY 2018 payment determination.

As noted in section VII.B. of this proposed rule, the net effect of our proposals is an estimated decrease in cost associated with proposed changes to the HH QRP on average of $3,700.74 per HHA annually, or $44,952,846.87 for all HHAs annually.

D. Alternatives Considered

1. HH PPS for CY 2018

We did not consider extending the rural add-on payment as this provision was statutory. Section 421(a) of the MMA extended 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, for episodes and visits ending before January 1, 2018. Therefore, for episodes and visits that end on or after January 1, 2018, a rural add-on payment will not apply.

In the alternatives considered section for the CY 2016 HH PPS proposed rule (80 FR 39839), we considered reducing the 60-day episode rate in CY 2016 only to account for nominal case-mix growth between CY 2012 and CY 2014. However, we instead proposed to reduce the 60-day episode rate over a 2-year period (CY 2016 and CY 2017) to lessen the impact on HHAs in a given year. In the CY 2016 HH PPS final rule (80 FR 68624), we finalized a reduction of 0.97 percent to the 60-day episode rate in each of the next 3 calendar years (CY 2016 through CY 2018. Therefore, the alternatives with regards to the 0.97 percent reduction in the national, standardized 60-day episode payment amount for CY 2018 were already considered in the CY 2016 HH PPS proposed and final rules and we did not consider alternatives for implementing this reduction for CY 2018.

We are not able to consider alternative values for the home health payment update percentage. The home health payment update percentage is based on the home health market basket update and section 1895(b)(3)(B) of the Act, as amended by section 411(d) of the MACRA, mandates that for home health payments for CY 2018, the market basket percentage increase shall be 1 percent.

2. HH PPS for CY 2019 (Proposed HHGM)

We considered proposing to implement the HHGM for CY 2018.

[230] Rural beneficiaries identified based on the CBSA code reported on the claim.

[231] Acuity is based on the average case-mx weight for non-LUPA episodes. Low acuity is defined as the bottom 25% (among HHVBP model participants); mid-acuity is the middle 50% and high acuity is the highest 25%. Note that one HHA was missing acuity information.

[232] OASIS measures run from January 1, 2015 to December 31, 2016; Claims from September 1, 2015 to September 30, 2016. Payment based on 2015 and 2016 Medicare claims data (2016 is used as the payment year—in actuality CY 2018 claims payments would determine actual payment adjustment amounts).

However, implementation of the HHGM will require provider education and training, updating and revising relevant manuals, and changing assessment and claims processing systems. Implementation starting in 2019 would provide an opportunity for CMS and providers to prepare.

For CY 2019, in addition to considering whether to implement the HHGM in a fully non-budget neutral manner for CY 2019 or implementing the HHGM with a HHGM partial budget neutrality adjustment factor that would have reduced the estimated impact of the HHGM by 50 percent in CY 2019 and the elimination of such factor in CY 2020, we also considered implementing the HHGM as fully budget neutral in CY 2019 or as partially budget-neutral with longer phase-out period (for example starting with a HHGM partial budget neutrality adjustment factor that would have reduced the estimated impact of the HHGM by 75 percent in CY 2019, a HHGM partial budget neutrality adjustment factor that would have reduced the estimated impact of the HHGM by 50 percent in CY 2020, a HHGM partial budget neutrality adjustment factor that would have reduced the estimated impact of the HHGM by 25 percent in CY 2021, and the elimination of such factor in CY 2022). However, we propose to implement the change in the unit of payment under the HHGM in a non-budget neutral manner as doing so better aligns home health payments with the costs of providing care. In addition, we do not believe a longer phase-out period is necessary if we were to implement the HHGM in a non-budget neutral manner with a HHGM partial budget neutrality adjustment factor applied in CY 2019 to be removed in CY 2020, as this 2-year timeframe would be sufficient to lessen the economic impact in the first year of implementation.

We also considered maintaining 60-day episodes of care as the unit of payment. As stated in the FY 2001 HH PPS final rule, ''We believe the 60-day episode definition is the most appropriate approach to define the unit of payment under HHA PPS. Public support for the 60-day episode as the unit of payment under PPS centered on the general consensus that HHAs and physicians predict home care needs over a 60-day timeframe due to current plan of care requirements and required updates to the comprehensive assessments that basically follow a 60-day timeframe. As discussed in detail in the proposed rule, research indicated that the 60-day episode captures the majority of stays experienced in the Phase II per-episode HHA PPS demonstration (65 FR 41136).'' However, we further noted that we ''will continue to monitor the appropriateness of the 60-day unit of payment and may consider modifying our approach to the episode definition in subsequent years of PPS, if warranted.'' During subsequent years, we have identified variation in average resource use between the first 30-day period within a 60-day episode and the second 30-day period within a 60-day episode. This difference in resources between the first and second 30-day periods within a 60-day episode led to the development of 30-day periods for the HHGM. In addition, the accuracy of the HHGM improves when a shorter, more constrained time period is examined. This in turn would improve the accuracy of the case-mix weights that are generated using 30-day periods instead of 60-day episodes. We note that the frequency of the required updates to the plan of care and the comprehensive assessment would remain unchanged under the proposed HHGM.

We considered whether to continue using the wage-weighted minutes of care (WWMC) approach to estimate resource use under the HHGM, as described in section III.E.2 of this proposed rule. Although the relationship in relative costs between the WWMC approach and the proposed cost-per-minute plus non-routine supplies (CPM+NRS) approach is very similar (correlation coefficient equal to 0.8016), 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 (*i.e.,* skilled nursing, physical therapy, occupational therapy, speech-language pathology, home health aide, and medical social services) under the HH PPS.

Finally, we considered not proposing the HH PPS case-mix methodology refinements for CY 2019. However, in maintaining the current case-mix methodology, the current payment system, with its various therapy thresholds, would continue to provide financial incentives that detract from a focus on patient characteristics and care needs when agencies are setting plans of care for their patients, and would continue to incentivize unnecessary therapy utilization. The proposed HHGM removes therapy thresholds from the case-mix adjustment methodology thereby eliminating the financial incentive to provide unnecessary therapy visits in order to maximize payment. In addition, we believe the proposed HHGM is a more simplified, clinically intuitive, and patient-centered approach to payment compared to the existing case-mix adjustment methodology. We invite comments on the alternatives discussed in this analysis.

3. HHVBP Model Proposals

An alternative to our proposal to use 40 completed HHCAHPS surveys beginning with PY 1 would be to continue calculating quality scores at 20 completed HHCAHPS surveys as finalized in the CY 2016 HH PPS final rule.

Another alternative would be to use 40 completed HHCAHPS surveys beginning with PY 2 and subsequent years, but keep the 20 completed HHCAHPS surveys calculation for PY 1; however, this would give HHAs a short amount of time to analyze from year to year a change in threshold from 20 to 40 completed HHCAHPS surveys.

Rather than removing the Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care measure from the set of applicable measures, an alternative would be to keep the measure in the set of applicable measures for the HHVBP Model. Doing so would continue HHAs' awareness of the importance of drug education for patient and caregivers during all episodes of care. Nevertheless, there would be a lack of variability in the measure across the participating HHAs and the measure does not address the quality or intensity of the education provided.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Tables 61 and 62, we have prepared an accounting statement showing the classification of the transfers and costs associated with the HH PPS provisions of this proposed rule. Table 61 provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this proposed rule for the HH PPS provisions in CY 2018. Table 62 provides our estimate as a result of the changes associated with the HHGM proposed for CY 2019. Table 63 provides our best estimates of the

changes associated with the HH QRP proposals.

TABLE 61—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CYS 2017 TO 2018

Category	Transfers
Annualized Monetized Transfers.	−$80 million.
From Whom to Whom?	Federal Government to HHAs.

TABLE 62—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS DUE TO IMPLEMENTATION OF PROPOSED HHGM, FROM CYS 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers (Not Budget Neutral)	−$950 million.
Annualized Monetized Transfers (Partially Budget Neutral)	−$480 million.
From Whom to Whom?	Federal Government to HHAs.

TABLE 63—ACCOUNTING STATEMENT: HH QRP CLASSIFICATION OF ESTIMATED COSTS, FROM CYS 2018 TO 2019

Category	Costs
Annualized Monetized Net Burden for HHAs Submission of the OASIS	−$44.9 million.

F. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. Under E.O. 13771, this rule would be considered deregulatory if finalized as proposed.

G. Conclusion

1. HH PPS

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is a decrease of 0.4 percent, or $80 million, in Medicare payments to HHAs for CY 2018. The −$80 million impact reflects the effects of a 0.5 percent reduction in payments due to the sunset of the rural add-on provision ($100 million decrease), a 1 percent CY 2018 HH payment update percentage ($190 million increase), and a 0.9 percent decrease in payments due to the 0.97 percent reduction to the national, standardized 60-day episode payment rate in CY 2017 to account for nominal case-mix growth ($170 million decrease). We estimate that the net impact of the proposed HHGM is a decrease of 4.3 percent ($950 million decrease) in Medicare payments to HHAs in CY 2019 if the proposed HHGM is implemented in a fully non-budget neutral manner. We estimate that the net impact of the proposed HHGM is a decrease of 2.2 percent ($480 million decrease) in Medicare payments to HHAs in CY 2019 if the proposed HHGM is implemented in a partially budget-neutral manner in CY 2019 with the removal of the HHGM partial budget neutrality adjustment factor in CY 2020.

This analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis.

2. HHVBP Model

In conclusion, we estimate there would be no net impact (to include either a net increase or reduction in payments) in this proposed rule in Medicare payments to HHAs competing in the HHVBP Model for CY 2018. However, the overall economic impact of the HHVBP Model provision is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model.

3. HH QRP

In conclusion, for CY 2019 we estimate that there will be a total decrease in costs of $44,952,846.87 associated with the proposed changes to the HH QRP.

X. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of states, local or tribal governments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section § 409.43 is amended by—
■ a. Revising paragraphs (c)(2) and (c)(3)(ii);
■ b. In paragraph (e)(1)(iii), removing the phrase ''during the 60-day episode'' and adding in its place the phrase ''within 60 days after discharge''.

The revisions read as follows:

§ 409.43 Plan of care requirements.

* * * * *

(c) * * *

(2) *Reduction or disapproval of anticipated payment requests.* CMS has

the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders as specified in paragraph (c)(1)(i) of this section and/or a prescribing referral as specified in paragraph (c)(1)(ii) of this section 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 Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a(i)(2)), the Civil False Claims Act (as defined in 31 U.S.C. 3729(c)), and the Criminal False Claims Act (18 U.S.C. 287)), the request for anticipated payment will be canceled and recovered unless the claim is submitted within the greater of one of the following:

(i) 60 days from the end of the episode (for claims beginning on or before December 31, 2018);

(ii) 60 days from the end of the 30-day period of care (for claims beginning on or after January 1, 2019); or

(iii) 60 days from the issuance of the request for anticipated payment.

(3) * * *

(ii) Before the claims for each episode (for a 60-day episode of care beginning on or before December 31, 2018) or period (for a 30-day period of care beginning on or after January 1, 2019) for services is submitted for the final percentage prospective payment.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 3. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 4. 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.

■ 5. 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.* For episodes beginning on or before December 31, 2018, an HHA receives a national, standardized prospective 60-day episode payment amount. For periods beginning on or after January 1, 2019, a HHA receives 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 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 medical review with respect to beneficiary eligibility, medical necessity, and 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 amount.

(g) *Split percentage payments.* 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, 2018:

(i) 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. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage-adjusted 60-day episode rate.

(ii) 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. 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, 2019:

(i) 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. 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) 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. 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.

§ 484.210 [Removed and Reserved]

■ 6. Section 484.210 is removed and reserved.

■ 7. Section 484.215 is amended by—

■ a. Revising the section heading;

■ b. Revising paragraph (d) introductory text; and

■ c. Adding paragraph (f).

The revisions and addition read as follows:

§ 484.215 Initial establishment of the calculation of the national, standardized prospective 60-day episode payment and 30-day payment rates.

* * * * *

(d) *Calculation of the unadjusted national average prospective payment amount for the 60-day episode.* For episodes beginning on or before December 31, 2018, CMS calculates the unadjusted national 60-day episode payment in the following manner:

* * * * *

(f) *For periods beginning on or after January 1, 2019, 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 updated pursuant to § 484.225.

■ 8. Section 484.220 is amended by—

■ a. Revising the section heading;

■ b. Revising the introductory text; and

■ c. In paragraph (a) introductory text, 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:

* * * * *

■ 9. Section 484.225 is amended by—
■ a. Revising the section heading;
■ b. Revising paragraph (a);
■ c. In paragraphs (b) and (c), removing the phrase ''national prospective 60-day episode'' and adding the phrase ''national standardized prospective''; and
■ d. Adding paragraph (d).

The revisions and addition read 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)(3)(B) of the Act.

* * * * *

(d) For CY 2019, 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.

■ 10. Section 484.230 is revised to read as follows:

§ 484.230 Low-utilization payment adjustments.

(a) For episodes beginning on or before December 31, 2018, an episode with four or fewer visits is paid the national per-visit amount by discipline updated annually by the applicable market basket for each visit type, in accordance with § 484.225. The national per-visit amount is adjusted by the appropriate wage index based on the site of service of the beneficiary. An amount will be 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. 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, 2019, 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. 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 will be used to create payment group specific thresholds with a minimum threshold of at least 2 visits for each case-mix group. A 30-day period with a total number of visits less than the threshold is paid the national per-visit amount by discipline updated annually by the applicable market basket for each visit type. The national per-visit amount is adjusted by the appropriate wage index based on the site of service for the beneficiary.

(c) An amount will be 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.

■ 11. 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, 2018.* (1) An HHA receives a national, standardized 60-day payment of a predetermined rate for home health services unless CMS determines that an intervening event has occurred, which 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. An intervening event is defined as either a beneficiary elected transfer or a discharge with goals met or no expectation of return to home health, but the beneficiary returned to home health during the 60-day episode.

(2) The PEP adjustment will not apply in situations of transfers among HHAs under common ownership. Those situations will be 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. 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. 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, 2019.* (1) An HHA receives a national, standardized 30-day payment of a predetermined rate for home health services unless CMS determines that an intervening event has occurred, which 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. An intervening event is defined as either a beneficiary elected transfer or a discharge and return to home health during the 30-day period.

(2) The partial payment adjustment will not apply in situations of transfers among HHAs of common ownership. Those situations will be 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. 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. 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 thus 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.

■ 12. Section 484.240 is revised to read as follows:

§ 484.240 Outlier payments.

(a) For episodes beginning on or before December 31, 2018, 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, 2019, 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 estimated cost beyond the threshold.

(d) CMS estimates the cost for each episode 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 estimated cost for all disciplines.

■ 13. Section 484.250 is amended by revising paragraph (a)(1) and adding paragraphs (d) through (f) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) The OASIS data described at § 484.55(b) and (d) for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484. 230, 484.235, and 484.240; and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

(d) *Exceptions and extension requirements.* (1) A HHA may request and CMS may grant exceptions or extensions to the reporting requirements under section 1895(b)(3)(B)(v) of the Act for one or more quarters, when there are certain extraordinary circumstances beyond the control of the HHA.

(2) A HHA may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to CMS HHAPU reconsiderations at *HHAPUReconsiderations@cms.hhs.gov* that contains all of the following information:

(i) HHA CMS Certification Number (CCN).

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address (The address must be a physical address, not a post office box).

(v) HHA's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the HHA believes it will be able to again submit data under section 1895(b)(3)(B)(v) of the Act and a justification for the proposed date.

(3) Except as provided in paragraph (d)(4) of this section, CMS will not consider an exception or extension request unless the HHA requesting such exception or extension has complied fully with the requirements in this paragraph (d).

(4) CMS may grant exceptions or extensions to HHAs without a request if it is determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affected the ability of a HHA to submit data under section 1895(b)(3)(B)(v) of the Act.

(e) *Reconsideration.* (1) HHAs that do not meet the quality reporting requirements under section 1895(b)(3)(B)(v) of the Act for a program year will receive a letter of non-compliance through the USPS and via notification in CASPER. An HHA may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests may be submitted to CMS by sending an email to CMS HHAPU reconsiderations at *HHAPureConsiderations@cms.hhs.gov* containing all of the following information:

(i) HHA CCN.

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address (The address must be a physical address, not a post office box).

(v) CMS identified reason(s) for non-compliance from the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation. CMS will not consider an exception or extension request unless the HHA has complied fully with the requirements in paragraph (e)(2) of this section.

(3) CMS will make a decision on the request for reconsideration and provide notice of the decision to the HHA through CASPER and via letter sent through the United States Postal Service.

(f) *Appeals.* (1) A HHA that is dissatisfied with CMS' decision on a reconsideration request submitted under paragraph (e) of this section may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

(2) [Reserved]

■ 14. Section 484.305 is amended by revising the definition of ''Applicable measure'' to read as follows:

§ 484.305 Definitions.

* * * * *

Applicable measure means a measure for which a competing HHA has provided a minimum of:

(1) 20 home health episodes of care per year for the OASIS-based measures;

(2) 20 home health episodes of care per year for the claims-based measures; or

(3) 40 completed surveys for the HHCAHPS measures.

* * * * *

Dated: June 29, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 30, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

[FR Doc. 2017–15825 Filed 7–25–17; 4:15 pm]

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