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42 CFR Parts 409 and 484

Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 484

[CMS-1648-P]

RIN 0938-AS80

Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; 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 would update the Home Health Prospective Payment System (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor, effective for home health episodes of care ending on or after January 1, 2017. This proposed rule also: Implements the last year of the 4-year phase-in of the rebasing adjustments to the HH PPS payment rates; updates the HH PPS case-mix weights using the most current, complete data available at the time of rulemaking; implements the 2nd-year of a 3-year phase-in of a reduction to the national, standardized 60-day episode payment to account for estimated casemix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014; proposes changes to the methodology used to calculate outlier payments (with regards to payments made under the HH PPS for high-cost "outlier" episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care)); proposes changes in payment for Negative Pressure Wound Therapy (NPWT) performed using a disposable device for patient's under a home health plan of care; discusses our efforts to monitor the potential impacts of the rebasing adjustments mandated; includes an update on subsequent research and analysis as a result of the findings from the home health study; solicits comments on a potential process for grouping HH PPS claims centrally during claims processing; and proposes changes to the Home Health Value-Based Purchasing (HHVBP) Model, which was implemented on January 1, 2016; and proposes updates 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 August 26, 2016.

ADDRESSES: In commenting, please refer to file code CMS-1648-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-1648-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-1648-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.

Michelle Brazil, (410) 786–1648 for information about the HH quality reporting program.

Lori Teichman, (410) 786–6684, for information about HHCAHPS.

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 at 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

APU Annual Payment Update

BBA Balanced Budget Act of 1997, Pub. L. 105–33

BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)

CAD Coronary Artery Disease

CAH Critical Access Hospital

CBSA Core-Based Statistical Area

CASPER Certification and Survey Provider Enhanced Reports

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, Pub. L. 109–171, enacted February 8, 2006

FDL Fixed Dollar Loss

FI Fiscal Intermediaries

FISS Fiscal Intermediary Shared System

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

HHŘG Home Health Resource Group HHVBP Home Health Value-Based Purchasing

HIPPS Health Insurance Prospective Payment System

HVBP Hospital Value-Based Purchasing 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 Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185)

IRF Inpatient Rehabilitation Facility LEF Linear Exchange Function LTCH Long-Term Care Hospital

LUPA Low-Utilization Payment Adjustment

MEPŚ Medical Expenditures Panel Survey 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

OT Occupational Therapy

OMB Office of Management and Budget MFP Multifactor productivity

PAMA Protecting Access to Medicare Act of 2014

PAC–PRD Post-Acute Care Payment Reform Demonstration

PEP Partial Episode Payment Adjustment

PT Physical Therapy PY Performance Year

PRRB Provider Reimbursement Review Board

QAP Quality Assurance Plan

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 SAF Standard Analytic File SLP Speech-Language Pathology SN Skilled Nursing

SN Skilled Nursing
SNF Skilled Nursing Facility

TPS Total Performance Score UMRA Unfunded Mandates Reform Act of 1995

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) 2017, as required under section 1895(b) of the Social Security Act (the Act). This would reflect the final year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national pervisit rates, and the NRS conversion factor finalized in the CY 2014 HH PPS final rule (78 FR 72256), as required under section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively referred to as the "Affordable Care Act").

This proposed rule would update the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act and includes a reduction to the national, standardized 60-day episode payment rate in CY 2017 of 0.97 percent, to account for case-mix growth unrelated to increases in patient acuity (nominal case-mix growth) between CY 2012 and CY 2014 under the authority of section 1895(b)(3)(B)(iv) of the Act. With regards to payments made under the HH PPS for high-cost "outlier" episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care), this rule proposes changes to the methodology used to calculate outlier payments under the authority of section 1895(b)(5) of the Act. Also, in accordance with section 1834(s)(1) of the Act, as amended by the Consolidated Appropriations Act of 2016 (Pub. L. 114-113), this rule proposes changes in payment for Negative Pressure Wound Therapy (NPWT) performed using a disposable device for patient's under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act. This proposed rule also discusses our efforts to monitor for potential impacts of the rebasing adjustments mandated by section 3131(a) of the Affordable Care Act, provides an update on subsequent research and analysis as a result of the

findings from the home health study required by section 3131(d) of the Affordable Care Act, and provides and update and solicits comments on a process to group HH PPS claims centrally during claims processing. Additionally, this rule proposes changes to the HHVBP Model, in which Medicare-certified HHAs in certain states are required to participate as of January 1, 2016, under the authority of section 1115A of the Act; and proposes changes to the home health quality reporting program requirements under the authority of section 1895(b)(3)(B)(v)(II) of the Act.

B. Summary of the Major Provisions

As required by section 3131(a) of the Affordable Care Act, and finalized in the CY 2014 HH PPS final rule (78 FR 77256, December 2, 2013), we are implementing the final year of the 4year 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 in section III.C.3. The rebasing adjustments for CY 2017 will reduce the national. standardized 60-day episode payment amount by \$80.95, increase the national per-visit payment amounts by 3.5 percent of the national per-visit payment amounts in CY 2010 with the increases ranging from \$1.79 for home health aide services to \$6.34 for medical social services, and reduce the NRS conversion factor by 2.82 percent. In addition, in section III.C.3 of this rule, we are implementing a reduction to the national, standardized 60-day episode payment rate in CY 2017 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. This reduction was finalized in the CY 2016 HH PPS final rule (80 FR 68624). Section III.A of this proposed rule discusses our efforts to monitor for potential impacts due to the rebasing adjustments mandated by section 3131(a) of 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 more current data. In section III.B.1 of this rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget neutral manner. In section III.C.1 of this rule, we propose to update the payment rates under the HH PPS by the home health payment update percentage of 2.3 percent (using the 2010-based Home Health Agency (HHA) market basket update of 2.8

percent, minus 0.5 percentage point for productivity), as required by section 1895(b)(3)(B)(vi)(I) of the Act, and in section III.C.2 of this rule, we propose to update the CY 2017 home health wage index using more current hospital wage data. In section III.D. we are proposing to revise the current methodology used to estimate the cost of an episode of care to determine whether the episode of care would receive an outlier payment. The methodology change includes calculating the cost of an episode of care using a cost-per-unit calculation, which takes into account visit length, rather than the current methodology that uses a cost-per-visit calculation. In section III.E of this proposed rule, as a result of the Consolidated Appropriations Act of 2016 (Pub. L. 114-113), we are proposing changes in payment for when Negative Pressure Wound Therapy (NPWT) is performed using a disposable device for a patient under a home health plan of care and for which payment is otherwise made under the HH PPS. In section III.F of this rule, we provide an update on our recent research and analysis pertaining to the home health study required by section 3131(d) of the Affordable Care Act. Finally, in section III.G of this proposed rule, we provide an update and solicit comments on a process for grouping the HH PPS claims centrally during claims processing.

In section IV of this rule, we are proposing the following changes to the HHVBP Model implemented January 1, 2016. We propose to remove the definition for "starter set"; propose to revise the definition for "benchmark"; propose to calculate benchmarks and achievement thresholds at the state level; propose a minimum requirement of eight HHAs in a cohort; propose to increase the time frame for submitting New Measure data; propose to remove four measures from the set of applicable measures; propose to adjust the reporting period and submission date for one of the New Measures; propose to add an appeals process that includes the existing recalculation process; and we are providing an update on the progress towards developing public reporting of performance under the HHVBP Model.

This proposed rule also proposes updates to the Home Health Quality Reporting Program in section V, including the adoption of four new quality measures, the removal of a number of measures, data submission requirements, and data review and correction policies.

C. Summary of Costs and Transfers

TABLE 1—SUMMARY OF C	OSTS AND	IRANSFERS
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Provision description	Costs	Transfers
CY 2017 HH PPS Payment Rate Update		The overall economic impact of the HH PPS payment rate update is an estimated -\$180 million (-1.0 percent) in payments to HHAs.
CY 2017 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. As for payments to HHAs, there are no aggregate increases or decreases to the HHAs competing in the model.

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, to 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 is to be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act requires an 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, respectively. 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 Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111-148, enacted March 23, 2010) 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

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 (OCESAA) for Fiscal Year 1999, (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 (BBRA) of 1999, (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 set out in section 3131 of the Affordable Care Act was an amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016. Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) 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 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113-185, enacted on Oct. 6, 2014) amended Title XVIII of the Act, in part, by adding a new section 1899B, which imposes new data reporting requirements for certain postacute care (PAC) providers, including HHAs. Under section 1899B(a)(1) of the Act, certain post-acute care (PAC) providers (defined in section 1899B(a)(2)(A) of the Act as HHAs, SNFs, IRFs, and LTCHs) must submit standardized patient assessment data in accordance with section 1899B(b) of the Act, data on quality measures required under section 1899B(c)(1) of the Act, and data on resource use, and other measures required under section 1899B(d)(1) of the Act. The Act also requires the Secretary to specify these measures insofar as they are respect to certain domains no later than the applicable specified application date that applies to each domain. The specific specified application dates that apply to each PAC provider type and domain are described in section 1899B(a)(2)(E) of the Act.

B. System for Payment of Home Health Services

Generally, Medicare 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 no longer part of the national standardized 60-day episode rate and is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor (See section II.D.4.e). 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.

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 examined data on demographics, family severity, and non-HH Part A Medicare expenditures to predict the average case-mix weight for 2005. 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 casemix 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 casemix. 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 also required that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we were required to phase in any adjustment over a 4-year period in equal increments, not to exceed 3.5 percent of the 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 specified that the maximum rebasing adjustment was 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 as reflected in Table 2, 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.

TABLE 2—MAXIMUM ADJUSTMENTS TO THE NATIONAL PER-VISIT PAYMENT RATES

[Not to exceed 3.5 percent of the amount(s) in CY 2010]

	2010 National per-visit payment rates	Maximum adjustments per year (CY 2014 through CY 2017)
Skilled Nursing	\$113.01	\$3.96
Home Health Aide	51.18	1.79
Physical Therapy	123.57	4.32
Occupational Therapy	124.40	4.35
Speech-Language Pathology	134.27	4.70
Medical Social Services	181.16	6.34

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, we continued to apply 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.

III. Proposed Provisions of the Home Health Prospective Payment System

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

1. Analysis of FY 2014 HHA Cost Report

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. In the CY 2014 HH PPS final rule, using

2011 cost report and 2012 claims data, we estimated the 2013 60-day episode cost to be \$2,565.51 (78 FR 72277). In that final rule, we stated that our analysis of 2011 cost report data and 2012 claims data indicated a need for a -3.45 percent rebasing adjustment to the national, standardized 60-day episode payment rate each year for 4 years. However, as specified by statute, the rebasing adjustment is limited to 3.5 percent of the CY 2010 national, standardized 60-day episode payment rate of \$2,312.94 (74 FR 58106), or \$80.95. We stated that given that a -3.45 percent adjustment for CY 2014 through CY 2017 would result in larger dollar amount reductions than the maximum dollar amount allowed under section 3131(a) of the Affordable Care Act of \$80.95, we were limited to implementing a reduction of \$80.95 (approximately 2.8 percent of the standardized payment amount for CY 2014) to the national, standardized 60day episode payment amount each year for CY 2014 through CY 2017.

In the CY 2015 HH PPS final rule, (79 FR 66032–66118) using 2012 cost report and 2013 claims data, we estimated the 2013 60-day episode cost to be \$2,485.24 (79 FR 66037). Similar to our discussion in the CY 2014 HH PPS final rule, we stated that absent the Affordable Care Act's limit to rebasing, in order to align payments with costs, a –4.21 percent adjustment would have been applied to the national, standardized 60-day episode payment amount each year for CY 2014 through CY 2017.

In the CY 2016 HH PPS proposed rule (80 FR 39846–39866), using 2013 cost

report and 2013 claims data, we estimated the 2013 60-day episode cost to be \$2,402.11 (80 FR 39846). Similar to our discussion in the CY 2014 HH PPS final rule and the CY 2015 HH PPS final rule, we stated that absent the Affordable Care Act's limit to rebasing, in order to align payments with costs, a -5.02 percent adjustment would have been applied to the national, standardized 60-day episode payment amount each year for CY 2014 through CY 2017.

For this proposed rule, we analyzed 2014 HHA cost report data and 2014 HHA claims data to determine whether the average cost per episode was higher using 2014 cost report data compared to the 2011 cost report and 2012 claims da006used in calculating the rebasing adjustments. To determine the 2014 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 2014 cost reports by size, facility type, and urban/rural location so the costs per visit were nationally representative according to 2014 claims data. The 2014 average number of visits was taken from 2014 claims data. We estimate the cost of a 60-day episode in CY 2014 to be \$2,373.87 using 2014 cost report data (Table 3). Our latest analysis of 2014 cost report and 2014 claims data suggests that an even larger reduction (-5.30 percent) than the reduction described in the CY 2014 HH PPS final rule (-3.45 percent) or the reductions described in the CY 2015 HH PPS final rule and the CY 2016 HH PPS proposed rule (-4.21 and -5.02 percent,

respectively) would have been needed in order to align payments with costs. The decrease in the estimated 60-day episode cost from \$2,402.11 in CY 2013 to \$2,373.87 in CY 2014 was due to both a lower average cost per visit for skilled nursing and home health aide services in 2014 compared to 2013 and lower average number of visits for skilled nursing and home health aide services per episode in 2014 compared to 2013.

TABLE 3—2014 ESTIMATED COST PER EPISODE

Discipline	2014 Average costs per visit	2014 Average number of visits	2014 60-Day episode costs
Skilled Nursing Home Health Aide Physical Therapy	\$128.68 56.59 155.90	9.09 2.19 5.18	\$1,169.70 123.93 807.56
Occupational Therapy	153.69	1.30	199.80
Speech-Language Pathology Medical Social Services	166.98 210.48	0.26 0.14	43.41 29.47
Total		18.16	2,373.87

Source: FY 2014 Medicare cost report data and 2014 Medicare claims data from the standard analytic file (as of June 30, 2015) for episodes (excluding low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes) ending on or before December 31, 2014 for which we could link an OASIS assessment.

2. Analysis of CY 2015 HHA Claims Data

In the CY 2014 HH PPS final rule (78 FR 72256), some commenters expressed concern that the rebasing of the HH PPS payment rates would result in HHA closures and would therefore diminish access to home health services. In addition to examining more recent cost report data, for this proposed rule we examined home health claims data from the first 2 years (CY 2014 and CY 2015) of the 4-year phase-in of the rebasing adjustments (CY 2014 through CY 2017), the first calendar year of the HH PPS (CY 2001), and claims data for the 3 years before implementation of the rebasing adjustments (CY 2011-2013). Preliminary analysis of CY 2015 home

health claims data indicates that the number of episodes decreased by 3.8 percent from 2013 to 2014, and decreased by 1.7 percent from 2014 to 2015. In addition, the number of home health users that received at least one episode of care decreased by 2.95 percent between 2013 and 2014, and decreased slightly by 0.5 percent from 2014 to 2015. The number of FFS beneficiaries has remained the relatively constant between 2013 and 2015. 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, and a continued decrease of 2.7 percent from 2014 to 2015. We note that in CY 2015 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 before the implementation of the HH PPS methodology in 2001. The number of home health users, as a percentage of FFS beneficiaries, has been decreasing since 2011, from 9.2 percent to 8.7 percent in 2015. We would note that preliminary FFS data on per-enrollee hospital and skilled nursing facility discharges and days indicates that there was a decrease in hospital discharges of approximately 0.7 percent and a decrease in SNF days of approximately 0.9 percent in CY 2015. Any decreases in hospital discharges and skilled nursing facility days could, in turn, impact home health utilization as those settings serve as important sources of home health referrals.

TABLE 4—HOME HEALTH STATISTICS, CY 2001 AND CY 2011 THROUGH CY 2015

	2001	2011	2012	2013	2014	2015
Number of episodes Beneficiaries receiving at least 1 episode	3,896,502	6,821,459	6,727,875	6,708,923	6,451,283	6,340,932
(Home Health Users)	2,412,318	3,449,231	3,446,122	3,484,579	3,381,635	3,365,512
Part A and/or B FFS beneficiaries	34,899,167	37,686,526	38,224,640	38,505,609	38,506,534	38,592,533
Episodes per Part A and/or B FFS bene-						
ficiaries	0.11	0.18	0.18	0.17	0.17	0.16
Home health users as a percentage of						
Part A and/or B FFS beneficiaries	6.9%	9.2%	9.0%	9.0%	8.8%	8.7%
HHAs providing at least 1 episode	6,511	11,446	11,746	11,889	11,693	11,381
HHAs per 10,000 Part A and/or B FFS						
beneficiaries	1.9	3.0	3.1	3.1	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, and accessed on April 7, 2016 for CY 2015 data 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.

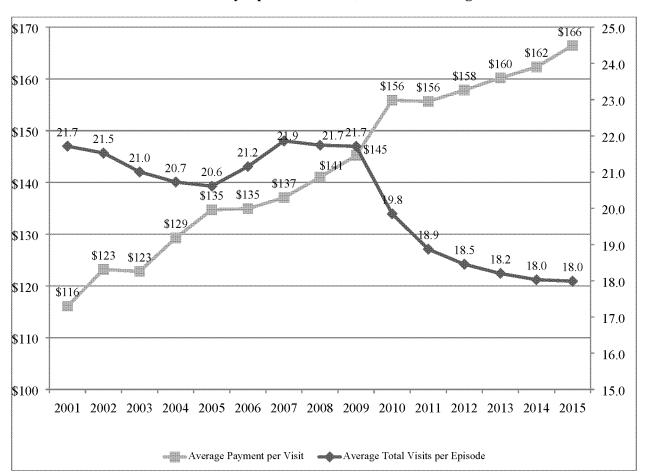
In addition to examining home health claims data from the first 2 years of the implementation of rebasing adjustments required by the Affordable Care Act and comparing utilization in those years (CY 2014 & CY 2015) to the 3 years prior to

and to the first calendar year following the implementation of the HH PPS (CY 2001), we subsequently examined trends in home health utilization for all years starting in CY 2001 and up through CY 2015. Figure 1, displays the average number of visits per 60-day episode of care and the average payment per visit. While the average payment per visit has steadily increased from approximately \$116 in CY 2001 to \$166 for CY 2015, 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. As noted in section II.C, we also implemented a series of reductions to the national, standardized 60-day episode payment rate to account for increases in nominal case-mix, starting in CY 2008. The reductions to the 60-day episode rate were: 2.75 percent each year for CY 2008, CY 2009, and CY 2010; 3.79 percent for CY 2011 and CY 2012; and a 1.32 percent payment reduction for CY 2013. Figure 2 displays the average number of visits by discipline type for a 60-day episode of care and shows that while the number of therapy visits per 60-day episode of care has increased steadily, the number of skilled nursing and home health aide visits have

decreased, between CY 2009 and CY 2015. Section III.F describes the results of the home health study required by section 3131(d) of the Affordable Care Act, which suggests that the current home health payment system may discourage HHAs from serving patients with clinically complex and/or poorly controlled chronic conditions who do not qualify for therapy but require a large number of skilled nursing visits. The home health study results seem to be consistent with the recent trend in the decreased number of visits per episode of care driven by decreases in skilled nursing and home health aide services evident in Figures 1 and 2. BILLING CODE 4120-01-P

Figure 1: Average Total Number of Visits and Average Payment per Visit for a Medicare Home Health 60-Day Episode of Care, CY 2001 through CY 2015



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.

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.

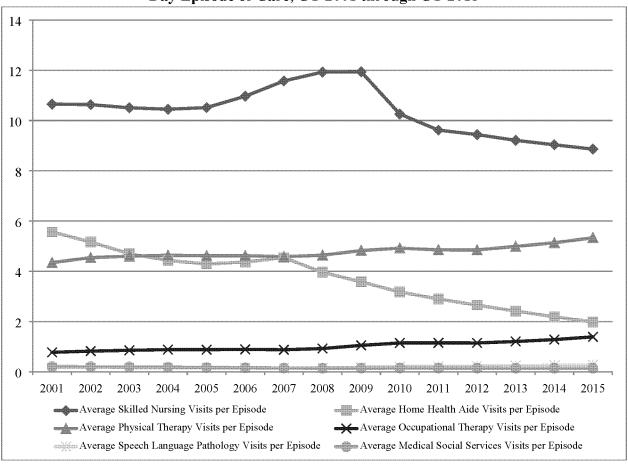


Figure 2: Average Number of Visits by Discipline Type for a Medicare Home Health 60-Day Episode of Care, CY 2001 through CY 2015

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.

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

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As part of our monitoring efforts, we also examined the trends in episode timing and service use over time. Currently, the first two 60-day episodes of care are considered "early" and third or later 60-day episodes of care are considered "late", as long as there is no more than a 60-day gap in care between one episode and the next. 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 2015. 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. Table 5 shows that the percentage of early and late episodes from CY 2008 to CY 2015 has remained relatively stable over time. There has been a slight decrease in the percentage of early episodes with 0 to 19 therapy visits from 65.9 percent in CY 2008 to 59.8 percent in ĈY 2015 and a slight increase in the percentage of late episodes with 0 to 19 therapy visits from 29.5 percent in CY 2008 to 33.5

percent in CY 2015. From CY 2014 to CY 2015, there was a slight decrease in the percentage of early and late episodes with 0 to 19 therapy visits and there was a slight increase in the percentage of episodes with 20+ therapy visits. In 2015, the case-mix weights for the third and later episodes of care with 0 to 19 therapy visits decreased as a result of the CY 2015 recalibration of the case-mix weights. Despite the decreases in the case-mix weights for the later episodes, the percentage of later episodes with 0 to 19 therapy visits did not change substantially.

TABLE 5—HOME HEALTH EPISODES BY EPISODE TIMING, CY 2008 THROUGH CY 2015

Year	All episodes	Number of early episodes (excluding episodes with 20+ visits)	% of early epi- sodes (excluding epi- sodes with 20+ visits)	Number of late episodes (excluding episodes with 20+ visits)	% of late episodes (excluding episodes with 20+ visits)	Number of episodes with 20+ visits	% of episodes with 20+ visits
2008	5,423,037	3,571,619	65.9	1,600,587	29.5	250,831	4.6
2009	6,530,200	3,701,652	56.7	2,456,308	37.6	372,240	5.7
2010	6,877,598	3,872,504	56.3	2,586,493	37.6	418,601	6.1
2011	6,857,885	3,912,982	57.1	2,564,859	37.4	380,044	5.5
2012	6,767,576	3,955,207	58.4	2,458,734	36.3	353,635	5.2
2013	6,733,146	4,023,486	59.8	2,347,420	34.9	362,240	5.4
2014	6,616,875	3,980,151	60.2	2,263,638	34.2	373,086	5.6
2015	6,340,931	3,789,676	59.8	2,123,485	33.5	427,770	6.7

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on April 7, 2016. **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 2015 (Figure 3). The percentage of first or only episodes with an acute admission source, defined as episodes with an inpatient hospital stay within the 14 days prior to a home health episode, has decreased from 38.6 percent in CY 2008 to 33.9 percent in CY 2015. 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 18.1 percent in CY 2015. The percentage of first or only episodes with a community admission source, defined as episodes which did not have an acute or post-acute stay in the 14 days prior to the home health episode, increased from 37.4 percent in CY 2008 to 41.9 percent in CY 2015. Our findings on the trends in admission source are

consistent to MedPAC's as outlined in their 2015 Report to the Congress.¹ However, 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."

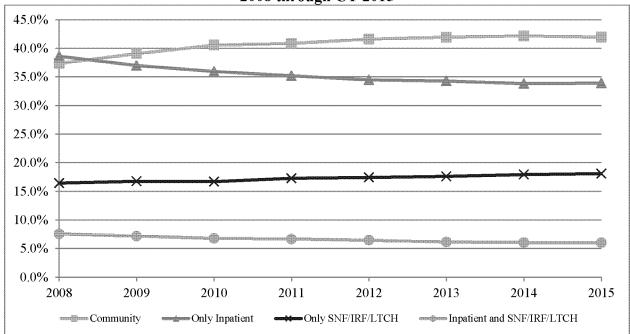


Figure 3: Home Health Episode Trends by Admission Source (First or Only Episodes), CY 2008 through CY 2015

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - Accessed on April 7, 2016.

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 2017 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 casemix 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 2017, 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 2017 HH PPS case-mix weights, we used CY 2015 home health claims data (as of December 31, 2015) with linked OASIS data. These data are the most current and complete data available at this time. We will use CY 2015 home health claims data (as of June 30, 2016) with linked OASIS data to generate the CY 2017 HH PPS case-mix weights in the CY 2017 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 2014 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 2015 home health claims data, are shown in Table 6. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

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TABLE 6: Case-Mix Adjustment Variables and Scores

		1			
	Episode number within sequence of adjacent episodes	or	1 or 2	3+	3+
	rr				
	Therapy visits	0-	14+	0-	14+
	• • • • • • • • • • • • • • • • • • • •	13		13	
	EQUATION:	1	2	3	4
-1	CLINICAL DIMENSION				
1	Primary or Other Diagnosis = Blindness/Low Vision				
2	Primary or Other Diagnosis = Blood disorders				
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms		5		5
4	Primary Diagnosis = Diabetes		3		2
5	• -		3		
3	Other Diagnosis = Diabetes Primary or Other Diagnosis = Dysphagia				
6	AND				
	Primary or Other Diagnosis = Neuro 3 – Stroke	2	18		12
	Primary or Other Diagnosis = Dysphagia				
7	AND				
,	M1030 (Therapy at home) = 3 (Enteral)	1	3		
8	Primary or Other Diagnosis = Gastrointestinal disorders				
	Primary or Other Diagnosis = Gastrointestinal disorders				
9	AND				
	M1630 (ostomy)= 1 or 2		5		
	Primary or Other Diagnosis = Gastrointestinal disorders				
	AND				
10	Primary or Other Diagnosis = Neuro 1 - Brain disorders and				
	paralysis, <i>OR</i> Neuro 2 - Peripheral neurological disorders, <i>OR</i>				
4.4	Neuro 3 - Stroke, <i>OR</i> Neuro 4 - Multiple Sclerosis				
11	Primary or Other Diagnosis = Heart Disease OR Hypertension				
12	Primary Diagnosis = Neuro 1 - Brain disorders and paralysis	3	12	7	9
	Primary or Other Diagnosis = Neuro 1 - Brain disorders and				
13	paralysis		4		4
	$\begin{array}{c} AND \\ M1840 \text{ (Toilet transfer)} = 2 \text{ and make } \end{array}$				
	M1840 (Toilet transfer) = 2 or more				
	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis <i>OR</i> Neuro 2 - Peripheral neurological disorders				
14	AND				
	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3				
15	Primary or Other Diagnosis = Neuro 3 - Stroke	2	10	1	3
	Primary or Other Diagnosis = Neuro 3 - Stroke <i>AND</i>	_			
16	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3				
	Primary or Other Diagnosis = Neuro 3 - Stroke				
17	AND				
	M1860 (Ambulation) = 4 or more				
					<u> </u>

		1	1		
	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
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		8		
19	Primary or Other Diagnosis = Ortho 1 - Leg Disorders or Gait Disorders AND M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4	7		7	
20	Primary or Other Diagnosis = Ortho 1 - Leg OR Ortho 2 - Other orthopedic disorders AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	2		2	
21	Primary or Other Diagnosis = Psych 1 – Affective and other psychoses, depression	2	4		2
22	Primary or Other Diagnosis = Psych 2 - Degenerative and other organic psychiatric disorders	1	1		
23	Primary or Other Diagnosis = Pulmonary disorders	1			3
24	Primary or Other Diagnosis = Pulmonary disorders <i>AND</i> M1860 (Ambulation) = 1 or more		3		
25	Primary Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications	5	19	5	11
26	Other Diagnosis = Skin 1 - Traumatic wounds, burns, post- operative complications	5	9	5	9
27	Primary or Other Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications <i>OR</i> Skin 2 – Ulcers and other skin conditions <i>AND</i> M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	2			
28	Primary or Other Diagnosis = Skin 2 - Ulcers and other skin conditions	1	14	6	14
29	Primary or Other Diagnosis = Tracheostomy	3	15	3	15
30	Primary or Other Diagnosis = Urostomy/Cystostomy		18		13
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	1	18	6	18
32	M1030 (Therapy at home) = 3 (Enteral)		19		12
33	M1200 (Vision) = 1 or more				

Episode number within sequence of adjacent episodes 2 1 1 or 0 2 3 + 3 + 3 + 3 +						
Therapy visits 13 14+ 13 14+ 13 14+ 13 14+ 13 14+ 13 14+ 13 34		Episode number within sequence of adjacent episodes	or		3+	3+
34 M1242 (Pain)= 3 or 4 3 1 35 M1308 = Two or more pressure ulcers at stage 3 or 4 6 10 6 10 36 M1324 (Most problematic pressure ulcer stage)= 1 or 2 4 20 7 16 37 M1324 (Most problematic pressure ulcer stage)= 3 or 4 9 31 11 25 38 M1334 (Stasis ulcer status)= 2 5 22 12 22 39 M1334 (Stasis ulcer status)= 3 8 23 14 23 40 M1342 (Surgical wound status)= 3 6 7 12 41 M1342 (Surgical wound status)= 3 6 7 12 42 M1400 (Dyspnea) = 2, 3, or 4 4 3 43 M1620 (Bowel Incontinence) = 2 to 5 4 3 44 M1630 (Ostomy)= 1 or 2 4 12 2 45 M2030 (Injectable Drug Use) = 0, 1, 2, or 3 1 1 46 M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3 1 1 47 M1830 (Bathing) = 2 or more 6 6 5 2 48		Therapy visits	-	14+	l ĭ	14+
35 M1308 = Two or more pressure ulcers at stage 3 or 4 6 10 6 10 36 M1324 (Most problematic pressure ulcer stage) = 1 or 2 4 20 7 16 37 M1324 (Most problematic pressure ulcer stage) = 3 or 4 9 31 11 25 38 M1334 (Stasis ulcer status) = 2 5 22 12 22 39 M1334 (Stasis ulcer status) = 3 8 23 14 23 40 M1342 (Surgical wound status) = 2 2 8 7 13 41 M1342 (Surgical wound status) = 3 6 7 12 42 M1400 (Dyspnea) = 2, 3, or 4		EQUATION:	1	2	3	4
36 M1324 (Most problematic pressure ulcer stage)= 1 or 2 4 20 7 16 37 M1324 (Most problematic pressure ulcer stage)= 3 or 4 9 31 11 25 38 M1334 (Stasis ulcer status)= 2 5 22 12 22 39 M1334 (Stasis ulcer status)= 3 8 23 14 23 40 M1342 (Surgical wound status)= 2 2 8 7 13 41 M1342 (Surgical wound status)= 3 6 7 12 42 M1400 (Dyspnea) = 2, 3, or 4	34	M1242 (Pain)= 3 or 4	3		1	
37 M1324 (Most problematic pressure ulcer stage)= 3 or 4 9 31 11 25 38 M1334 (Stasis ulcer status)= 2 5 22 12 22 39 M1334 (Stasis ulcer status)= 3 8 23 14 23 40 M1342 (Surgical wound status)= 2 2 8 7 13 41 M1342 (Surgical wound status)= 3 6 7 12 42 M1400 (Dyspnea) = 2, 3, or 4 4 3 43 M1620 (Bowel Incontinence) = 2 to 5 4 3 44 M1630 (Ostomy)= 1 or 2 4 12 2 45 M2030 (Injectable Drug Use) = 0, 1, 2, or 3 1 1 FUNCTIONAL DIMENSION 46 M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3 1 1 47 M1830 (Bathing) = 2 or more 6 6 5 2 48 M1840 (Toilet transferring) = 2 or more 1 3 1 49 M1850 (Transferring) = 2 or more 3 2 50 M1860 (Ambulation) = 1, 2 or 3 7 4	35	M1308 = Two or more pressure ulcers at stage 3 or 4	6	10	6	10
38 M1334 (Stasis ulcer status)= 2 39 M1334 (Stasis ulcer status)= 3 40 M1342 (Surgical wound status)= 2 41 M1342 (Surgical wound status)= 3 42 M1400 (Dyspnea) = 2, 3, or 4 43 M1620 (Bowel Incontinence) = 2 to 5 44 M1630 (Ostomy)= 1 or 2 45 M2030 (Injectable Drug Use) = 0, 1, 2, or 3 FUNCTIONAL DIMENSION 46 M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3 47 M1830 (Bathing) = 2 or more 48 M1840 (Toilet transferring) = 2 or more 49 M1850 (Transferring) = 2 or more 50 M1860 (Ambulation) = 1, 2 or 3 7 4 4	36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	4	20	7	16
39 M1334 (Stasis ulcer status)= 3 40 M1342 (Surgical wound status)= 2 41 M1342 (Surgical wound status)= 3 42 M1400 (Dyspnea) = 2, 3, or 4 43 M1620 (Bowel Incontinence) = 2 to 5 44 M1630 (Ostomy)= 1 or 2 45 M2030 (Injectable Drug Use) = 0, 1, 2, or 3 FUNCTIONAL DIMENSION 46 M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3 47 M1830 (Bathing) = 2 or more 48 M1840 (Toilet transferring) = 2 or more 49 M1850 (Transferring) = 2 or more 50 M1860 (Ambulation) = 1, 2 or 3 7 4 4	37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	9	31	11	25
40 M1342 (Surgical wound status)= 2	38	M1334 (Stasis ulcer status)= 2	5	22	12	22
41 M1342 (Surgical wound status)= 3 6 7 12 42 M1400 (Dyspnea) = 2, 3, or 4 4 3 43 M1620 (Bowel Incontinence) = 2 to 5 4 12 2 8 44 M1630 (Ostomy)= 1 or 2 4 12 2 8 45 M2030 (Injectable Drug Use) = 0, 1, 2, or 3 1 1 1 FUNCTIONAL DIMENSION 46 M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3 1 1 1 47 M1830 (Bathing) = 2 or more 6 6 5 2 48 M1840 (Toilet transferring) = 2 or more 1 3 1 49 M1850 (Transferring) = 2 or more 3 2 50 M1860 (Ambulation) = 1, 2 or 3 7 4	39	M1334 (Stasis ulcer status)= 3	8	23	14	23
42 M1400 (Dyspnea) = 2, 3, or 4 43 M1620 (Bowel Incontinence) = 2 to 5 44 M1630 (Ostomy)= 1 or 2 45 M2030 (Injectable Drug Use) = 0, 1, 2, or 3 FUNCTIONAL DIMENSION 46 M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3 47 M1830 (Bathing) = 2 or more 48 M1840 (Toilet transferring) = 2 or more 49 M1850 (Transferring) = 2 or more 50 M1860 (Ambulation) = 1, 2 or 3 7 4	40	M1342 (Surgical wound status)= 2	2	8	7	13
43 M1620 (Bowel Incontinence) = 2 to 5 4 3 44 M1630 (Ostomy) = 1 or 2 4 12 2 8 45 M2030 (Injectable Drug Use) = 0, 1, 2, or 3 1 1 1 FUNCTIONAL DIMENSION 46 M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3 1 1 1 47 M1830 (Bathing) = 2 or more 6 6 5 2 48 M1840 (Toilet transferring) = 2 or more 1 3 1 49 M1850 (Transferring) = 2 or more 3 2 50 M1860 (Ambulation) = 1, 2 or 3 7 4	41	M1342 (Surgical wound status)= 3		6	7	12
44 M1630 (Ostomy)= 1 or 2 4 12 2 8 45 M2030 (Injectable Drug Use) = 0, 1, 2, or 3	42	M1400 (Dyspnea) = 2, 3, or 4				
45 M2030 (Injectable Drug Use) = 0, 1, 2, or 3 FUNCTIONAL DIMENSION 46 M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3 1 1 47 M1830 (Bathing) = 2 or more 6 6 5 2 48 M1840 (Toilet transferring) = 2 or more 1 3 1 49 M1850 (Transferring) = 2 or more 3 2 50 M1860 (Ambulation) = 1, 2 or 3 7 4	43	M1620 (Bowel Incontinence) = 2 to 5		4		3
FUNCTIONAL DIMENSION 46 M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3 1 1 47 M1830 (Bathing) = 2 or more 6 6 5 2 48 M1840 (Toilet transferring) = 2 or more 1 3 1 49 M1850 (Transferring) = 2 or more 3 2 50 M1860 (Ambulation) = 1, 2 or 3 7 4	44	M1630 (Ostomy)= 1 or 2	4	12	2	8
46 M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3 1 1 47 M1830 (Bathing) = 2 or more 6 6 5 2 48 M1840 (Toilet transferring) = 2 or more 1 3 1 49 M1850 (Transferring) = 2 or more 3 2 50 M1860 (Ambulation) = 1, 2 or 3 7 4						
47 M1830 (Bathing) = 2 or more 6 6 5 2 48 M1840 (Toilet transferring) = 2 or more 1 3 1 49 M1850 (Transferring) = 2 or more 3 2 50 M1860 (Ambulation) = 1, 2 or 3 7 4	FUNCTION	AL DIMENSION				
48 M1840 (Toilet transferring) = 2 or more 1 3 1 49 M1850 (Transferring) = 2 or more 3 2 50 M1860 (Ambulation) = 1, 2 or 3 7 4	46	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	1		1	
49 M1850 (Transferring) = 2 or more 3 2 50 M1860 (Ambulation) = 1, 2 or 3 7 4	47	M1830 (Bathing) = 2 or more	6	6	5	2
50 M1860 (Ambulation) = 1, 2 or 3 7 4	48	M1840 (Toilet transferring) = 2 or more	1	3		1
1,11000 (1,111000) 1,2013	49	M1850 (Transferring) = 2 or more	3		2	
51 M1860 (Ambulation) = 4 or more 8 10 7 9	50	M1860 (Ambulation) = 1, 2 or 3	7		4	
	51	M1860 (Ambulation) = 4 or more	8	10	7	9

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of December 31, 2015) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Note(s): Points are additive, however, points may not be given for the same line item in the table more than once.

Please see Medicare Home Health Diagnosis Coding guidance at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding billing.html for definitions of primary and secondary diagnoses.

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In updating the four-equation model for CY 2017, using 2015 home health claims data (the last update to the fourequation model for CY 2016 used CY 2014 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 2014 and CY 2015. The CY 2017 four-equation model resulted in 110 point-giving variables being used in the model (as compared to the 124 variables for the CY 2016 recalibration). There were ten variables that were added to the model and 24 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 2016 and the four-equation model for CY 2017, the points for 37 variables increased in the CY 2017 four-equation model and the points for 38 variables decreased in the CY 2017 4-equation model. There were 25 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 2017 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.
- ullet 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.² 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 of the CY 2017 four-equation model points are shown in Table 7.

TABLE 7—CY 2017 CLINICAL AND FUNCTIONAL THRESHOLDS

		1st and 2n	d Episodes	3rd+ E	3rd+ 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	2.1	3	2.2	4. (2&4).	
Dimension	Severity level.						
Clinical	C1 C2 C3	2 to 3	0 to 1 2 to 7 8+	1	0 to 1 2 to 9	0 to 3. 4 to 17. 18+.	
Functional	F1 F2 F3	0 to 13 14	0 to 7	0 to 6 7 to 10	0 1 to 11	0 to 2. 3 to 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 8 shows the regression coefficients for the variables in the payment regression model updated with CY 2015 home health claims data. The R-squared value for the payment regression model is 0.4919 (an increase from 0.4822 for the CY 2016 recalibration).

TABLE 8—PAYMENT REGRESSION MODEL

Variable description	New payment regression coefficients
Step 1, Clinical Score Me-	\$25.75
Step 1, Clinical Score High Step 1, Functional Score Me-	60.84
diumStep 1, Functional Score	71.60
High	108.83

 $^{^2}$ For Step 1, 62% of episodes were in the medium functional level (All with score 14).

TABLE 8—PAYMENT REGRESSION MODEL—Continued

New payment

Variable description	regression coefficients
Step 2.1, Clinical Score Me-	
dium	53.35
Step 2.1, Clinical Score High	129.94
Step 2.1, Functional Score	
Medium	11.54
Step 2.1, Functional Score	
High	67.03
Step 2.2, Clinical Score Me-	
dium	33.94
Step 2.2, Clinical Score High	188.53
Step 2.2, Functional Score	
Medium	0.31
Step 2.2, Functional Score	22.24
High	63.34
Step 3, Clinical Score Me-	0.05
diumStep 3, Clinical Score High	9.35 95.01
Step 3, Clinical Score High Step 3, Functional Score Me-	95.01
dium	56.44
Step 3, Functional Score	30.44
High	88.01
Step 4, Clinical Score Me-	00.01
dium	76.63
Step 4, Clinical Score High	261.74
Step 4, Functional Score Me-	
dium	22.89
Step 4, Functional Score	
High	73.10
Step 2.1, 1st and 2nd Epi-	
sodes, 14 to 19 Therapy	
Visits	498.19
Step 2.2, 3rd+ Episodes, 14	
to 19 Therapy Visits	515.73

For Step 2.2, 83.2% of episodes were in the medium functional level (Most with score 2 or 3). For Step 3, 51.3% of episodes were in the medium functional level (Most with score 10).

TABLE 8—PAYMENT REGRESSION MODEL—Continued

Variable description	New payment regression coefficients
Step 3, 3rd+ Episodes, 0–13 Therapy Visits Step 4, All Episodes, 20+	-73.96
Therapy Visits	906.64
Intercept	393.43

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of December 31, 2015) 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 wageweighted 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

For Step 2.1, 71.0% of episodes were in the low functional level (Most with score 6).

For Step 4, 54.4% of episodes were in the medium functional level (Most with score 6).

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.³

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 casemix for the weights is equal to 1.0000.⁴ This last step creates the proposed CY 2017 case-mix weights shown in Table 9.

TABLE 9—PROPOSED CY 2017 CASE-MIX PAYMENT WEIGHTS

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2017 weights
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5972
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.7322
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8671
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	1.0021
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.1370
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.7059
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.8224
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9389
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0554
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1719
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7624
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8835
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	1.0045
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.1255
10135	1st and 2nd Episodes, 10 Thorapy Visits	C1F3S5	1.2466
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.6363
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7787
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.9210
10214	1st and 2nd Episodes, 7 to 5 Hierapy Visits	C2F1S4	1.0634
10215	1st and 2nd Episodes, 10 Therapy Visits	C2F1S5	1.2057
10221	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S1	0.7450
10227	1st and 2nd Episodes, 6 to 3 Therapy Visits	C2F2S2	0.7430
10223	1st and 2nd Episodes, 8 Therapy Visits	C2F2S2	0.8689
10224		C2F2S3	1.1167
10225	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	_
	1st and 2nd Episodes, 11 to 13 Therapy Visits		1.2406
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.8015
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.9300
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	1.0584
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1868
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.3153
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6896
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.8431
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9967
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.1502
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3038
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7983
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.9334
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0685
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.2036
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3387
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.8548
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9944
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1341
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.2737
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4133

³ Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Medicare Payment Policy. March 2011, P. 176.

⁴ 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 9—PROPOSED CY 2017 CASE-MIX PAYMENT WEIGHTS—Continued

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2017 weights
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2720
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4503
21113 21121	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3 C1F2S1	1.6287 1.2884
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4719
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6554
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3676
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5480
21133 21211	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3 C2F1S1	1.7283 1.3481
21212	1st and 2nd Episodes, 14 to 13 Therapy Visits	C2F1S2	1.5366
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.7251
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3645
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5582
21223 21231	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3 C2F3S1	1.7518 1.4437
21232	1st and 2nd Episodes, 14 to 13 Therapy Visits	C2F3S2	1.6342
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.8247
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4573
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6952
21313 21321	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3 C3F2S1	1.9330 1.4738
21322	1st and 2nd Episodes, 14 to 13 Therapy Visits	C3F2S2	1.7168
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9597
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5530
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.7928
21333 22111	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3 C1F1S1	2.0326 1.2970
22112	3rd+ Episodes, 14 to 13 Therapy Visits	C1F1S1	1.4670
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.6370
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2974
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4779
22123 22131	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3 C1F3S1	1.6584 1.3873
22132	3rd+ Episodes, 14 to 13 Therapy Visits 3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S1	1.5611
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.7349
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3454
22212	3rd+ Episodes, 16 to 17 Therapy Visits		1.5348
22213 22221	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3 C2F2S1	1.7242 1.3458
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5457
22223	3rd+ Episodes, 18 to 19 Therapy Visits		1.7455
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.4358
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.6289
22233 22311	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3 C3F1S1	1.8220 1.5659
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.7676
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9692
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5664
22322 22323	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2 C3F2S3	1.7785 1.9906
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.6563
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8617
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0671
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4850
30112 30113	3rd+ Episodes, 6 Therapy Visits	C1F1S2 C1F1S3	0.6474 0.8098
30114	3rd+ Episodes, 7 to 9 merapy visits	C1F1S4	0.8098
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.1346
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5706
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.7160
30123 30124	3rd+ Episodes, 7 to 9 Therapy Visits 3rd+ Episodes, 10 Therapy Visits	C1F2S3 C1F2S4	0.8614 1.0067
30125	3rd+ Episodes, 10 Therapy Visits	C1F2S5	1.1521
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6186
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7723
30133	3rd+ Episodes, 7 to 9 Therapy Visits		0.9261
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0798

TABLE 9—PROPOSED CY 2017 CASE-MIX PAYMENT WEIGHTS—Continued

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2017 weights
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2336
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4992
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6684
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8377
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	1.0069
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1761
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5848
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7370
30223	3rd+ Episodes, 7 to 9 Therapy Visits		0.8892
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0414
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1936
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6328
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7934
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9540
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.1146
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2752
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6292
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.8165
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	1.0039
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1912
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3786
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7149
30322	3rd+ Episodes, 6 Therapy Visits		0.8852
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0555
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.2258
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3961
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7628
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.9415
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1202
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.2989
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4776
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.8071
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.8389
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.9087
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.9136
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.9454
40231	All Episodes, 20+ Therapy Visits		2.0152
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.1709
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.2027
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.2725

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 2017 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 2017 HH PPS case-mix weights (developed using CY 2015 home health claims data) are applied to CY 2015 utilization (claims) data to total payments when CY 2016 HH PPS case-mix weights (developed using CY 2014 home health claims data) are applied to CY 2015 utilization data. This produces a case-mix budget neutrality factor for CY 2017 of 1.0062, based on CY 2015 claims data as of December 31, 2015.

C. Proposed CY 2017 Home Health Payment Rate Update

1. Proposed CY 2017 Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2017 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 67080–67090).

Section 3401(e) of the Affordable Care Act, adding new section 1895(b)(3)(B)(vi) to the Act, requires that, in CY 2015 (and in subsequent

calendar years), 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. The statute defines the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act, 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.

Using IHS Global Insight's (IGI) first guarter 2016 forecast, the MFP adjustment for CY 2017 (the 10-year moving average of MFP for the period ending CY 2017) is projected to be 0.5 percent. Thus, in accordance with section 1895(b)(3)(B)(iii) of the Act, we propose to base the CY 2017 market basket update, which is used to determine the applicable percentage increase for the HH payments, on the most recent estimate of the proposed 2010-based HH market basket (currently estimated to be 2.8 percent based on IGI's first quarter 2016 forecast). We propose to then reduce this percentage increase by the current estimate of the MFP adjustment for CY 2017 of 0.5 percentage point (the 10-year moving average of MFP for the period ending CY 2017 based on IGI's first quarter 2016 forecast), in accordance with 1895(b)(3)(B)(vi). Therefore, the current estimate of the CY 2017 HH payment update is 2.3 percent (2.8 percent market basket update, less 0.5 percentage point MFP adjustment). Furthermore, we note that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data to determine the CY 2017 market basket update and MFP adjustment in the final rule.

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 2017, the home health payment update would be 0.3 percent (2.3 percent minus 2 percentage points).

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2. Proposed CY 2017 Home Health Wage Index

a. Background

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 2017, 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, prereclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2017, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013 (FY 2013 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).

b. Updates

Previously, we determined each HHA's labor market area based on definitions of metropolitan statistical areas (MSAs) issued by the Office of Management and Budget (OMB). In the CY 2006 HH PPS final rule (70 FR 68132), we adopted revised labor market area definitions as discussed in the OMB Bulletin No. 03-04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of micropolitan statistical areas and corebased statistical areas (CBSAs). The bulletin is available online at www.whitehouse.gov/omb/bulletins/ b03-04.html.

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. This bulletin is available online at http:// www.whitehouse.gov/sites/default/files/ omb/bulletins/2013/b-13-01.pdf. This bulletin states that it "provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the Federal Register (75 FR 37246-37252) and Census Bureau data."

While the revisions OMB published on February 28, 2013 are not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2006, the February 28, 2013 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart.

In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we finalized changes to the HH PPS wage index based on the OMB delineations, as described in OMB Bulletin No. 13–01. In CY 2015, we included a one-year transition to those delineations by using a blended wage index for CY 2015.

The OMB's most recent update to the geographic area delineations was published on July 15, 2015 in OBM bulletin 15–01. This bulletin is available online at https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/15-01.pdf. The revisions to the delineations that affect the HH PPS are changes to CBSA titles and the addition of CBSA 21420, Enid, Oklahoma. CBSA 21420 encompasses Garfield County, Oklahoma.

In order 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 2017 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 CBSAs as a reasonable proxy. For FY 2017, there are no rural geographic areas without hospitals for which we would apply this policy. 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 2017, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980).

The proposed CY 2017 wage index is available on the CMS Web site at http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html

3. Proposed CY 2017 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 42 CFR 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 2017 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.C. 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 casemix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments.

Ín accordance with section 1895(b)(3)(B) of the Act, this document constitutes 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 two 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 wageadjusted 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 casemix 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 pervisit 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 2017 National, Standardized 60-Day Episode Payment

Section 1895(3)(A)(i) of the Act required 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 2017 national, standardized 60-day episode payment rate, we would apply a wage index standardization factor, a case-mix budget neutrality factor described in section III.B, 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), the rebasing adjustment described in section II.C, and the MFP-adjusted home health market basket update

discussed in section III.C.1 of this proposed rule.

To calculate the wage index standardization factor, henceforth referred to as the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the proposed CY 2017 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2016 wage index. By dividing the total payments for non-LUPA episodes using the proposed CY 2017 wage index by the total payments for non-LUPA episodes using the CY 2016 wage index, we obtain a wage index budget neutrality factor of 0.9990. We would apply the wage index budget neutrality factor of 0.9990 to the proposed CY 2017 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 2017 national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2017 case-mix weights are applied to CY 2015 utilization (claims) data to total payments when CY 2016 case-mix weights are applied to CY 2015 utilization data. The case-mix budget neutrality factor for CY 2017 would be 1.0062 as described in section III.B.1 of this proposed rule.

Next, as discussed in the CY 2016 HH PPS final rule (80 FR 68646), we would apply a reduction of 0.97 percent to the national, standardized 60-day episode payment rate in CY 2017 to account for nominal case-mix growth between CY 2012 and CY 2014. Then, we would apply the -\$80.95 rebasing adjustment finalized in the CY 2014 HH PPS final rule (78 FR 72256), and discussed in section II.C. Lastly, we would update the proposed payment rates by the proposed CY 2017 HH payment update percentage of 2.3 percent (MFP-adjusted home health market basket update) as described in section III.C.1 of this proposed rule. The proposed CY 2017 national, standardized 60-day episode payment rate is calculated in Table 10.

TABLE 10—PROPOSED CY 2017 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2016 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)	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update	Proposed CY 2017 national, standardized 60-day episode payment
\$2,965.12	× 0.9990	× 1.0062	× 0.9903	-\$80.95	1.023	\$2,936.68

The proposed CY 2017 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the proposed CY 2017 HH payment update (2.3 percent) minus 2 percentage points and is shown in Table 11.

TABLE 11—PROPOSED CY 2017 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2016 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)	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update minus 2 percentage points	Proposed CY 2017 national, standardized 60-day episode payment
\$2,965.12	× 0.9990	× 1.0062	× 0.9903	-\$80.95	× 1.003	\$2,879.27

c. Proposed CY 2017 National Per-Visit

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 2017 national per-visit rates, we start with the

CY 2016 national per-visit rates. We then apply a wage index budget neutrality factor to ensure budget

neutrality for LUPA per-visit payments and then we increase each of the six per-visit rates by the maximum rebasing adjustments described in section II.C. of this rule. We calculate the wage index budget neutrality factor by simulating total payments for LUPA episodes using the proposed CY 2017 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2016 wage index. By dividing the total payments for LUPA episodes using the proposed CY 2017 wage index by the total payments for LUPA episodes using the CY 2016 wage index, we obtain a wage index budget neutrality factor of 0.9998. We would apply the wage index budget neutrality factor of 0.9998 in order to calculate the CY 2017 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. Finally, the per-visit rates for each discipline are updated by the proposed CY 2017 HH payment update percentage of 2.3 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 addon 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 2017 national per-visit rates are shown in Tables 12 and 13.

TABLE 12: PROPOSED CY 2017 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH Discipline type	CY 2016 per- visit payment	Wage index budget neutrality factor	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update	Proposed CY 2017 per-visit payment
Home Health Aide Medical Social Services Occupational Therapy Physical Therapy Skilled Nursing Speech Language Pathology	215.47 147.95 146.95 134.42	× 0.9998 × 0.9998 × 0.9998 × 0.9998 × 0.9998	+ 6.34 + 4.35 + 4.32 + 3.96	× 1.023 × 1.023 × 1.023 × 1.023	\$64.09 226.87 155.77 154.72 141.54 168.16

The proposed CY 2017 per-visit payment rates for an HHA that does not submit the required quality data are

updated by the proposed CY 2017 HH payment update percentage (2.3

percent) minus 2 percentage points and is shown in Table 13.

TABLE 13—PROPOSED CY 2017 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline type	CY 2016 per- visit rates	Wage index budget neutrality factor	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment up- date minus 2 percentage points	Proposed CY 2017 per-visit rates
Home Health Aide	\$60.87	× 0.9998	+ \$1.79	× 1.003	\$62.84
Medical Social Services	215.47	× 0.9998	+ 6.34	× 1.003	222.43
Occupational Therapy	147.95	× 0.9998	+ 4.35	× 1.003	152.73
Physical Therapy	146.95	× 0.9998	+ 4.32	× 1.003	151.69
Skilled Nursing	134.42	× 0.9998	+ 3.96	× 1.003	138.77
Speech Language Pathology	159.71	× 0.9998	+ 4.70	× 1.003	164.87

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, 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 \$261.16 (1.8451 multiplied by \$141.54), subject to area wage adjustment.

e. Proposed CY 2017 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 2017 NRS conversion factor, we start with the CY 2016 NRS conversion factor (\$52.71) and apply the -2.82 percent rebasing adjustment described in section II.C. of this rule (1-0.0282 = 0.9718). We then update the conversion factor by the proposed CY 2017 HH payment update percentage (2.3 percent). We do not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or casemix adjusted when the final claim payment amount is computed. The proposed NRS conversion factor for CY 2017 is shown in Table 14.

TABLE 14—PROPOSED CY 2017 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2016 NRS conversion factor	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update	Proposed CY 2017 NRS conversion factor
\$52.71	× 0.9718	× 1.023	\$52.40

Using the CY 2015 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 15.

TABLE 15—PROPOSED CY 2017 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 0.9742 2.6712 3.9686 6.1198 10.5254	\$14.14 51.05 139.97 207.95 320.68 551.53

For HHAs that do not submit the required quality data, we begin with the CY 2016 NRS conversion factor (\$52.71) and apply the -2.82 percent rebasing adjustment discussed in section II.C of

this proposed rule (1–0.0282 = 0.9718). We then update the NRS conversion factor by the proposed CY 2017 HH payment update percentage (2.3 percent) minus 2 percentage points. The

proposed CY 2017 NRS conversion factor for HHAs that do not submit quality data is shown in Table 16.

TABLE 16—PROPOSED CY 2017 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY
DATA

CY 2015 NRS Conversion factor	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update percentage minus 2 percentage Points	Proposed CY 2017 NRS conversion factor
\$52.71	× 0.9718	× 1.003	\$51.38

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 17.

TABLE 17—PROPOSED CY 2017 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed CY 2017 NRS payment amounts
1	0	0.2698 0.9742 2.6712 3.9686 6.1198 10.5254	\$13.86 50.05 137.25 203.91 314.44 540.80

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 Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Public Law 114–10) amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018.

Section 421 of the MMA, as amended, waives budget neutrality related to this provision, as the statute specifically states that the Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Act applicable to HH services furnished during a period to offset the increase in payments resulting in the application of this section of the statute.

For CY 2017, home health payment rates for services provided to beneficiaries in areas that are defined as rural under the OMB delineations would be increased by 3 percent as mandated by section 210 of the MACRA. The 3 percent rural add-on is applied to the national, standardized 60-day episode payment rate, national per visit rates, and NRS conversion factor when HH services are provided in rural (non-CBSA) areas. Refer to Tables 18 through 21 for these payment rates.

TABLE 18—PROPOSED CY 2017 PAYMENT AMOUNTS FOR 60-DAY EPISODES FOR SERVICES PROVIDED IN A RURAL AREA

For HHAs that DO submit qualit	y data		For HHAs that DO NOT submit quality data			
Proposed CY 2017 national, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural national, standardized 60-day episode payment rate	Proposed CY 2017 national, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural national, standardized 60-day episode payment rate	
\$2,936.68	× 1.03	\$3,024.78	\$2,879.27	× 1.03	\$2,965.65	

TABLE 19—PROPOSED CY 2017 PER-VISIT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

	For HHA	As that DO submit qua	ality data	For HHAs that DO NOT submit quality data			
HH Discipline type	Proposed CY 2017 per-visit rate	Multiply by the 3 percent rural add- on	Proposed CY 2017 rural per-visit rates	Proposed CY 2017 per-visit rate	Multiply by the 3 percent rural addon	Proposed CY 2017 rural per-visit rates	
HH Aide	\$64.09 226.87 155.77 154.72 141.54 168.16	× 1.03 × 1.03 × 1.03 × 1.03 × 1.03 × 1.03	\$66.01 233.68 160.44 159.36 145.79 173.20	\$62.84 222.43 152.73 151.69 138.77 164.87	× 1.03 × 1.03 × 1.03 × 1.03 × 1.03 × 1.03	\$64.73 229.10 157.31 156.24 142.93 169.82	

TABLE 20—PROPOSED CY 2017 NRS CONVERSION FACTORS FOR SERVICES PROVIDED IN A RURAL AREA

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
Proposed CY 2017 conversion factor	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural NRS conversion factor	Proposed CY 2017 conversion factor	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural NRS conversion factor
\$52.40	× 1.03	\$53.97	\$51.38	× 1.03	\$52.92

TABLE 21—PROPOSED CY 2017 NRS PAYMENT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

	1 to 14		at DO submit y data	For HHAs that DO NOT submit quality data		
Severity level	Points (scoring)	Relative weight	Proposed CY 2017 NRS payment amounts for rural areas	Relative weight	Proposed CY 2017 NRS payment amounts for rural areas	
1	1 to 14	0.2698 0.9742 2.6712 3.9686 6.1198 10.5254	\$14.56 52.58 144.16 214.19 330.29 568.06	0.2698 0.9742 2.6712 3.9686 6.1198 10.5254	\$14.28 51.55 141.36 210.02 323.86 557.00	

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 national, standardized 60-day case-mix and wage-adjusted episode payment amounts in the case of episodes that incur unusually high costs due to patient care needs. 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 is the sum of the national wage-adjusted per-visit payment amounts for all visits 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 fixeddollar 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), 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 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 re-designating 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 subparagraph (B) 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.

2. Proposed Changes to the Methodology Used To Estimate Episode Cost

As stated earlier, an episode's estimated cost is determined by multiplying the national wage-adjusted per-visit payment amounts by discipline by the number of visits by discipline reported on the home health claim. An episode's estimated cost is then used to

determine whether an episode will receive an outlier payment and the amount of the outlier payment. Analysis of CY 2015 home health claims data indicates that there is significant variation in the visit length by discipline for outlier episodes. Those agencies with 10 percent of their total payments as outlier payments are providing shorter but more frequent skilled nursing visits than agencies with less than 10 percent of their total payments as outlier payments (see Table 22).

TABLE 22—AVERAGE NUMBER AND LENGTH OF SKILLED NURSING VISITS BY THE PERCENTAGE OF OUTLIER PAYMENTS TO TOTAL PAYMENTS AT THE AGENCY LEVEL (CURRENT OUTLIER METHODOLOGY), CY 2015

	Avg. # of skilled nursing visits	Avg. minutes per skilled nursing visit
<1% Total		
Outlier Pay- ments	21.7	47.2
1% to <5% Total Outlier Pay-		
ments 5% to <10%	26.7	44.0
Total Outlier Payments	26.7	44.3
10% Total Outlier Pay-		
ments	44.5	35.6

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

As shown in Table 23, the number of skilled nursing visits is significantly higher than the number of visits for the five other disciplines of care and therefore, outlier payments are predominately driven by the provision of skilled nursing services.

TABLE 23—AVERAGE NUMBER OF VISITS BY DISCIPLINE FOR OUTLIER EPISODES

Discipline	Average number of visits
Home health aide	8.8
Medical social services	0.3
Occupational therapy	2.3
Physical therapy	5.1
Skilled nursing	34.0

TABLE 23—AVERAGE NUMBER OF VISITS BY DISCIPLINE FOR OUTLIER EPISODES—Continued

Discipline	Average number of visits
Speech-language pathology	0.7

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

As a result of the analysis of CY 2015 home health claims data, we are concerned the current methodology for calculating outlier payments may create a financial disincentive for providers to treat medically complex beneficiaries who require longer visits. The home health environment differs from hospitals and other institutional environments. In the home setting, the patient has a greater role in determining how, when, and even if, certain interventions will be implemented. Individual skill, cognitive and functional ability, and financial resources affect the ability of home health patients to safely manage their health care needs, interventions, and medication regimens.⁵ Clinically complex patients generally use more health services, have functional limitations, need more assistance to perform activities of daily living (ADLs), require social support and community resources, and require more complex medical interventions.⁶ For example, patients using home total parenteral nutrition (TPN) must cope with very high-tech needs at home and because of the complexity of TPN therapy, a high level of knowledge and expertise is required in the clinical management of these patients.⁷ In addition to the direct patient care needs, patient education aims at instruction on the care of the central venous access device, administration procedures and monitoring for complications, overall well-being, parenteral nutrition composition and frequency, test results, medications, practical and psychosocial

⁵ Ibid.

⁶ 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. AHRQ Publication No. 12–0010, https://pcmh.ahrq.gov/page/coordinating-care-adults-complex-care-needs-patient-centered-medical-home-challenges-and.

⁷Huisman-deWaal, G. Achterberg, T., Jansen, J., Wanten, G., Schoonhoven, L. (2010). "High-tech" home care: Overview of professional care in patients on home parenteral nutrition and implications for nursing care. Journal of Clinical Nursing, (20), 2125–2134.

issues.8 Visit frequency for home TPN patients varies and length of nursing visits can range from 15 minutes for infusion site and catheter assessment to 10 hours for direct patient care.9 For those patients who require assistance with bathing, research has shown older persons are more likely to have negative expectations regarding the inevitability of further physical decline after they experience bathing difficulties. 10 As older home health patients decline, they may be more likely to accept assistance with bathing and this may have the unintended consequence of reliance on bathing assistance, which could lead to further functional decline in the performance of other ADLs. To mitigate further functional decline, home health nursing intensity and visit time increases as home nursing interventions are targeted to work with patients and caregivers on bathing sub-tasks, assistance in modifying the home environment through the acquisition and use of adaptive equipment and devising strategies to support patients in dealing with pain and fatigue that could prevent independent bathing.11

Higher nursing visit intensity and longer visits are a generally a response to instability of the patient's condition,

and/or inability to effectively and safely manage their condition and self-care activities; therefore, more clinically complex, frail, elderly patients will require more intensive and frequent home health surveillance, increased home health care utilization, and costs.¹² ¹³

In addition to the clinical information described above, Mathematica Policy Research published a report in 2010 titled "Home Health Independence Patients: High Use, but Not Financial Outliers." 14 In this report, Mathematica described their analysis of the relationships among the proxy demonstration target group for the Home Health Independence Demonstration, patients who receive outlier payments, and the agencies that serve them. As part of their research, Mathematica examined the degree of overlap between the proxy demonstration target group, who are ill, permanently disabled beneficiaries, and those beneficiaries receiving outlier payments. The study found that "Only a small fraction of proxy demonstration patients generate outlier payments and that differences between the proxy demonstration and outlier patient groups examined in this study suggest

that outlier payments are not generally being used to serve the types of severely, permanently disabled beneficiaries that were addressed by the demonstration concept."

Therefore, we are proposing to change the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. Using this approach, we would convert the national per-visit rates in section III.C.3. into per 15 minute unit rates (see Table 24). The new per-unit rates by discipline would then be used, along with the visit length data by discipline reported on the home health claim in 15 minute increments (15 minutes = 1 unit), 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. We note that this change in the methodology would be budget neutral as we would still target to pay out 2.5 percent of total payments as outlier payments in accordance with section 1895(b)(5)(A) of the Act, which requires us to pay up to, but no more than, 2.5 percent of total HH PPS payments as outlier payments.

TABLE 24—PROPOSED COST-PER-UNIT PAYMENT RATES FOR THE CALCULATION OF OUTLIER PAYMENTS

Visit type	Proposed CY 2017 national per-visit payment rates	Average minutes- per-visit	Cost-per-unit (1 unit = 15 minutes)
Home health aide	\$64.09	62.2	\$15.46
Medical social services	226.87	56.4	60.34
Occupational therapy	155.77	47.1	49.61
Physical therapy	154.72	46.6	49.80
Skilled nursing	141.54	44.7	47.50
Speech-language pathology	168.16	48.1	52.44

SOURCE: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

NOTE(S): Excludes LUPAs.

We believe that this proposed change to the outlier methodology will result in more accurate outlier payments where the calculated cost per episode accounts for not only the number of visits during an episode of care, but also the length of the visits performed. This, in turn, may address some of the findings from the home health study, where margins were lower for patients with medically complex needs that typically require longer visits, thus potentially creating an incentive to treat less complex patients. Table 25 shows the difference in the average number of visits and the average minutes per visit for outlier episodes under the current outlier methodology and the proposed outlier methodology by the percentage of outlier payments to total payments at the agency level.

⁸ Ibid

⁹ Piamjariyakul, U., Ross, V., Yadrich, D.M., Williams, A., Howard, L., Smith, C. (2010). Complex Home Care: Part I-Utilization and Costs to Families for Health Care Services Each Year. Nursing Economics. 28(4), 255–263

¹⁰ Friedman, B., Yanen, L., Liebel, D., Powers, B. (2014). Effects of Home Visiting Nurse Intervention versus Care as Usual on Individual Activities of

Daily Living: A Secondary Analysis of a Randomized Trial. BMC Geriatrics. 14(24), 1–13.

¹¹ Ibid.

¹² 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.

¹³ Riggs, J., Madigan, E., Fortinsky, R. (2011). Home Health Care Nursing Visit Intensity and Heart Failure Patient Outcomes. Home Health Care Managing Practice. 23(6), 412–420.

¹⁴ Cheh, Valerie and Schurrer, John. Home Health Independence Patients: High Use, but Not Financial Outliers, Report to Centers for Medicare and Medicaid, Mathematical Policy Research. March 31, 2010.

TABLE 25—AVERAGE NUMBER OF VISITS AND MINUTES PER VISIT BY THE PERCENTAGE OF OUTLIER PAYMENTS TO TOTAL PAYMENTS AT THE AGENCY LEVEL FOR OUTLIER EPISODES FOR THE CURRENT AND PROPOSED OUTLIER METH-ODOLOGIES, CY 2015

	Metho	Outlier dology er Visit)	Proposed Outlier Methodology (Cost per Unit)	
	Avg. # of visits	Avg. min- utes per visit	Avg. # of visits	Avg. min- utes per visit
<1% Total Outlier Payments	39.7 44.7 44.7 60.7	48.9 49.2 49.6 44.0	38.5 43.5 54.8 56.4	52.6 52.0 55.2 65.6

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

Analysis of the impact of the change from a cost-per-visit to a cost-per-unit approach indicates that approximately two-thirds of outlier episodes under the cost-per-unit approach would have still received outlier payments under the current cost-per-visit approach, while about one-third of outlier episodes under the current cost per visit approach would not receive outlier payments under the cost-per-unit approach. Table 26 shows the average number of visits and the visit length for

the episodes that would receive outlier payments under the current cost-pervisit approach, but not under the proposed cost-per-unit approach, as well as the average number of visits and the visit length for the episodes that would receive outlier payments under the proposed cost-per-unit approach, but not under the current cost-per-visit approach. Those episodes that would only receive outlier payments under the current cost-per-visit approach have less average resource use (calculated by

multiplying the number of visits with the number of minutes) than those episodes that would only receive outlier payments under the proposed cost-perunit approach. These results indicate that the change from the current cost-per-visit methodology to the proposed cost-per-unit methodology would result in more accurate outlier payments that better account for the intensity of the visits performed rather than only visit volume.

Table 26—Average Number of Visits and Visit Length for Episodes That Receive Outlier Payments Only Under the Current Outlier Methodology and for Episodes That Receive Outlier Payments Only Under the Proposed Outlier Methodology, CY 2015

	ceive outlier pa	only would re- ayments under methodology	Episodes that only would re- ceive outlier payments under the proposed methodology		
	Avg. # of visits	Avg. minutes per visit	Avg. # of visits	Avg. minutes per visit	
<1% Total Outlier Payments 1% to <5% Total Outlier Payments 5% to <10% Total Outlier Payments 10% Total Outlier Payments	36.8 37.6 43.8 46.1	39.9 38.5 36.4 27.5	29.8 30.6 30.2 31.9	63.4 65.6 85.9 104.5	

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

In addition, we examined the impact of changing from the current cost-pervisit methodology to the proposed costper-unit methodology on a subset of the vulnerable patient populations identified in the home health study. Our simulations indicate that certain subgroups identified in the home health study may benefit from the change from the current outlier methodology to the proposed outlier methodology. Table 27 shows some of the vulnerable patient populations that may benefit from the proposed changes to the outlier methodology. As shown in Table 27, preliminary analysis indicates that a

larger percentage of episodes of care for patients with a fragile overall health status will qualify for outlier payments under the proposed methodology than under the current methodology (24.1 percent versus 20.1 percent). Similarly, a larger percentage of episodes of care for patients who need assistance with bathing will qualify for outlier payments under the proposed methodology than under the current methodology (29.1 percent versus 27.0 percent). In addition, a larger percentage of episodes of care for patients who need caregiver assistance or who have surgical wounds will qualify for outlier payments under

the proposed methodology versus under the current methodology (7.7 percent versus 6.7 percent and 19.0 percent versus 18.1 percent, respectively). Furthermore, there are small increases in the percentage of episodes of care that would qualify for outlier payments for the patients who need parenteral nutrition or have poorly controlled cardiac dysrhythmia or pulmonary disorders. These results suggest that the proposed change to the outlier methodology may address some of the findings from the home health study and may alleviate potential financial

disincentives to treat patients with medically complex needs.

TABLE 27—IMPACT OF THE PROPOSED OUTLIER METHODOLOGY CHANGE ON SUBGROUPS OF VULNERABLE PATIENT POPULATIONS IDENTIFIED IN THE HOME HEALTH STUDY

Subgroups identified in the home health study	Overall percentage for all non-LUPA episodes (%)	Percent of outliers based on cost-per- visit approach (%)	Percent of outliers based on cost-per-unit approach (%)
Needs caregiver assistance Fragile-serious overall status Needs assistance with bathing Parenteral Nutrition Poorly Controlled Cardiac Dysrhythmia Poorly Controlled Pulmonary Disorder	20.1 0.2 4.3	6.7 20.1 27.0 0.2 3.4 5.4	7.7 24.1 29.1 0.4 3.8 6.0
Surgical Wound		18.1	19.0

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

In concert with our proposal to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, we are proposing to implement 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. Specifically, we propose to limit the amount of time per day (summed across the six disciplines of care) to 8 hours or 32 units per day when estimating the cost of an episode for outlier calculation purposes. We note that this proposal is consistent with the definition of "part-time" or "intermittent" set out in section 1861(m) of the Act, which limits the amount of skilled nursing and home health aide minutes combined to less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). We also note that we are not limiting the amount of care that can be provided on any given day. We are only limiting the time per day that can be credited towards the estimated cost of an episode when determining if an episode should receive outlier payments and calculating the amount of the outlier payment. For instances when more than 8 hours of care is provided by one discipline of care, the number of units for the line item will be capped at 32 units for the day for outlier calculation purposes. For rare instances when more than one discipline of care is provided and there is more than 8 hours of care provided in one day, the episode cost associated with the care provided during that day will be calculated using a hierarchical method based on the cost per unit per discipline shown in Table 24. The

discipline of care with the lowest associated cost per unit will be discounted in the calculation of episode cost in order to cap the estimation of an episode's cost at 8 hours of care per day. For example, if an HHA provided 4.5 hours of skilled nursing and 4.5 hours of home health aide services, all 4.5 hours of skilled nursing would be counted in the episode's estimated cost and 3.5 hours of home health aide services would be counted in the episode's estimated cost (8 hours -4.5hours = 3.5 hours) since home health aide services has a lower cost-per-unit than skilled nursing services.

We note that preliminary analysis suggests that this proposed cap will have a limited impact on episodes overall. Out of approximately 5.4 million episodes in our preliminary analytic file for 2015, only 15,384 episodes or 0.28 percent of all home health episodes reported instances where over 8 hours of care were provided in a single day (which could have resulted from data entry errors as we currently do not use visit length for payment). Of those 15,384 episodes, only 1,591 would be outlier episodes under the proposed outlier methodology. Therefore, we estimate that only 1,600 episodes or so, out of 5.4 million episodes, would be impacted due to the proposed 8 hour cap.

3. Proposed Fixed Dollar Loss (FDL)

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.

In the CY 2011 HH PPS final rule (75 FR 70398), in targeting total outlier payments as 2.5 percent of total HH PPS payments, we implemented an FDL ratio of 0.67, and we maintained that ratio in CY 2012. Simulations based on CY 2010 claims data completed for the CY 2013 HH PPS final rule showed that outlier payments were estimated to comprise approximately 2.18 percent of total HH PPS payments in CY 2013, and as such, we lowered the FDL ratio from 0.67 to 0.45. We stated that lowering the FDL ratio to 0.45, while maintaining a loss-sharing ratio of 0.80, struck an effective balance of compensating for high-cost episodes while allowing more episodes to qualify as outlier payments (77 FR 67080). 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 wageadjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

For this proposed rule, simulating payments using preliminary CY 2015 claims data (as of December 31, 2015) and the CY 2016 payment rates (80 FR 68649 through 68652), we estimate that outlier payments in CY 2016 would comprise 2.23 percent of total payments. Based on simulations using CY 2015 claims data and the CY 2017 payment rates in section III.C.3 of this proposed rule, we estimate that outlier payments would comprise approximately 2.58 percent of total HH PPS payments in CY 2017 under the current outlier methodology, a percent change of approximately 15.7 percent. This increase is attributable to the increase in the national per-visit amounts through the rebasing adjustments and the decrease in the national, standardized 60-day episode payment amount as a result of the rebasing adjustment and the nominal case-mix growth reduction.

Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we are proposing a change to the FDL ratio for CY 2017 as we believe that maintaining an FDL ratio of 0.45 with a loss-sharing ratio of 0.80 is no longer appropriate given the percentage of outlier payments projected for CY 2017. We note that we are not proposing a change to the loss-sharing ratio (0.80) in order for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.) Under the current outlier methodology, the FDL ratio would need to be changed from 0.45 to 0.48 to pay up to, but no more than, 2.5 percent of total payments as outlier payments. Under the proposed outlier methodology which would use a cost per unit rather than a cost per visit when calculating episode costs, we estimate that we will pay out 2.74 percent in outlier payments in CY 2017 using an FDL ratio of 0.48 and that the FDL ratio will need to be changed to 0.56 to pay up to, but no more than, 2.5 percent of total payments as outlier payments.

Therefore, in addition to the proposal to change the methodology used to calculate outlier payments, we are proposing to change the FDL ratio from 0.45 to 0.56 for CY 2017. 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 2015 claims data as of June 30, 2016) and therefore, we may adjust the final FDL ratio accordingly. We invite public comments on the proposed changes to the outlier payment calculation methodology and

the associated changes in the regulations text at § 484.240 as well as the proposed change to the FDL ratio.

E. Proposed Payment Policies for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device

1. Background

Negative pressure wound therapy (NPWT) is a medical procedure in which a vacuum dressing is used to enhance and promote healing in acute, chronic, and burn wounds. The therapy involves using a sealed wound dressing attached to a pump to create a negative pressure environment in the wound. Applying continued or intermittent vacuum pressure helps to increase blood flow to the area and draw out excess fluid from the wound. Moreover, the therapy promotes wound healing by preparing the wound bed for closure, by reducing edema, by promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. The wound type and/or the location of the wound determine whether the vacuum can either be applied continuously or intermittently. NPWT can be utilized for varying lengths of time, as indicated by the severity of the wound, from a few days of use up to a span of several months.

In addition to the conventional NPWT systems classified as durable medical equipment (DME), NPWT can also be performed with a single-use disposable system that consists of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy. These disposable systems consist of a small pump, which eliminates the need for a bulky canister. Unlike conventional NPWT systems classified as DME, disposable NPWT systems have a preset continuous negative pressure, there is no intermittent setting, they are pocketsized and easily transportable, and they are generally battery-operated with disposable batteries.15

Section 1895 of the Act requires that the HH PPS includes payment for all covered home health services. Section 1861(m) of the Act defines what items and services are considered to be "home health services" when furnished to a Medicare beneficiary under a home health plan of care when provided in the beneficiary's place of residence. Those services include:

- Part-time or intermittent nursing
- Physical or occupational therapy or speech-language pathology services

- Medical social services
- Part-time or intermittent services of a home health aide
 - Medical supplies
 - A covered osteoporosis drug
 - Durable medical equipment (DME) The unit of payment under the HH

PPS is a national, standardized 60-day episode payment amount with applicable adjustments. The national, standardized 60-day episode payment amount includes costs for the home health services outlined above per section 1861(m) of the Act, except for DME and the covered osteoporosis drug. Section 1814(k) of the Act specifically excludes DME from the national, standardized 60-day episode rate and consolidated billing requirements. DME continues to be paid outside of the HH PPS. The cost of the covered osteoporosis drug (injectable calcitonin), which is covered where a woman is postmenopausal and has a bone fracture, is also not included in the national, standardized 60-day episode payment amount, but must be billed by the HHA while a patient is under a home health plan of care since the law requires consolidated billing of osteoporosis drugs. The osteoporosis drug itself continues to be paid on a reasonable cost basis.

Medical supplies are included in the definition of "home health services" and the cost of such supplies is included in the national, standardized 60-day episode payment amount. Medical supplies are items that, due to their therapeutic or diagnostic characteristics, are essential in enabling HHA personnel to conduct home visits or to carry out effectively the care the physician has ordered for the treatment or diagnosis of the patient's illness or injury. Supplies are classified into two categories, specifically:

• Routine: Supplies used in small quantities for patients during the usual course of most home visits; or

• Non-routine: Supplies needed to treat a patient's specific illness or injury in accordance with the physician's plan of care and meet further conditions.

Both routine and non-routine medical supplies are included in the national, standardized 60-day episode payment amount for every Medicare home health patient regardless of whether or not the patient requires medical supplies during the episode. The law requires that all medical supplies (routine and nonroutine) be provided by the HHA while the patient is under a home health plan of care. A disposable NPWT system would be considered a non-routine supply for home health.

As required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the

¹⁵ Single use negative pressure wound therapy. CME Online. 2013 www.pfiedler.com.

Act, for home health services to be covered, the patient must receive such services under a plan of care established and periodically reviewed by a physician. As described in § 484.18 of the Medicare Conditions of Participation (CoPs), the plan of care that is developed in consultation with the agency staff, is to cover all pertinent diagnoses, including the types of services and equipment required for the treatment of those diagnoses as well as any other appropriate items, including DME. Consolidated billing requirements ensure that only the HHA can bill for home health services, with the exception of DME and therapy services provided by physicians, when a patient is under a home health plan of care. The types of service most affected by the consolidated billing edits tend to be non-routine supplies and outpatient therapies, since these services are routinely billed by providers other than HHAs, or are delivered by HHAs to patients not under home health plans of care.

As provided under section 1834(k)(5) of the Act, a therapy code list was created based on a uniform coding system (that is, the HCPCS) to identify and track these outpatient therapy services paid under the Medicare Physician Fee Schedule (MPFS). The list of therapy codes, along with their respective designation, can be found on the CMS Web site, specifically at http://www.cms.hhs.gov/TherapyServices/05_Annual Therapy

Update.asp#TopOfPage. Two of the designations that are used for therapy services are: "Always therapy" and "sometimes therapy." An "always therapy" service must be performed by a qualified therapist under a certified therapy plan of care, and a "sometimes therapy" service may be performed by physician or a non-physician practitioner outside of a certified therapy plan of care. CPT codes 97607 and 97608 are categorized as a "sometimes" therapy, which may be performed by either a physician or a non-physician practitioner outside of a certified therapy plan of care, as described in section 200.9 of Chapter 4 of the Medicare Claims Processing Manual.16

2. The Consolidated Appropriations Act of 2016

As mentioned in section III.A.1 above, for patients under a home health plan of care, payment for part-time or intermittent skilled nursing, physical

therapy, speech-language pathology, occupational therapy, medical social services, part-time or intermittent home health aide visits, and routine and nonroutine supplies are included in the episode payment amount. A disposable NPWT system is currently considered a non-routine supply and thus payment for the disposable NPWT system is included in the episode payment amount. The Consolidated Appropriations Act of 2016 (Pub. L 114– 113) amends both section 1834 of the Act (42 U.S.C. 1395m) and section 1861(m)(5) of the Act (42 U.S.C. 1395x(m)(5)), requiring a separate payment to a HHA for an applicable disposable device when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit. Section 1834(s)(2) of the Act defines an applicable device as a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy used in lieu of a conventional NPWT DME system.

As required by the Consolidated Appropriations Act of 2016 (Pub. L 114–113), the separate payment amount for NPWT using a disposable system is to be set equal to the amount of the payment that would be made under the Medicare Hospital Outpatient Prospective Payment System (OPPS) using the Level I Healthcare Common Procedure Coding System (HCPCS) code, otherwise referred to as Current Procedural Terminology (CPT–4) codes, for which the description for a professional service includes the furnishing of such a device.

Under the OPPS, CPT codes 97607 and 97608 (APC 5052—Level 2 Skin Procedures), include furnishing the service as well as the disposable NPWT device. The codes are defined as follows:

- HCPCS 97607—Negative pressure wound therapy, (for example, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.
- HCPCS 97608—Negative pressure wound therapy, (for example, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system,

topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.

3. Proposed Payment Policies for NPWT Using a Disposable Device

For the purposes of paying for NPWT using a disposable device for a patient under a Medicare home health plan of care and for which payment is otherwise made under section 1895(b) of the Act, CMS is proposing that for instances where the sole purpose for an HHA visit is to furnish NPWT using a disposable device, Medicare will not pay for the visit under the HH PPS. Instead, we propose that since furnishing NPWT using a disposable device for a patient under a home health plan of care is to be paid separately, based on the OPPS amount, which includes payment for both the device and furnishing the service, the HHA must bill these visits separately under type of bill 34x (used for patients not under a HH plan of care, Part B medical and other health services, and osteoporosis injections) along with the appropriate HCPCS code (97607 or 97608). Visits performed solely for the purposes of furnishing NPWT using a disposable device are not to be reported on the HH PPS claim (type of bill 32x).

If NPWT using a disposable device is performed during the course of an otherwise covered HHA visit (for example, while also furnishing a catheter change), we propose that the HHA must not include the time spent furnishing NPWT in their visit charge or in the length of time reported for the visit on the HH PPS claim (type of bill 32x). Providing NPWT using a disposable device for a patient under a home health plan of care will be separately paid based on the OPPS amount relating to payment for covered OPD services. In this situation, the HHA bills for NPWT performed using a disposable device under type of bill 34x along with the appropriate HCPCS code (97607 or 97608). Additionally, this same visit should also be reported on the HH PPS claim (type of bill 32x), but only for the time spent furnishing the services unrelated to the provision of NPWT.

As noted in section III.E.1, since these two CPT codes (97607 and 97608) are considered "sometimes" therapy codes, NPWT using a disposable device for patients under a home health plan of care can be performed, in accordance to State law, by a registered nurse, physical therapist, or occupational therapist and the visits would be reported on the type of bill 34x using revenue codes 0559, 042X, 043X. The

¹⁶ https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ clm104c04.pdf.

descriptions for CPT codes 97607 and 97608 include performing a wound assessment, therefore we believe that it would only be appropriate for these visits to be performed by a registered nurse, physical therapist, or occupational therapist as defined in § 484.4 of the Medicare Conditions of Participation (CoPs).

The payment amount for both 97607and 97608 will be set equal to the amount of the payment that would be made under the OPPS and subject to the area wage adjustment policies in place under the OPPS, for CY 2017 and each subsequent year. Please see Medicare Hospital OPPS Web page for Addenda A and B at https://www.cms.gov/ Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/ Addendum-A-and-Addendum-B-Updates.html. These addenda are a "snapshot" of HCPCS codes and their status indicators, APC groups, and OPPS payment rates that are in effect at the beginning of each quarter. Section 504(b)(1) of the Consolidated Appropriations Act of 2016 (Pub. L 114-113) amends section 1833(a)(1) of the Act, which requires that furnishing the NPWT using a disposable device be subject to beneficiary coinsurance in the amount of 20 percent. The amount paid to the HHA by Medicare will be equal to 80 percent of the lesser of the actual charge or the payment amount as determined by the OPPS for the year.

In order for a beneficiary to receive NPWT using a disposable device under the home health benefit, the beneficiary must also qualify for the home health benefit in accordance with the existing eligibility requirements. To be eligible for Medicare home health services, as set out in sections 1814(a) and 1835(a) of the Act, a physician must certify that the Medicare beneficiary (patient) meets the following criteria:

- Is confined to the home
- Needs skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or have a continuing need for occupational therapy
- Is under the care of a physician
- Receive services under a plan of care established and reviewed by a physician; and
- Has had a face-to-face encounter related to the primary reason for home health care with a physician or allowed Non-Physician Practitioner (NPP) within a required timeframe.

As set forth in §§ 409.32 and 409.44, to be considered a skilled service, the

service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel. Additionally, care is deemed as "reasonable and necessary" based on information reflected in the home health plan of care, the OASIS as required by § 484.55, or a medical record of the individual patient. Coverage for NPWT using a disposable device will be determined based upon a doctor's order as well as patient preference. Research has shown that patients prefer wound dressing materials that afford the quickest wound healing, pain reduction, maximum exudate absorption to minimize drainage and odor, and they indicated some willingness to pay out of pocket costs.¹⁷ Treatment decisions as to whether to use a disposable NPWT system versus a conventional NPWT DME system is determined by the characteristics of the wound, as well as, patient goals and preferences discussed with the ordering physician to best achieve wound healing and reduction.

We are soliciting public comment on all aspects of the proposed payment policies for furnishing a disposable NPWT device as articulated in this section as well as the corresponding proposed changes to the regulations at § 409.50 in section VII of this proposed rule.

F. Update on Subsequent Research and Analysis Related to Section 3131(d) of the Affordable Care Act

Section 3131(d) of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), (collectively referred to as "The Affordable Care Act"), directed the Secretary of Health and Human Services (the Secretary) to conduct a study on HHA costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas and in treating beneficiaries with high levels of severity of illness and to submit a Report to Congress on the study's findings and recommendations. As part of the study, the Affordable Care Act stated that we may also analyze methods to potentially revise the home health prospective payment system (HH PPS). In the CY 2016 HH PPS proposed rule (80 FR 39840), we summarized the Report to Congress on the home health study, required by section 3131(d) of the Affordable Care Act, and provided

information on the initial research and analysis conducted to potentially revise the HH PPS case-mix methodology to address the home health study findings outlined in the Report to Congress. In this proposed rule, we are providing an update on additional research and analysis conducted on the Home Health Groupings Model (HHGM), one of the model options referenced in the CY 2016 HH PPS proposed rule (80 FR 39866).

The premise of the HHGM starts with a clinical foundation where home health episodes are grouped by primary diagnosis based on what home health interventions would be required during the episode of care. In addition to the clinical groupings, the HHGM incorporates other information from the OASIS and claims data to further group home health episodes for payment. Each home health episode is categorized into different sub-groups within each of the five categories below:

- *Timing* (early or late; that is, episode is placed into 1 of 2 groups)
- Referral source (community, acute, or post-acute admission source; that is, episode is placed into 1 of 3 groups)
- Clinical grouping (musculoskeletal rehab, neuro/stroke rehab, wounds, MMTA, behavioral, or complex; that is, episode is placed into 1 of 6 groups)
- Functional/cognitive level (low, medium, or high; that is, episode is placed into 1 of 3 groups)
- Comorbidity adjustment (first, second, or third, tier based on secondary diagnoses; that is, episode is placed into 1 of 3 groups)

In total there would be 324 possible payment groupings an episode can be grouped into under the HHGM. Unlike the current payment model, the HHGM does not rely on the number of therapy visits performed to influence payment.

Similar to the current payment system, episodes under the HHGM are first classified as "early" or "late" depending on when they occur within a sequence of adjacent episodes, as outlined in our regulations at § 484.230. Currently, the first two 60-day episodes of care are considered "early" and third or later 60-day episodes of care are considered "late". However, recent analysis shows that there is a substantial difference in the number of visits that occur during the first 30 days of a 60day episode of care compared to the second 30 days in a 60-day episode of care (see Figure 4, below).

¹⁷ Corbett, L., Ennis, W. (2014). What Do Patients Want? Patient Preferences in Wound Care. 3(8), 537–543.

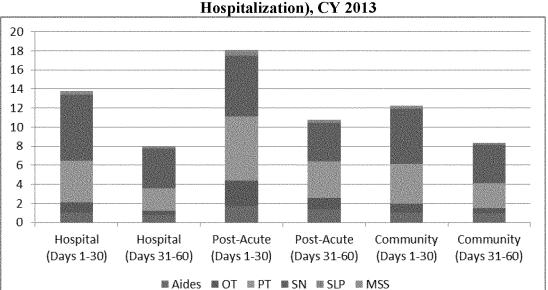


Figure 4: Average Visits for the First 30 Days Versus Second 30 Days of a 60-day Episode of Care (First Episodes that Last 60 days with No Intervening Hospitalization). CY 2013

Source: CY 2013 home health claims data for claims with a through date on or before December 31, 2013 from the June 30, 2014 standard analytic file for which there was a linked OASIS assessment. **Note(s)**: Low-utilization payment adjustment (LUPA) and outlier episodes were excluded from this analysis.

Given the differences in the number of visits occurring in the first 30 days versus the second 30 days in a 60-day episode of care, and to better account for the relationship between episode characteristics and episode cost, we modeled all episodes as 30-day episodes of care, instead of 60-day episodes of care as in the current payment system. Under the HHGM, the first 30-day episode in a sequence of adjacent episodes was classified as an early episode. All subsequent episodes in a sequence (second or later) of adjacent episodes were classified as late episodes if separated by no more than a 60-day gap in care.

After taking into account whether the 30-day episode of care was "early" versus "late", each episode was then classified into one of three referral source categories depending on whether the beneficiary was admitted from an acute or post-acute care facility within 14 days prior to being admitted to home health (community, acute, or postacute). Patients admitted to home health from the community, an acute setting of care, or a post-acute setting of care had different observable patterns of resource use and thus, under the HHGM, episodes of care for those patients would be paid differently.

We then grouped episodes into one of six clinical groups based on the primary diagnosis listed on the OASIS for each episode. We created these groups to describe the most common types of care that HHAs provide. We have reviewed all possible ICD-9-CM codes that could be recorded on the OASIS and assigned each code into one of the following clinical groups: Musculoskeletal Rehabilitation; Neuro/Stroke Rehabilitation; Wound Care; Medication Management, Teaching and Assessment (MMTA); Behavioral Health Care; and Complex Medical Care.

The HHGM designates a functional/ cognitive level for each episode based on items identified on the OASIS that impact resource use. Using home health episodes from 2013, we estimated a regression model that determines the relationship between the responses for certain OASIS items and resource use.18 The coefficients from the regression show how much more or less, on average, an episode's resource use is depending on responses to these items which is then used to predict resource use for each individual episodes. Ranking the episodes by predicted resource use and then identifying thresholds that divides episodes into three groups of roughly the same size allows us to assign each episode to into

a low, medium or high functional/cognitive level.

Finally, our exploratory analyses have determined that secondary diagnoses (comorbidities) provide additional information that can predict resource use even after controlling for episode timing, referral source, the clinical grouping (based in the patient's primary diagnosis) and functional/cognitive level. Therefore, we further differentiated episodes into based on the presence of certain secondary diagnoses. We explored two options. For the first option we determined the commonly occurring comorbidities (incidence of over 0.1 percent) reported on the OASIS that were also associated with above average resource use. We then divided the comorbidities into a low or high group based on average resource use associated with the comorbidity. We then placed episodes into three tiers: Episodes for beneficiaries with no comorbidities reported on the OASIS in the low or high group (Tier 1); episodes for beneficiaries with comorbidities in the low, but not high group as reported on the OASIS (Tier 2); and episodes for beneficiaries with comorbidities in the high group reported on the OASIS (Tier 3). For the second option, we used the major complication or comorbidity (MCC) and complication and comorbidity (CC) list from the Inpatient Prospective Payment System (IPPS).

^{18 &}quot;Resource use" is an estimate of the cost of an episode. It is measured by multiplying the number of minutes of services that occur during an episode by a wage rate for the disciplines providing the

Using the CC and MMC list we placed episodes into three tiers: Episodes where beneficiaries had no MCC or CC diagnoses reported on either the OASIS or any inpatient or professional claim within 90 days of the start of home care (Tier 1); episodes where beneficiaries had CC but no MCC diagnoses reported on either the OASIS or any inpatient or professional claim within 90 days of the start of home care (Tier 2); and episodes where beneficiaries had at least one MCC diagnosis reported on either the OASIS or any inpatient or professional claim within 90 days of the start of home care (Tier 3).

We determined the case-mix weight for each of the 324 different HHGM payment groups by estimating a regression between episode resource use and binary variables controlling for the five dimensions described above (episode timing, admission source, HHGM clinical group, functional/ cognitive level, and comorbidities). After estimating this model on home health episodes from 2013 (excluding LUPA and outlier episodes), we then used the results of the model to predict the expected average resource use of each episode based on these six characteristics. We divide the predicted resource use of each episode by the overall average resource use (of all 2013 episodes) to calculate the average casemix of all episodes within a particular payment group (that is, each combination of the sub-groups within the five main groups). That case-mix weight is then used to adjust the base payment rate to then determine each episode's payment.

In many ways, the structure of the HHGM is similar to the current payment system. However, by either adding to or removing certain components of the current payment system, the HHGM could help to strengthen the HH PPS by addressing the margin differences noted in the home health study and by removing unintended financial incentives (for example, the current therapy thresholds). As noted in the 3131(d) study, margin differences exist across beneficiary characteristics such as parenteral nutrition, traumatic wounds, whether bathing assistance was needed, and admission source. These margin differences would be addressed by moving to a HHGM approach where those characteristics are better accounted for in the model. Additionally, the HHGM aligns with how clinicians generally identify the types of patients they see in home health, which, in turn, better defines the home health benefit in a more transparent manner so that the payer understands the primary reason for

home care. We feel that the HHGM will address the findings highlighted in the 3131(d) report, specifically improving the payment accuracy for purchased home health services, promote fair compensation to HHAs, and increase the quality of care for beneficiaries. We plan to release a more detailed Technical Report in the future on this additional research and analysis conducted on the HHGM. When we release the technical report, we are also planning to release a list of the ICD-9-CM and ICD-10-CM codes assigned to each of the clinical groups within the HHGM to further assist the industry in analyzing the HHGM model. While we are not soliciting comments on the HHGM in this proposed rule, once the Technical Report is released, we will post a link on our Home Health Agency (HHA) Center Web site (https:// www.cms.gov/center/provider-Type/ home-Health-Agency-HHA-Center.html) to receive comments and feedback on the model.

FF. Update on Future Plans To Group HH PPS Claims Centrally During Claims Processing

In the CY 2011 HH PPS proposed rule (75 FR 43236) we solicited comments on potential plans to group HH PPS claims centrally during claims processing and received many comments in support of this initiative. In grouping HH PPS Claims centrally during processing, we are describing a process whereby all of the information necessary to group the claim and assign a Health Insurance Prospective Payment System (HIPPS) score which determines payment is available and processed within the Fiscal Intermediary Shared System (FISS). In that rule, we discussed the potential use of the treatment authorization field to group HH PPS claims within the claims processing system. In conducting further analysis, we determined that the use of the treatment authorization field was not a viable option. In our analysis, we determined that the information we planned to report in this field was not permitted by the Health Insurance Portability Accountability Act (HIPAA). In this section, we are soliciting comments on another process identified whereby all of the information necessary to group HH PPS claims occurs centrally during claims processing.

As we outlined in the previous rule, Medicare makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment amount that is adjusted for case-mix and geographic wage variations. The national, standardized 60-day episode

payment amount includes services from the six HH disciplines (skilled nursing, HH aide, physical therapy, speechlanguage pathology, occupational therapy, and medical social services) and non-routine medical supplies. Durable medical equipment covered under HH is paid for outside the HH PPS payment. To adjust for case-mix, the HH PPS uses a 153-category casemix classification to assign patients to a home health resource group (HHRG). Clinical needs, functional status, and service utilization are computed from responses to selected data elements in the Outcome & Assessment Information Set (OASIS) instrument. On Medicare claims, the HHRGs are represented as HIPPS codes.

At a patient's start of care and before the start of each subsequent 60-day episode, the HHA is required to perform a comprehensive clinical assessment of the patient and complete the OASIS assessment instrument. The OASIS instrument collects data concerning 3 dimensions of the patient's condition: (1) Clinical severity (orthopedic, neurological or diabetic conditions, etc.); (2) Functional status (comprised of 6 activities of daily living (ADLs)); and (3) Service utilization (therapy visits provided during episode). HHAs enter data collected from their patients' OASIS assessments into a data collection software tool. For Medicare patients, the data collection software invokes HH PPS Grouper software to assign a HIPPS code to the patient's OASIS assessment. The HHA includes the HIPPS code assigned by HH PPS Grouper software on the Medicare HH PPS bill, ultimately enabling our claims processing system to reimburse the HHA for services provided to patients receiving Medicare home health services.

The HHA is separately required to electronically submit OASIS assessments for their Medicare and Medicaid patients to us. On the HH PPS Web site at https://www.qtso.com/ havendownload.html, we provide a free OASIS assessment data collection tool (IHAVEN) which includes the HH PPS grouper software, a separate HH PPS grouper program which can be incorporated into an HHA's own data collection software, and HH PPS data specifications for use by HHAs or software vendors desiring to build their own HH PPS grouper. Most HHAs do not use the JHAVEN freeware, instead preferring to employ software vendors to create and maintain a customized assessment data collection tool which can be integrated into the HHA's billing software. Likewise, many vendors employed by HHAs do not utilize the

HH PPS grouper freeware, instead preferring to build their own HH PPS grouper from the data specifications which we provide.

Prior to the CY 2008, we made infrequent, minor changes to the HH PPS Grouper software. Since CY 2008, the HH PPS Grouper became more complex and more sensitive to annual diagnosis coding changes. As a result, in recent years, HHAs have been required to update their grouper software twice a year. Most HHAs employ software vendors to effectuate these updates. HHAs have expressed concerns to us that the bi-annual grouper updates coupled with the additional complexity of the grouper has increased provider and vendor burden.

We continue to identify OASIS assessments submitted with erroneous HIPPS codes through a process of comparing the submitted HIPPS code to the HIPPS code returned by our assessment system. These errors may occur when HHAs or their software vendors inaccurately replicate the HH PPS Grouper algorithm into the HHA's customized software. HHAs have expressed concerns that the HH PPS Grouper complexities increase their vulnerability to submit an inaccurate HIPPS code on the Medicare bill. We believe that embedding the HH PPS Grouper within the claims processing system would mitigate the provider's vulnerability and improve payment accuracy.

We recently implemented a process where we match the claim and the OASIS assessment in order to validate the HIPPS code on the Medicare bill. In addition, we have conducted an analysis and prototype testing of a javabased grouper with our FISS maintenance contractor. We believe that making additional enhancements to the claim and OASIS matching process would enable us to collect all of the other necessary information to assign a HIPPS code within the claims processing system. Adopting such a process would improve payment accuracy by improving the accuracy for HIPPS codes on bills, decrease costs, and burden to HHAs.

We are soliciting public comments on this potential enhancement as described above. If we implemented grouping HH PPS claims centrally within the claims processing system, the HHA would no longer have to maintain a separate process outside of our claims processing system, thus reducing the costs and burden to HHAs associated with the updates of the grouper software as well as the ongoing agency costs associated with embedding the HH PPS Grouper within JHAVEN. Finally, this

enhancement would also address current payment vulnerabilities associated with the reporting of incorrect HIPPS codes on the claim.

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, we implemented the HHVBP Model to begin 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 Medicarecertified HHAs that provide 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 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 calendar year (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, or determined by claims data and, (2) three New Measures where points are achieved for reporting data.

B. Smaller- and Larger-Volume Cohorts Proposals

The HHVBP Model compares a competing HHA's performance on quality measures against the performance of other competing HHAs within the same state and size cohort. Within each of the nine selected states, each competing HHA is grouped to either the smaller-volume cohort or the larger-volume cohort, as defined in § 484.305. The larger-volume cohort is defined as the group of competing HHAs within the boundaries of selected states that are participating in HHCAHPS in accordance with § 484.250 and the smaller-volume cohort is defined as the group of competing HHAs within the boundaries of selected states that are exempt from participation in HHCAHPS in accordance with § 484.250 (80 FR 68664). An HHA can be exempt from the HHCAHPS reporting requirements for a calendar year period if it has less than 60 eligible unique HHCAHPS patients annually as specified in § 484.250. In the CY 2016 HH PPS final rule, we finalized that when there are too few HHAs in the smaller-volume cohort in each state (such as when there are only one or two HHAs competing within a smallervolume cohort in a given state) to compete in a fair manner, the HHAs would be included in the larger-volume cohort for purposes of calculating the TPS and payment adjustment percentage without being measured on HHCAHPS (80 FR 68664).

1. Proposal to Eliminate Smaller- and Larger-Volume Cohorts Solely for Purposes of Setting Performance Benchmarks and Thresholds

In the CY 2016 HH PPS final rule (80 FR 68681–68682), we finalized a scoring methodology for determining achievement points for each measure under which HHAs will receive points along an achievement range, which is a scale between the achievement threshold and a benchmark. The achievement thresholds are calculated as the median of all HHAs' performance on the specified quality measure during the baseline period and the benchmark is calculated as the mean of the top decile of all HHAs' performance on the specified quality measure during the baseline period.

We previously finalized that under the HHVBP Model, we would calculate both the achievement threshold and the benchmark separately for each selected state and for HHA cohort size. Under this methodology, benchmarks and achievement thresholds would be calculated for both the larger-volume cohort and for the smaller-volume cohort of HHAs in each state (which we defined in each state based on a baseline period from January 1, 2015 through December 31, 2015). We also finalized that, in determining improvement points for each measure, HHAs would receive points along an improvement range, which we defined as a scale indicating the change between an HHA's performance during the performance period and the HHA's performance in the baseline period divided by the difference between the benchmark and the HHAs performance in the baseline period. We finalized that both the benchmarks and the achievement thresholds would be calculated separately for each state and for HHA cohort size.

We finalized the above policies based on extensive analyses of the 2013–2014 OASIS, claims, and HHCAHPS archived data. We believed that these data were sufficient to predict the effect of using cohorts for benchmarking and threshold purposes because they have been used for several years in other CMS quality initiatives such as the Home Health Quality Reporting Program.

Since the publication of the CY 2016 HH PPS final rule, we have continued to evaluate the calculation of the

benchmarks and achievement thresholds using the most recent CY 2015 data that is now available. We have calculated benchmarks and achievement thresholds for the OASIS measures for the smaller- and largervolume cohorts and state-wide for each of the nine states using these data. Our review of the benchmarks and achievement thresholds for each of the cohorts and states indicates that the benchmark values for the smallervolume cohorts varied considerably more from state-to-state than the benchmark values for the larger-volume cohorts. Some inter-state variation in the benchmarks and achievement thresholds for each of the measures was expected due to different state regulatory environments. However, the overall variation in these values was more than we expected, given the previous analyses we did. For example, with respect to the Improvement in Bed Transferring measure, we discovered that variation in the benchmark values between the smaller-volume cohorts was nearly three times greater than the variation in the benchmark values for the larger-volume cohorts or the statewide benchmarks. We also discovered that this large variation affected most of the measures. We are concerned that this high variation is not the result of expected differences like state regulatory policy, but is instead the result of (1) the cohort is so small that there are not enough HHAs in the cohort to calculate the values using the finalized methodology (mean of the top

decile); or (2) the cohort is large enough to calculate the values using the finalized methodology, but there are not enough HHAs in the cohort to generate reliable values.

We have included three tables in this proposed rule to help illustrate this issue. Each of the three tables include the 10 benchmarks for the OASIS measures that were calculated for the Model using the 2015 QIES roll-up file data for each state. We did not include the claims measures and the HHCAHPS measures in this example because we do not have all of the 2015 data available. These three tables demonstrate the relationship between the size of the cohort and degree of variation of the different benchmark values among the states. Table 28, Table 29 and Table 30 represent the benchmarks for the OASIS measures for the smaller-volume cohorts, larger-volume cohorts and state-wide (which includes HHAs from both smaller- and larger-volume cohorts) respectively. For example, the difference in benchmark values for Iowa and Nebraska (two of the four states that have smaller-volume cohorts) for the Improvement in Bed Transfers measure is 13.1 (72.7 for Iowa and 85.8 for Nebraska) for the smaller-volume cohort (Table 28), 4.1 (78.1 for Iowa to 82.2 for Nebraska) for the larger-volume cohort (Table 29) and 5.5 (77.6 for Iowa to 83.1 for Nebraska) for the state level cohort (Table 30). We believe that the higher range for the smaller-volume cohorts is a result of there being a fewer number of HHAs in these cohorts.

TABLE 28—SMALLER-VOLUME COHORT BENCHMARKS

					State				
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Oasis-Based Measures:									
Discharged to Community	77.0	88.8	73.6	82.0		75.1	81.1	79.4	
Drug Education on All Medications Pro- vided to Patient/Caregiver during all									
Episodes of Care	100.0	100.0	100.0	100.0		98.5	100.0	100.0	
Improvement in Ambulation- Locomotion	90.6	90.5	72.7	75.6		60.1	84.0	85.2	
Improvement in Bathing	82.0	91.2	79.5	71.8		72.1	77.4	81.5	
Improvement in Bed Transferring	68.8	80.4	72.7	74.1		55.1	85.8	79.0	
Improvement in Dyspnea	84.2	90.4	81.3	62.6		62.5	80.3	93.7	
Improvement in Management of Oral Medications Improvement in Pain Interfering with Ac-	63.0	74.0	58.4	62.0		62.8	65.8	58.9	
tivity	83.2	97.3	82.6	82.3		58.5	78.2	69.0	
Influenza Immunization Received for Current Flu Season	73.4	89.8	90.8	83.8		89.2	83.6	88.9	
Ever Received	95.8	91.5	95.8	95.3		83.6	97.0	100.0	

TABLE 29—LARGER-VOLUME COHORT BENCHMARKS

					State				
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Oasis-Based Measures:									
Discharged to Community	82.1	85.6	78.3	81.2	81.1	78.2	80.3	81.0	83.1
Drug Education on All Medications Pro-									
vided to Patient/Caregiver during all									
Episodes of Care	99.8	100.0	99.9	100.0	99.9	99.7	99.9	99.8	99.7
Improvement in Ambulation- Locomotion	76.4	92.4	76.7	76.1	76.5	75.2	80.8	77.2	70.8
Improvement in Bathing	84.2	94.2	81.9	81.0	81.0	78.9	86.6	83.5	77.7
Improvement in Bed Transferring	76.4	85.4	78.1	80.2	77.5	74.5	82.2	76.8	73.5
Improvement in Dyspnea	85.9	90.5	81.3	82.2	85.1	85.5	80.7	84.2	80.7
Improvement in Management of Oral									
Medications	69.4	80.5	68.1	73.2	71.7	63.9	68.1	72.2	64.0
Improvement in Pain Interfering with Ac-									
tivity	88.6	96.7	81.0	89.5	84.4	81.5	86.0	81.7	75.5
Influenza Immunization Received for									
Current Flu Season	88.0	93.3	88.1	90.1	87.9	88.0	95.2	88.2	87.0
Pneumococcal Polysaccharide Vaccine									
Ever Received	92.5	93.6	94.4	93.8	92.1	93.4	97.0	92.7	92.7

TABLE 30—STATE LEVEL COHORT BENCHMARKS

		State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA	
Oasis-Based Measures:										
Discharged to Community	81.8	86.3	77.7	81.9	81.1	78.2	80.5	80.9	83.1	
Drug Education on All Medications Pro-										
vided to Patient/Caregiver during all										
Episodes of Care	99.8	100.0	100.0	100.0	99.9	99.7	99.9	99.8	99.7	
Improvement in Ambulation- Locomotion	77.5	92.1	76.2	76.3	76.5	75.2	82.9	77.9	70.8	
Improvement in Bathing	84.1	93.8	81.8	80.3	81.0	78.9	84.6	83.5	77.7	
Improvement in Bed Transferring	75.9	84.8	77.6	80.1	77.5	74.5	83.1	77.3	73.5	
Improvement in Dyspnea	85.8	90.5	81.9	81.7	85.1	85.5	81.3	85.8	80.7	
Improvement in Management of Oral										
Medications	69.1	79.6	67.3	72.0	71.7	64.1	68.3	72.2	64.0	
Improvement in Pain Interfering with Ac-										
tivity	88.1	96.8	81.5	88.4	84.4	81.5	84.3	81.7	75.5	
Influenza Immunization Received for										
Current Flu Season	87.6	92.9	88.9	90.1	87.9	88.3	94.4	88.2	87.0	
Pneumococcal Polysaccharide Vaccine										
Ever Received	92.9	93.3	94.8	94.2	92.1	93.4	97.0	93.3	92.7	

The three tables are based on the analysis using the most current data available. The results highlight that there is a greater degree of interstate variation in the benchmark values for the cohorts that have fewer HHAs as compared to the variation in benchmark values for the cohorts that have a greater number of HHAs.

We also performed a similar analysis with the achievement thresholds and comparing how the individual benchmarks and achievement thresholds would fluctuate from one year to the next for the smaller-volume cohorts, larger-volume cohorts, and the state level cohorts. The results of those analyses were similar.

Based on the analyses that we have described, we are concerned that if we separate HHAs into smaller- and largervolume cohorts by state for purposes of calculating the benchmarks and

achievement thresholds, HHAs in the smaller-volume cohorts could be required to meet performance standards that are greater than the level of performance that HHAs in the largervolume cohorts would be required to achieve. For this reason, we are proposing to calculate the benchmarks and achievement thresholds at the state level rather than at the smaller- and larger-volume cohort level for all model years, beginning with CY 2016. This change will eliminate the increased variation caused by having few HHAs in the cohort but still takes into account that there will be some inter-state variation in the values due to state regulatory differences.

We seek public comments on this proposal.

2. The Payment Adjustment Methodology

We finalized in the CY 2016 HH PPS final rule that we would use a linear exchange function (LEF) to translate a competing HHA's TPS into a valuebased payment adjustment percentage under the HHVBP Model (80 FR 68686). We also finalized that we would calculate the LEF separately for each smaller-volume cohort and largervolume cohort. In addition, we finalized that if an 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, we would not include the HHA in the LEF and we would not calculate a payment adjustment percentage for that HHA.

Since the publication of the CY 2016 HH PPS final rule, we have continued to evaluate the payment adjustment methodology using the most recent data available. We updated our analysis of the 10 OASIS quality measures and two claims-based measures using the newly available 2014 QIES Roll Up File data, which was not available prior to the issuance of that final rule. 19 We also determined the size of the cohorts using the 2014 Quality Episode File based on OASIS assessments rather than archived quality data sources that were used in the CY 2016 rule, whereby the HHAs reported at least five measures with over 20 episodes of care. Based on this data, we determined that with respect to performance year 2016, there were only three states (AZ, FL, NE) that have more than 10 HHAs in the smaller-volume cohort; one state (IA) that has 8-10 HHAs in the smaller-volume cohort. three states (NC, MA, TN) that have 1-3 HHAs in the smaller-volume cohort; and two states (MD, WA) that have no HHAs in the smaller-volume cohort. In the CY 2016 HH PPS final rule (80 FR 68664), we finalized that when there are too few HHAs in the smaller-volume cohort in each state to compete in a fair manner, the HHAs in that cohort would be included in the larger-volume cohort for purposes of calculating their payment adjustment percentage. The CY 2016 rule further defines too few as when there is only one or two HHAs competing within a smaller-volume cohort in a given state.

We also used the more current data source mentioned above to analyze the effects of outliers on the LEF. As indicated by the payment distributions set forth in Table 23 of this rule, the LEF is designed so that the majority of the payment adjustment values fall closer to the median and only a small percentage of HHAs receive adjustments at the higher and lower ends of the distribution. However, when we looked at the more recent data, we discovered that if there are only three or four HHAs in the cohort, one HHA outlier could skew the payment adjustments and deviate the payment distribution from the intended design of the LEF payment methodology where HHAs should fall close to the median of the payment distribution. For example, if there are only three HHAs in the cohort, we concluded that there is a high likelihood that those HHAs would have payment adjustments of -2.5 percent, -2.0percent and +4.5 percent when the maximum payment adjustment is 5 percent, none falling close to the mean, with the result that those HHAs would

receive payment adjustments at the higher or lower ends of the distribution. As the size of the cohort increases, we determined that this became less of an issue, and that the majority of the HHAs would have payment adjustments that are close to the median. This is illustrated in the payment distribution in Table 23 of this rule. Under the payment distribution for the largervolume cohorts, 80 percent of the HHAs in AZ, IA, FL and NE would receive a payment adjustment ranging from -2.2percent to +2.2 percent when the maximum payment adjustment is 5 percent (See state level cohort in Table 23). Arizona is a state that has a smallervolume cohort with only nine HHAs but its payment distribution is comparable, ranging from -1 percent to +1 percent even with one outlier that is at 5

In order to determine the minimum number of HHAs that would have to be in a smaller-volume cohort in order to insulate that cohort from the effect of outliers, we analyzed performance results related to the OASIS and claimsbased measures, as well as HHCAHPS, using 2013 and 2014 data. We specifically simulated the impact that outliers would have on cohort sizes ranging from four HHAs to twelve HHAs. We found that the LEF was less susceptible to large variation from outlier impacts once the cohort size reached a minimum of eight HHAs. We also found that a minimum of eight HHAs would allow for four states with smaller-volume cohorts to have 80 percent of their payment adjustments fall between -2.3 percent and +2.4percent. As a result of this analysis, we are proposing that a smaller-volume cohort have a minimum eight HHAs in order for the HHAs in that cohort to be compared only against each other, and not against the HHAs in the largervolume cohort. We believe this proposal would better mitigate the impact of outliers as compared to our current policy, while also enabling us to evaluate the impact of the Model on competition between smaller-volume

We are also proposing that if a smaller-volume cohort in a state has fewer than eight HHAs, those HHAs would be included in the larger-volume cohort for that state for purposes of calculating the LEF and payment adjustment percentages. If finalized, this change would apply to the CY 2018 payment adjustments and thereafter. We will continue to analyze and review the most current cohort size data as it becomes available. We seek public comments on this proposal.

C. Quality Measure Proposals

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 68671–68673) 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 (IMPACT) Act of 2014 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 ²⁰ (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 5 and 6 of the CY 2016 HH PPS final rule identified 15 outcome measures (five from the HHCAHPS, eight from 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).

During implementation of the Model, we determined that four of the measures finalized for PY1 require further consideration before inclusion in the HHVBP Model measure set as described below. Specifically, we are proposing to remove the following measures, as described in Figure 4a of the CY 2016 HH PPS final rule, from the set of applicable measures: (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

¹⁹We did not update our analysis of the HHCAHPS measures because more recent data was not available

²⁰ 2015 Annual Report to Congress, http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm.

October 1 and March 31?; and (4) Reason Pneumococcal Vaccine Not Received. We are proposing to remove these four measures, for the reasons discussed below, beginning with the CY 2016 Performance Year (PY1) calculations, and believe this will not cause substantial change in the first annual payment adjustment that will occur in CY 2018, as each measure is equally weighted and will not be represented in the calculations. The proposed revisions to the measure set, as set forth in Table 31 would be applicable to each performance year subject to any changes made through future rulemaking.

We are proposing to remove the "Care Management: Types and Sources of Assistance" measure because (1) a numerator and denominator for the measure were not made available in the CY2016 HH PPS final rule; and (2) the potential OASIS items that could be utilized in the development of the measure were not fully specified in the CY 2016 HH PPS final rule. We want to further consider the appropriate numerator and denominator for the OASIS data source before proposing the inclusion of this measure in the HHVBP Model.

We are proposing to remove the "Prior Functioning ADL/IADL" measure because (1) the NQF endorsed measure

(NQF0430) included in the 2016 HH PPS final rule does not apply to home health agencies; and (2) the NQF endorsed measure (NQF0430) refers to a measure that utilizes the AM–PAC (Activity Measure for Post-Acute Care) tool that is not currently (and has never been) collected by home health agencies.

We are proposing to remove the "Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31?" measure because this datum element (OASIS item M1041) is used to calculate another HHVBP measure "Influenza Immunization Received for Current Flu Season" and was not designed as an additional and separate measure of performance.

We are proposing to remove the "Reason Pneumococcal Vaccine Not Received" measure because (1) these data are reported as an element of the record for clinical decision making and inform agency policy (that is, so that the agency knows what proportion of its patients did not receive the vaccine because it was contraindicated (harmful) for the patient or that the patient chose to not receive the vaccine); and (2) this measure itemizes the reason for the removal of individuals for whom the vaccine is not

appropriate, which is already included in the numerator of the "Pneumococcal Polysaccharide Vaccine Ever Received" measure also included in the HHVBP Model

Because the starter set is defined as the quality measures selected for the first year of the Model only, we propose to revise § 484.315 to refer to "a set of quality measures" rather than "a starter set of quality measures" and to revise § 484.320 (a), (b), (c), and (d) to remove the phrase "in the starter set". We are also proposing to delete the definition of "Starter set" in § 484.305 because that definition would no longer be used in the HHVBP Model regulations following the proposed revisions to §§ 484.315 and 484.320.

The proposed revised set of applicable measures is presented in Table 31, which excludes the four measures we propose to be removed. We propose that this measure set will be applicable to PY1 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. Moving forward, we plan to utilize an implementation contractor who will invite a group of measure experts to provide advice on the adjustment of the current measure set.

TABLE 31—PROPOSED MEASURE SET FOR THE HHVBP MODEL 21

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 epi- sodes of care where the value recorded on the dis- charge assessment indi- cates less impairment in ambulation/locomotion at discharge than at the start (or resumption) of care.	Number of home health epi- sodes of care ending with a discharge during the re- porting period, other than those covered by generic or measure-specific exclu- sions.
Clinical Quality of Care	Improvement in Bed Transferring.	Outcome	NQF0175	OASIS (M1850)	Number of home health epi- sodes of care where the value recorded on the dis- charge assessment indi- cates less impairment in bed transferring at dis- charge than at the start (or resumption) of care.	Number of home health epi- sodes of care ending with a discharge during the re- porting period, other than those covered by generic or measure-specific exclu- sions.
Clinical Quality of Care	Improvement in Bathing	Outcome	NQF0174	OASIS (M1830)	Number of home health epi- sodes of care where the value recorded on the dis- charge assessment indi- cates less impairment in bathing at discharge than at the start (or resumption) of care.	Number of home health epi- sodes of care ending with a discharge during the re- porting period, other than those covered by generic or measure-specific exclu- sions.
Clinical Quality of Care	Improvement in Dyspnea	Outcome	NA	OASIS (M1400)	Number of home health epi- sodes of care where the discharge assessment indi- cates less dyspnea at dis- charge than at start (or re- sumption) of care.	Number of home health epi- sodes of care ending with a discharge during the re- porting period, other than those covered by generic or measure-specific exclu- sions.

²¹For more detailed information on the proposed measures utilizing OASIS refer to the *OASIS-C1/ICD-9*, Changed Items & Data Collection Resources data 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/ HHQIQualityMeasures.html. For information on HHCAHPS measures see https:// homehealthcahps.org/SurveyandProtocols/ SurveyMaterials.aspx.

TABLE 31—PROPOSED MEASURE SET FOR THE HHVBP MODEL 21—Continued

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Communication & Care Coordination.	Discharged to Community	Outcome	NA	OASIS (M2420)	Number of home health epi- sodes where the assess- ment completed at the dis- charge indicates the patient remained in the community after discharge.	Number of home health epi- sodes of care ending with discharge or transfer to in- patient facility during the reporting period, other than those covered by generic or measure-specific exclu- sions.
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 un- planned 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 Inter- fering with Activity.	Outcome	NQF0177	OASIS (M1242)	Number of home health epi- sodes of care where the value recorded on the dis- charge assessment indi- cates less frequent pain at discharge than at the start (or resumption) of care.	Number of home health epi- sodes of care ending with a discharge during the re- porting period, other than those covered by generic or measure-specific exclu- sions.
Patient Safety	Improvement in Management of Oral Medications.	Outcome	NQF0176	OASIS (M2020)	Number of home health epi- sodes of care where the value recorded on the dis- charge assessment indi- cates less impairment in taking oral medications cor- rectly at discharge than at start (or resumption) of care.	Number of home health epi- sodes of care ending with a discharge during the re- porting period, other than those covered by generic or measure-specific exclu- sions.
Population/Community Health	Influenza Immunization Received for Current Flu Season.	Process	NQF0522	OASIS (M1046)	Number of home health epi- sodes during which pa- tients (a) received vaccina- tion from the HHA or (b) had received vaccination from HHA during earlier episode of care, or (c) was determined to have re- ceived vaccination from an- other provider.	Number of home health epi- sodes of care ending with discharge, or transfer to in- patient facility during the reporting period, other than those covered by generic or measure-specific exclu- sions.
Population/Community Health	Pneumococcal Poly- saccharide Vaccine Ever Received.	Process	NQF0525	OASIS (M1051)	Number of home health epi- sodes during which pa- tients were determined to have ever received Pneu- mococcal Polysaccharide Vaccine (PPV).	Number of home health epi- sodes of care ending with discharge or transfer to in- patient facility during the reporting period, other than those covered by generic or measure-specific exclu- sions.
Clinical Quality of Care	Drug Education on All Medications Provided to Patient/ Caregiver during all Episodes of Care.	Process	NA	OASIS (M2015)	Number of home health epi- sodes of care during which patient/caregiver was in- structed on how to monitor the effectiveness of drug therapy, how to recognize potential adverse effects, and how and when to re- port problems (since the previous OASIS assess- ment).	Number of home health epi- sodes of care ending with a discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclu- sions.
Patient & Caregiver-Centered Experience.	Care of Patients	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Communications between Providers and Patients.	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Specific Care Issues	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Overall rating of home health care.	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Willingness to recommend the agency.	Outcome		CAHPS	NA	NA.

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Population/Community Health	Influenza Vaccination Coverage for Home Health Care Personnel.	Process	NOF0431 (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 (c) declined influenza vaccination; 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) vac- cination: 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.

In the CY 2016 HH PPS final rule, we finalized that HHAs will be required to begin reporting data on each of the three New Measures no later than October 7, 2016 for the period July 2016 through September 2016 and quarterly thereafter. We now propose to require annual, rather than quarterly reporting for one of the three New Measures, "Influenza Vaccination Coverage for Home Health Personnel," with the first annual submission in April 2017 for PY2. Specifically, we are proposing to require an annual submission in April for the prior 6-month reporting period of October 1-March 31 to coincide with the flu season. Under this proposal, for PY1, the HHA would report on this measure in October 2016 and January 2017. HHAs would report on this measure in April 2017 for PY2 and annually in April thereafter. We believe that changing the reporting and submission periods for this measure from quarterly to annually would avoid the need for HHAs to have to report zeroes in multiple data fields for the two quarters (July through September, and April through June) that fall outside of

the parameters of the denominator (October through March).

We are not proposing to change the quarterly reporting and submission requirements as set forth in the CY 2016 HH PPS final rule (80 FR 68674–68678) for the other two New Measures, "Advanced Care Planning", and "Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?"

We are also proposing to increase the timeframe for submitting New Measures data from seven calendar days (80 FR 68675–68678) to fifteen calendar days following the end of each reporting period to account for weekends and holidays.

We invite public comment on our proposals.

D. Appeals Process Proposal

In the CY 2016 HH PPS final rule (80 FR 68689), we stated that we intended to propose an appeals mechanism in future rulemaking prior to the application of the first payment adjustments scheduled for CY 2018. We are proposing an appeals process for the HHVBP Model which includes the

period to review and request recalculation of both the Interim Performance Reports and the Annual TPS and Payment Adjustment Reports, as finalized in the CY 2016 HH PPS final rule (80 FR 68688–68689) and subject to the modifications we are proposing here, and reconsideration request process for the Annual TPS and Payment Adjustment Report only, as described later in this section, which may only occur after an HHA has first submitted a recalculation request for the Annual TPS and Payment Adjustment Report.

Ås finalized in the CY 2016 HH PPS final rule, HHAs have the opportunity to review their Interim Performance Report following each quarterly posting. The Interim Performance Reports are posted on the HHVBP Secure Portal quarterly, setting forth the HHA's measure scores based on available data to date. The first Interim Performance Report will be provided to all competing HHAs in July 2016 and will include performance scores for the OASIS-based measures for the first quarter of CY 2016. See Table 32 for data provided in each report. The quarterly Interim Performance Reports

will provide competing HHAs with the opportunity to identify and correct calculation errors and resolve discrepancies, thereby minimizing challenges to the annual performance scores linked to payment adjustment.

Competing HHAs also have the opportunity to review their Annual TPS and Payment Adjustment Report. We will inform each competing HHA of its TPS and payment adjustment percentage in an Annual TPS and Payment Adjustment Report provided prior to the calendar year for which the payment adjustment will be applied. The annual TPS will be calculated based on the calculation of performance measures contained in the Interim Performance Reports that have already been received by the HHAs for the performance year.

We are proposing specific timeframes for the submission of recalculation and reconsideration requests to ensure that the final payment adjustment percentage for each competing Medicare-certified HHA can be submitted to the Fiscal Intermediary Shared Systems in time to allow for application of the payment adjustments beginning in January of the following calendar year. We believe HHVBP payment adjustments should be timely and that the appeals process should be designed so that determinations on recalculations and reconsiderations can

be made in advance of the applicable payment year to reduce burden and uncertainty for competing HHAs.

In this proposed rule, we are proposing to add new § 484.335, titled "Appeals Process for the Home Health Value-Based Purchasing Model," which would codify the recalculation request process finalized in the CY 2016 HH PPS final rule and also a proposed reconsideration request process for the Annual TPS and Payment Adjustment Report. The first level of this appeals process would be the recalculation request process, as finalized in the CY 2016 HH PPS final rule and subject to the proposed modifications described later in this section. We are proposing that the reconsideration request process for the Annual TPS and Payment Adjustment Report would complete the appeals process, and would be available only when an HHA has first submitted a recalculation request for the Annual TPS and Payment Adjustment Report under the process finalized in the CY 2016 HH PPS final rule, subject to the modifications we are proposing here. We believe that this proposed appeals process will allow the HHAs to seek timely corrections for errors that may be introduced during the Interim Performance Reports that could affect an HHA's payments.

To inform our proposal for an appeals process under the HHVBP Model we

reviewed the appeals policies for two CMS programs that are similar in their program goals to the HHVBP Model, the Medicare Shared Savings Program ²² and Hospital Value-Based Purchasing Program, ²³ as well as the appeals policy for the Comprehensive Care for Joint Replacement Model ²⁴ that is being tested by the Center for Medicare and Medicaid Innovation (CMMI).

Under section 1115Å(d) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites or participants to test those models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.
- The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act.
- Decisions about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in section 1115A(c)(1) or (2) of the Act.

TABLE 32—HHVBP MODEL PERFORMANCE REPORT DATA SCHEDULE

Report type	Publication date	OASIS-Based measures and new measures	Claims- and HHCAHPS-based measures
Interim Performance Scores	January	3 quarters of previous PY (9 months); [Jan-Sept].	2 quarters of previous PY (6 months); [Jan-Jun].
Interim Performance Scores	April	12 months of previous PY [Jan-Dec]	3 quarters of previous PY (9 months); [Jan-Sept].
Interim Performance Scores	July	1st quarter of next PY (3 months); [Jan-Mar].	12 months of previous PY; [Jan-Dec].
Interim Performance Scores	October	2 quarters of next PY (6 months); [Jan-Jun].	1st quarter of next PY (3 months); [Jan-Mar].
Annual TPS and Payment Adjustment Percentage.	August	Entire 12 months of pr	revious PY; [Jan-Dec].
Annual TPS and Payment Adjustment Percentage; (Final).	November	Entire 12 months of previous PY [Jan-De ation request	ec] after all recalculations and reconsider- ts processed.

²² Title 42—Public Health, Chapter IV—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B, Part 425—Medicare Shared Savings Program, Subpart I—Reconsideration Review Process. (http://www.ecfr.gov/cgi-bin/text-idx?SID=880f6bd18190 4fc648f0e9a885103dba&mc=true&node=sp42.3.425.i&rgn=div6)

²³ Title 42—Public Health, Chapter IV—Centers for Medicare & Medicaid Services, Department of

Health and Human Services, Subchapter B, Part 412—Prospective Payment System for Inpatient Hospital Services, Subpart I—Adjustments to the Base Operating DRG Payment Amounts Under the Prospective Payment Systems for Inpatient Operating Costs (http://www.ecfr.gov/cgi-bin/text-idx?SID=dd15db0a13792035b9b42b342270fad6 &mc=true&node=sg42.2.412_1155_6412_1159.sg4 &rgn=div7)

²⁴ Title 42—Public Health, Chapter IV—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter H—Health Care Infrastructure and Model Programs, Part 510—Comprehensive Care for Joint Replacement Model. http://www.ecfr.gov/cgi-bin/text-idx?SID=a18d6f5665d1fbf2e1ae955e1bf1b97c&mc=true&node=pt42.5.510&rgn=div5)

1. Recalculation

HHAs may submit recalculation requests for both the Interim Performance Reports and the Annual TPS and Payment Adjustment Report via a form located on the HHVBP Secure Portal that is only accessible to the competing HHAs. The request form would be entered by a person who has legal authority to sign on behalf of the HHA and, as finalized in the CY 2016 HH PPS final rule, must be submitted within 30 calendar days of the posting of each performance report on the model-specific Web site. For the reasons discussed later in this section, we are proposing to change this policy to require that recalculation requests for both the Interim Performance Report and the Annual TPS and Payment Adjustment Report be submitted within 15 calendar days of the posting of the Interim Performance Report and the Annual TPS and Payment Adjustment Report on the HHVBP Secure Portal instead of 30 calendar days.

For both the Interim Performance Reports and the Annual TPS and Payment Adjustment Report, requests for recalculation must contain specific information, as set forth in the CY 2016 HH PPS final rule (80 FR 68688). We are proposing that requests for reconsideration of the Annual TPS and Payment Adjustment Report must also contain this same information.

- The provider's name, address associated with the services delivered, and CMS Certification Number (CCN);
- The basis for requesting recalculation to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect;
- Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box); and,
- A copy of any supporting documentation the HHA wishes to submit in electronic form via the model-specific Web page.

Following receipt of a request for recalculation of an Interim Performance Report or the Annual TPS and Payment Adjustment Report, CMS or its agent will:

- Provide an email acknowledgement, using the contact information provided in the recalculation request, to the HHA contact notifying the HHA that the request has been received;
- Review the request to determine validity, and determine whether the recalculation request results in a score

change, altering performance measure scores or the HHA's TPS;

- Conduct a review of quality data if recalculation results in a performance score or TPS change, and recalculate the TPS using the corrected performance data if an error is found; and,
- Provide a formal response to the HHA contact, using the contact information provided in the recalculation request, notifying the HHA of the outcome of the review and recalculation process.

We anticipate providing this response as soon as administratively feasible following the submission of the request.

We will not be responsible for providing HHAs with the underlying source data utilized to generate performance measure scores because HHAs have access to this data via the QIES system.

We are proposing that recalculation requests for the Interim Performance Reports must be submitted within 15 calendar days of these reports being posted on the HHVBP Secure Portal, rather than 30 calendar days as finalized in the CY 2016 HH PPS final rule. We believe this would allow recalculations of the Interim Performance Reports posted in July to be completed prior to the posting of the Annual TPS and Payment Adjustment Report in August. We are proposing that recalculation requests for the TPS or payment adjustment percentage must be submitted within 15 calendar days of the Annual TPS and Payment Adjustment Report being posted on the HHVBP Secure Portal, rather than 30 days as finalized in the CY 2016 HH PPS final rule. We are proposing to shorten this timeframe to allow for a second level of appeals, the proposed reconsideration request process, to be completed prior to the generation of the final data files containing the payment adjustment percentage for each competing Medicare-certified HHA and the submission of those data files to the Fiscal Intermediary Share Systems. We contemplated longer timeframes for the submission of both recalculation and reconsideration requests for the Annual TPS and Payment Adjustment Reports, but believe that this would result in appeals not being resolved in advance of the payment adjustments being applied beginning in January of the following calendar year. We invite comments on this proposed timeframe for recalculation requests, as well as any alternatives.

2. Reconsideration

We are proposing that if we determine that the calculation was correct and deny the HHA request for recalculation of the Annual TPS and Payment
Adjustment Report, or if the HHA
disagrees with the results of a CMS
recalculation of such report, the HHA
may submit a reconsideration request
for the Annual TPS and Payment
Adjustment Report. The reconsideration
request and supporting documentation
would be required to be submitted via
the form on the HHVBP Secure Portal
within 15 calendar days of CMS'
notification to the HHA contact of the
outcome of the recalculation request for
the Annual TPS and Payment
Adjustment Report.

We propose that an HHA may request reconsideration of the outcome of a recalculation request for its Annual TPS and Payment Adjustment Report only. We believe that the ability to review the Interim Performance Reports and submit recalculation requests on a quarterly basis provides competing HHAs with a mechanism to address potential errors in advance of receiving their annual TPS and payment adjustment percentage. Therefore, we expect that in many cases, the reconsideration request process proposed in this rule would result in a mechanical review of the application of the formulas for the TPS and the LEF, which could result in the determination that a formula was not accurately applied. Reconsiderations would be conducted by a CMS official who was not involved with the original recalculation request.

We are proposing that an HHA must submit the reconsideration request and supporting documentation via the HHVBP Secure Portal within 15 calendar days of CMS' notification to the HHA contact of the outcome of the recalculation process so that a decision on the reconsideration can be made prior to the generation of the final data files containing the payment adjustment percentage for each competing Medicare-certified HHA and the submission of those data files to the Fiscal Intermediary Share Systems. We believe that this would allow for finalization of the interim performance scores, TPS, and annual payment adjustment percentages in advance of the application of the payment adjustments for the applicable performance year. As noted above, we contemplated longer timeframes for the submission of both recalculation and reconsideration requests, but believe this would result in appeals not being resolved in advance of the payment adjustments being applied beginning in January of the following calendar year. CMS invites comments on its proposed timeframe for reconsideration requests, as well as any alternatives.

We finalized in the CY 2016 HH PPS final rule (80 FR 68688) that the final TPS and payment adjustment percentage would be provided to competing HHAs in a final report no later than 60 calendar days in advance of the payment adjustment taking effect. We are now proposing that the final TPS and payment adjustment percentage be provided to competing HHAs in a final report no later than 30 calendar days in advance of the payment adjustment taking effect to account for unforeseen delays that could occur between the time the Annual TPS and Payment Adjustment Reports are posted and the appeals process is completed.

We solicit comments on our proposals related to the appeals process for the HHVBP Model described in this section and the associated proposed regulation text at § 484.335.

E. Public Display of Total Performance Scores for the HHVBP Model

In the CY 2016 HH PPS final rule (80 FR 68658), we stated that one of the three goals of the HHVBP Model is to "Enhance current public reporting processes". Annual publicly-available performance reports would be a means of developing greater transparency of Medicare data on quality and aligning the competitive forces within the market to deliver care based on value over volume. The publicly-reported reports will inform home health industry stakeholders (consumers, physicians, hospitals) as well as all competing HHAs delivering care to Medicare beneficiaries within selected state boundaries on their level of quality relative to both their peers and their own past performance. These public reports would provide home health industry stakeholders, including providers and suppliers that refer their patients to HHAs, an opportunity to confirm that the beneficiaries they are referring for home health services are being provided the best possible quality of care available.

We received support via public comments to publicly report the HHVBP Model performance data because they would inform industry stakeholders of quality improvements. These comments noted several areas of value in performance data. Specifically, commenters suggested that public reports would permit providers to direct patients to a source of information about higher-performing HHAs based on quality reports. Commenters offered that to the extent possible, accurate comparable data will encourage HHAs to improve care delivery and patient outcomes, while better predicting and managing quality performance and

payment updates. Although competing HHAs have direct technical support and other tools to encourage best practices, we believe public reporting of their Total Performance Score will encourage providers and patients to utilize this information when selecting a HHA to provide quality care.

We have employed a variety of means to ensure that we maintain transparency while developing and implementing the HHVBP Model. This same care is being taken as we plan public reporting in collaboration with other CMS components that use many of the same quality measures. We continue to engage and inform stakeholders about various aspects of the HHVBP Model through CMS Open Door Forums and updates to the HHVBP Model Innovation Center Web page (https:// innovation.cms.gov/initiatives/homehealth-value-based-purchasing-model). We have held several webinars since December 2015 to educate competing HHAs. Topics of the webinars ranged from an overview of the HHVBP Model to specific content areas addressed in the CY 2016 HH PPS final rule. The primary purpose of the focused attention provided to the competing HHAs through the HHVBP learning systems and webinars is to facilitate direct communication, sharing of information, and collaboration.

Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit patient-level quality of care data using the Outcome and Information Assessment Set (OASIS) and the Home Health Consumer Assessment of Health Care Providers and Systems (HHCAHPS). Section 1895(b)(3)(B)(v)(III) of the Act states that this quality data is to be made available to the public. Thus, home health agencies have been required to collect OASIS data since 1999 and report HHCAHPS data since 2012. Use of OASIS measures for the HHVBP Model logically follows, as the validation through experience creates greater efficiency than constructing an entirely new set of measures.

We are considering various public reporting platforms for the HHVBP Model including Home Health Compare (HHC) and the Center for Medicare and Medicaid Innovation (CMMI) Web page as a vehicle for maintaining information in a centralized location and making information available over the Internet. We believe the public reporting of competing HHAs' performance scores under the HHVBP Model supports our continuing efforts to empower consumers by providing more information to help them make health care decisions, while also encouraging providers to strive for higher levels of

quality. As the public reporting mechanism for the HHVBP Model is being developed, we are considering which data elements reported will be meaningful to stakeholders and may inform the selection of HHAs for care.

We are considering public reporting for the HHVBP Model, beginning no earlier than CY 2019, to allow analysis of at least eight quarters of performance data for the Model and the opportunity to compare how those results align with other publicly reported quality data. We are encouraged by the previous stakeholder comments and support for public reporting that could assist patients, physicians, discharge planners, and other referral sources to choose higher-performing HHAs.

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 for a particular year, the 2 percentage point reduction under section 1895(b)(3)(B)(v)(I) of the Act may result in this percentage increase, after application of the productivity adjustment under section 1895(b)(3)(B)(vi)(I) of the Act, 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.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) imposed new data reporting requirements for certain postacute care (PAC) providers, including HHAs. For more information on the statutory background of the IMPACT Act, please refer to the CY 2016 HH PPS final rule (80 FR 68690 through 68692).

In that final rule, we established our approach for identifying cross-setting measures and processes for the adoption of measures, including the application and purpose of the Measures Application Partnership (MAP) and the notice and comment rulemaking process. More information on the

IMPACT Act is also available at https://www.govtrack.us/congress/bills/113/hr4994.

In the CY 2016 HH PPS final rule (80 FR 68692), we also discussed the reporting of OASIS data as it relates to the implementation of ICD-10 on October 1, 2015. We submitted a new request for approval to OMB for the OASIS-C1/ICD-10 version under the Paperwork Reduction Act (PRA) process, including a new OMB control number (see 80 FR 15796). The new information collection request for OASIS-C1/ICD-10 version was approved under OMB control number 0938-1279 with a current expiration date of May 31, 2018. To satisfy requirements in the IMPACT Act that HHAs submit standardized patient assessment data in accordance with section 1899B(b) and to create consistency in the lookback period across selected OASIS items, we have created a modified version of the OASIS, OASIS-C2. We have submitted request for approval to OMB for the OASIS-C2 version under the PRA process (81 FR 18855); also see https:// www.cms.gov/Regulations-and-Guidance/Legislation/ PaperworkReductionActof1995/PRA-Listing.html. The OASIS-C2 version will replace the OASIS-C1/ICD-10 and will be effective for data collected with an assessment completion date (M0090) on and after January 1, 2017. Information regarding the OASIS-C1/ ICD-10 and C2 can be located on the OASIS Data Sets Web page at https:// www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/ OASIS-Data-Sets.html.

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 Home Health Quality Reporting Program (HH QRP), such as alignment with the CMS Quality Strategy,²⁵ which incorporates the three broad aims of the National Quality Strategy.²⁶ Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous

evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. Quality reporting programs (QRPs), coupled with public reporting of quality information are critical to the advancement of health care quality improvement efforts. Valid, reliable, and relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for us in all of our QRPs.

In this proposed rule, we propose to adopt for the HH QRP one measure that we are specifying under section 1899B(c)(1)(C) of the Act to meet the Medication Reconciliation domain: (1) Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post-Acute Care Home Health Quality Reporting Program (Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP) Further, we are proposing to adopt for the HH QRP three measures to meet the "Resource Use and other Measures" domains required by section 1899B(d)(1) of the Act: (1) Total Estimated Medicare Spending per Beneficiary—Post Acute Care Home Health Quality Reporting Program (MSPB-PAC HH QRP); (2) Discharge to Community—Post Acute Care Home Health Quality Reporting Program (Discharge to Community-PAC HH QRP); and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for Post-Acute Care Home Health Quality Reporting Program (Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP).

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for prerulemaking input on each measure, as required by section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015 for the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP; on August 25, 2015, September 25, 2015, and October 5, 2015, for the Discharge to Community-PAC HH QRP; on August 12-13, 2015, and October 14, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP; and on October 29-30, 2015, for the MSPB-PAC HH QRP measures. In addition, we released draft quality

measure specifications for public comment on the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP from September 18, 2015 to October 6, 2015, for the Discharge to Community-PAC HH QRP from November 9, 2015 to December 8, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP from November 2, 2015 to December 1, 2015, and for the MSPB-PAC HH QRP measures from January 13, 2016 to February 5, 2016. Further, we opened a public mailbox, PACQualityInitiative@ cms.hhs.gov, for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site, on the IMPACT Act of 2014 Data Standardization & Cross Setting Measures Web page at https:// www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/ IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-MeasuresMeasures.html.

Additionally, we sought public input from the MAP Post-Acute Care, Long-Term Care Workgroup during the annual public meeting held December 14-15, 2015. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act, tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. The MAP reviewed each measure proposed in this rule for use in the HH QRP. For more information on the MAP, we refer readers to the CY 2016 HH PPS final rule (80 FR 68692 through 68694). Further, for more information on the MAP's recommendations, we refer readers to the MAP 2015-2016 Considerations for Implementing Measures in Federal Programs public report at http://www.qualityforum.org/ Publications/2016/02/MAP 2016 Considerations for Implementing Measures in Federal Programs - PAC-LTC.aspx.

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the HH QRP, we are proposing measures for the HH QRP for the purposes of satisfying the measure domains required under the IMPACT Act measures that most closely align with the national priorities identified in the National Quality Strategy (http://www.ahrq.gov/workingforquality/) and with respect to which the MAP supports the measure concept. Further, we discuss below the importance and high-priority status of

²⁵ http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ QualityInitiativesGenInfo/CMS-Quality-Strategy.html.

 $^{^{26}}$ http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.

these proposed measures in the HH setting.

C. Process for Retaining, Removing, and Replacing Previously Adopted Home Health Quality Reporting Program Measures for Subsequent Payment Determinations

Consistent with the policies of other provider QRPs, including the Hospital Inpatient Quality Reporting Program (Hospital IQR) (77 FR 53512 through 53513), the Hospital Outpatient Quality Reporting Program (Hospital OQR) (77 FR 68471), the LTCH QRP (77 FR 53614 through 53615), and the IRF QRP (77 FR 68500 through 68507), we are proposing that when we initially adopt a measure for the HH QRP for a payment determination, this measure will be automatically retained for all subsequent payment determinations unless we propose to remove or replace the measure, or unless the exception discussed below applies.

We are proposing to define the term "remove" to mean that the measure is no longer a part of the HH QRP measure set, data on the measure will no longer be collected for purposes of the HH QRP, and the performance data for the measure will no longer be displayed on HH Compare. We are also proposing to use the following criteria when considering a quality measure for removal: (1) Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made; (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; and (6) a measure that is more strongly associated with desired patient outcomes for the particular topic is available. These items may still appear on OASIS for previously established purposes that are non-related to our HH QRP. HHAs will be able to access these reports using the Certification and Survey Provider Enhanced Reports (CASPER) system and can use the information for their own monitoring and quality improvement efforts.

Further, we are proposing to define "replace" to mean that we would adopt a different quality measure in place of a currently used quality measure, for one or more of the reasons described above. Additionally, we are proposing that any such "removal" or

"replacement" will take place through notice-and-comment rulemaking, unless we determine that a measure is causing concern for patient safety. Specifically, in the case of a HH QRP measure for which there is a reason to believe that the continued collection raises possible safety concerns or would cause other unintended consequences, we propose to promptly remove the measure and publish the justification for the removal in the Federal Register during the next rulemaking cycle. In addition, we will immediately notify HHAs and the public through the usual communication channels, including listening session, memos, email notification, and Web postings. If we removed a measure under these circumstances, we would also not continue to collect data on that measure under our alternative authorities for purposes other than the HH QRP.

We invite public comment on our proposed policy for retaining, removing and replacing previously adopted quality measures, including the criteria we propose to use when considering whether to remove a quality measure from the HH QRP.

D. Quality Measures That Will Be Removed From the Home Health Quality Initiative, and Quality Measures That Are Proposed for Removal From the HH QRP Beginning With the CY 2018 Payment Determination

In 2015, we undertook a comprehensive reevaluation of all 81 HH quality measures, some of which are used only in the Home Health Quality Initiative (HHQI), and others which are also used in the HH QRP. This review of all the measures was performed in accordance with the guidelines from the CMS Measure Management System (MMS) (https://www.cms.gov/Medicare/ Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.html). The goal of this reevaluation was to streamline the measure set, consistent with MMS guidance and in response to stakeholder feedback. This reevaluation included a review of the current scientific basis for each measure, clinical relevance, usability for quality improvement, and evaluation of measure properties, including reportability, and variability. Our measure development and maintenance contractor convened a Technical Expert Panel (TEP) on August 21, 2015, to review and advise on the reevaluation results. The TEP provided feedback on which measures are most useful for patients, caregivers, clinicians, and stakeholders, and on analytics and an environmental scan conducted to inform measure set

revisions. Further information about the TEP feedback is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Health-Quality-Reporting-Program-HHQRP-TEP-.zip.

As a result of the comprehensive reevaluation described above, we identified 28 HHQI measures that were either "topped out" and/or determined to be of limited clinical and quality improvement value by TEP members. Therefore, these measures will no longer be included in the HHQI. A list of these measures, along with our reasons for no longer including them in the HHQI, can be found at the following link https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.

In addition, based on the results of the comprehensive reevaluation and the TEP input, we are proposing to remove 6 process measures from the HH QRP, beginning with the CY 2018 payment determination, because they are "topped out" and therefore no longer have sufficient variability to distinguish between providers in public reporting. These 6 measures are different than the 28 measures that will no longer be

28 measures that will no longer be included within the HHQI. If this proposal is finalized, items used to calculate one or more of these six measures may still appear on the OASIS for previously established purposes that are not related to the HH QRP.

The 6 process measures we are

The 6 process measures we are proposing to remove from the HH QRP are:

- Pain Assessment Conducted;
- Pain Interventions Implemented During All Episodes of Care;
- Pressure Ulcer Risk Assessment Conducted;
- Pressure Ulcer Prevention in Plan of Care;
- Pressure Ulcer Prevention Implemented During All Episodes of Care; and
- Heart Failure Symptoms Addressed During All Episodes of Care.

The technical analysis that supports our proposal to remove the six process measures can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.

We invite public comment on our above proposal to remove 6 process measures from the HH QRP.

E. Proposed Process for Adoption of Updates to HH QRP Measures

We believe that it is important to have in place a sub-regulatory process to

incorporate non-substantive updates into the measure specifications so that these measures remain up-to-date. We also recognize that some changes are substantive in nature and might not be appropriate for adoption using a sub-

regulatory process.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505), we finalized a policy for the Hospital IQR Program under which we use a subregulatory process to make nonsubstantive updates to measures used for that program. For what constitutes substantive versus nonsubstantive changes, we make this determination on a case-by-case basis. Examples of nonsubstantive changes to measures might include: Updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure. Nonsubstantive changes may also include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. Examples of changes that we might consider to be substantive would be those in which: The changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change might be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice.

We are proposing to implement the same process for adopting updates to measures in the HH QRP, and would apply this process, including our policy for determining on a case-by-case basis whether an update is substantive or nonsubstantive. We believe this process adequately balances our need to incorporate updates to the HH QRP measures in the most expeditious manner possible while preserving the public's ability to comment on updates that do not fundamentally change a measure that it is no longer the same measure that we originally adopted.

We invite public comment on this proposal.

F. Modifications to Guidance Regarding Assessment Data Reporting in the OASIS

We are proposing modifications to our coding guidance modifications related to certain pressure ulcer items on the OASIS. In the CY 2016 HH PPS final rule (80 FR 68700), we adopted the NQF #0678 Percent of Residents or Patients

with Pressure Ulcers that are New or Worsened (Short Stay) measure for use in the HH QRP for the CY 2018 HH QRP payment determination and subsequent years. Concurrent with the effective date for OASIS-C2 of January 1, 2017, we would use modified guidance for the reporting of current $\bar{\text{pressure}}$ ulcers. The purpose of this modification is to align with reporting guidance used in other post-acute care settings and with the policies of relevant clinical associations. Chapter 3 of the OASIS-C1/ICD-10 Guidance Manual currently states "Stage III and IV (full thickness) pressure ulcers heal through a process of contraction, granulation, and epithelialization. They can never be considered 'fully healed' but they can be considered closed when they are fully granulated and the wound surface is covered with new epithelial tissue." We utilize professional organizations, such as the National Pressure Ulcer Advisory Panel (NPUAP) to provide clinical insight and expertise related to the use and completion of relevant OASIS items. Based on the currently published position statements and best practices available from the NPUAP,²⁷ effective January 1, 2017, full-thickness (Stage 3 or 4) pressure ulcers should not be reported on OASIS as unhealed pressure ulcers once complete reepithelialization has occurred. This represents a change in past guidance, and will allow OASIS data collection to conform to professional clinical guidelines, and align with pressure ulcer reporting practices in other postacute care settings. In addition to revising guidance related to closed Stage 3 and 4 pressure ulcers, we are changing the reporting instructions when a graft is applied to a pressure ulcer. Current guidance states that when a graft is placed on a pressure ulcer, the wound remains a pressure ulcer and is not concurrently reported as a surgical wound on the OASIS. In order to align with reporting guidance in other postacute care settings, effective January 1, 2017, once a graft is applied to a pressure ulcer, the wound will be reported on OASIS as a surgical wound, and no longer be reported as a pressure ulcer.

G. Proposed HH QRP Quality, Resource Use, and Other Measures for the CY 2018 Payment Determination and Subsequent Years

For the CY 2018 payment determination and subsequent years, in addition to the quality measures we would retain if our proposed policy on retaining measures is finalized, we are proposing to adopt four new measures. These four measures were developed to meet the requirements of the IMPACT Act. These proposed measures are:

- MSPB–PAC HH QRP;
- Discharge to Community-PAC HH QRP;
- Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP; and
- Drug Regimen Review Conducted With Follow-Up for Identified Issues-PAC HH QRP

For the risk-adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding agencies to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on agencies' results on our measures.

The NQF is currently undertaking a 2year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the resource use measures.

²⁷ http://www.npuap.org/wp-content/uploads/ 2012/01/Reverse-Staging-Position-Statement.pdf.

1. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: MSPB–PAC HH QRP

Section 1899B(d)(1)(A) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is October 1, 2016 for SNFs, IRFs and LTCHs and January 1, 2017 for HHAs), the Secretary specify a measure to address the domain of resource use measures, including total estimated Medicare spending per beneficiary. We are proposing to adopt the measure, MSPB-PAC HH QRP, for which we would begin to collect data on January 1, 2017 for the CY 2018 payment determination and subsequent years as a Medicare fee-for-service (FFS) claims-based measure to meet this requirement.

Rising Medicare expenditures for post-acute care as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an average annual rate of 6.1 percent and doubled to \$59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.28 A study commissioned by the Institute of Medicine found that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.²⁹

We reviewed the NQF's consensusendorsed measures and were unable to identify any NOF-endorsed resource use measures for PAC settings. Therefore, we are proposing to adopt this MSPB-PAC HH QRP measure under section 1899B(e)(2)(B) of the Act, which allows us to specify a measure under section 1899B that is not NQF-endorsed if the measure deals with a specified area or medical topic the Secretary has determined to be appropriate for which there is no feasible or practical NQFendorsed measure. We recognize that there are other measures that address Medicare spending per beneficiary, but we are not aware of any such measures that have been endorsed or adopted specifically for the home health setting. Given the current lack of resource use measures for PAC settings, our proposed MSPB-PAC HH QRP measure has the potential to provide valuable information to HHAs on their relative Medicare spending in delivering

services to approximately 3.5 million Medicare beneficiaries.³⁰

The proposed MSPB-PAC HH QRP episode-based measure would provide actionable and transparent information to support HHAs' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB-PAC HH ORP measure holds HHAs accountable for the Medicare payments within an "episode of care" (episode), which includes the period during which a patient is directly under the HHA's care, as well as a defined period after the end of the HHA treatment, which may be reflective of and influenced by the services furnished by the HHA. MSPB-PAC HH QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2014, Medicare FFS beneficiaries experienced 5,379,410 MSPB-PAC HH QRP episodes triggered by admission to a HHA. The mean payment-standardized, riskadjusted episode spending for these episodes was \$10,348 during that fiscal year. There was substantial variation in the Medicare payments for these MSPB-PAC HH QRP episodes—ranging from approximately \$2,480 at the 5th percentile to approximately \$31,964 at the 95th percentile. This variation was partially driven by variation in payments occurring following HH treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve posttreatment care planning and coordination. While some stakeholders throughout the measure development process supported the MSPB-PAC measures and believe that measuring Medicare spending is critical for improving efficiency, others believe that resource use measures do not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, we believe that HHAs involved in the provision of high quality PAC care as well as appropriate discharge planning and post-discharge care coordination will perform well on this measure because beneficiaries will experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can recognize HHAs that

are involved in the provision of high quality care at lower cost.

We have undertaken development of MSPB-PAC measures for each of the four PAC settings. In addition to this measure proposal, we proposed a LTCHspecific MSPB-PAC measure in the FY 2017 IPPS/LTCH proposed rule (81 FR 25216 through 25220), an IRF-specific MSPB-PAC measure in the FY 2017 IRF PPS proposed rule (81 FR 24197 through 24201), and a SNF-specific MSPB-PAC measure in the FY 2017 SNF PPS proposed rule (81 FR 24258 through 24262). These four settingspecific MSPB-PAC measures are closely aligned in terms of episode construction and measure calculation. Each of the MSPB-PAC measures assess Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined similarly for each of the MSPB-PAC measures. However, developing setting-specific measures allows us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. For example, the MSPB-PAC HH QRP measure compares episodes triggered by Partial Episode Payment (PEP) and Low-Utilization Payment Adjustment (LUPA) claims only with episodes of the same type, as detailed below.

The MSPB-PAC measures mirror the general construction of the inpatient prospective payment system (IPPS) hospital MSPB measure, which was adopted for the Hospital IQR Program beginning with the FY 2014 program, and was implemented in the Hospital VBP Program beginning with the FY 2015 program. The measure was endorsed by the NQF on December 6, 2013 (NQF #2158).31 The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers during a hospital MSPB episode, which comprises the periods immediately prior to, during, and following a patient's hospital inpatient stay.3233 Similarly, the MSPB-PAC

MedPAC, "A Data Book: Health Care Spending and the Medicare Program," (2015). 114.
 Institute of Medicine, "Variation in Health Care

²⁹ Institute of Medicine, "Variation in Health Care Spending: Target Decision Making, Not Geography," (Washington, DC: National Academies 2013). 2.

³⁰ Figures for 2013. MedPAC, "Medicare Payment Policy," Report to the Congress (2015). xvii–xviii.

³¹ QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). http://www.qualitynet.org/dcs/ ContentServer?pagename=QnetPublic%2F Page%2FQnetTier3&cid=1228772053996.

³² QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.

³³ FY 2012 IPPS/LTCH PPS final rule (76 FR

measures assess all Medicare Part A and Part B payments for FFS claims with a start date that begins at the episode trigger and continues for the length of the episode window (which, as discussed in this section, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB-PAC HH QRP episode). However, there are differences between the MSPB–PAC measures, as proposed, and the hospital MSPB measure that reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB-PAC measures exclude a limited set of services (for example, for clinically unrelated services) provided to a beneficiary during the episode window while the hospital MSPB measure does not exclude any services.34

MSPB–PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. A home health episode beginning within 30 days of discharge from an inpatient hospital will therefore be included: Once in the hospital's MSPB measure, and once in the HHA's MSPB–PAC measure. Aligning the hospital MSPB and MSPB–PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We have sought and considered the input of stakeholders throughout the measure development process for the MSPB-PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015, in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015, to which 7 responses were received by December 8, 2015. The MSPB-PAC TEP Summary Report is available at https:// www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Technical-Expert -Panel-on-Medicare-Spending-Per-Beneficiary.pdf. The measures were also presented to the MAP Post-Acute Care/ Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB-PAC measures were under development, there were three voting options for members: Encourage continued development, do not encourage further consideration, and insufficient

information.35 The MAP PAC/LTC Workgroup voted to "encourage continued development" for each of the MSPB–PAC measures.³⁶ The MAP PAC/ LTC Workgroup's vote of "encourage continued development" was affirmed by the MAP Coordinating Committee on January 26, 2016.³⁷ The MAP's concerns about the MSPB-PAC measures, as outlined in its final report, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care," and Spreadsheet of Final Recommendations were taken into consideration during our measure development process and are discussed as part of our responses to public comments we received during the measure development process, described below.38 39

Since the MAP's review and recommendation of continued development, we have continued to refine the risk adjustment model and conduct measure testing for the proposed MSPB–PAC measures. The proposed MSPB–PAC measures are both consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was originally open from January 13 to 27, 2016 and twice extended to January 29 and February 5. A total of 45 comments on the MSPB–PAC measures were received during this 3.5 week period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations. 40 The MSPB–PAC

Public Comment Summary Report is available https://www.cms.gov/
Medicare/Quality-Initiatives-PatientAssessment-Instruments/Post-AcuteCare-Quality-Initiatives/Downloads/
2016_03_24_mspb_pac_public_
comment_summary_report.pdf and contains the public comments. If finalized, the proposed MSPB-PAC HH QRP measure, along with the other MSPB-PAC measures, as applicable, will be submitted for NQF consideration of endorsement.

To calculate the MSPB-PAC HH QRP measure for each HHA, we first define the construction of the MSPB-PAC HH QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further in this section. More detailed specifications for the proposed MSPB-PAC measures, including the MSPB-PAC HH QRP measure in this proposed rule, are available at https:// www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016 04 06 mspb_pac_measure_specifications_for_ rulemaking.pdf.

a. Episode Construction

An MSPB-PAC HH QRP episode begins at the episode trigger, which is defined as the patient's admission to a HHA. This admitting HHA is the provider for whom the MSPB-PAC HH QRP measure is calculated (that is, the attributed provider). The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB-PAC HH QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, HHAs will not be required to report any additional data to CMS for calculation of this measure. Thus, there will be no additional data collection burden from the implementation of this measure.

Our proposed MSPB–PAC HH QRP episode construction methodology differentiates between episodes triggered by standard HH claims (for which there is no PEP or LUPA adjustment) and claims for which PEP and LUPA adjustments apply, reflecting the HHA PPS payment policy. Standard, PEP, and LUPA episodes would be compared only with standard, PEP and LUPA episodes, respectively. Differences in episode construction

 $^{^{34}\,\}mathrm{FY}$ 2012 IPPS/LTCH PPS final rule (76 FR 51620).

³⁵ National Quality Forum, Measure Applications Partnership, "Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016" (February 2016) http://www.qualityforum.org/WorkArea/ linkit.aspx?LinkIdentifier=id&ItemID=81693.

³⁶ National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, "Meeting Transcript—Day 2 of 2" (December 15, 2015) 104–106 http://www.quality forum.org/WorkArea/linkit.aspx?LinkIdentifier=id& ItemID=81470.

³⁷ National Quality Forum, Measure Applications Partnership, "Meeting Transcript—Day 1 of 2" (January 26, 2016) 231–232 http://www.quality forum.org/WorkArea/linkit.aspx?LinkIdentifier= id&ItemID=81637.

³⁸ National Quality Forum, Measure Applications Partnership, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care" Final Report, (February 2016) http://www.qualityforum.org/ Publications/2016/02/MAP_2016_Considerations_ for Implementing_Measures_in_Federal_Programs_ -_PAC-LTC.aspx.

³⁹ National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) http:// www.qualityforum.org/WorkArea/linkit.aspx?Link Identifier=id&ItemID=81593.

⁴⁰ National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final

Recommendations" (February 1, 2016) http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.

between these three episode types are noted below; they otherwise share the same definition.

The episode window is comprised of a treatment period and an associated services period. For MSPB-PAC HH Standard and LUPA QRP episodes, the treatment period begins at the trigger (that is, on the first day of the home health claim) and ends after 60 days. For MSPB-PAC PEP QRP episodes, the treatment period begins at the trigger (that is, on the first day of the home health claim) and ends at discharge. The treatment period includes those services that are provided directly or reasonably managed by the HHA that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period. Certain services are excluded from the MSPB-PAC HH QRP episodes because they are clinically unrelated to HHA care, and/or because HHAs may have limited influence over certain Medicare services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given HHA's Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that have been determined by clinicians to be outside of the control of a HHA include: planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB-PAC HH QRP episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the associated services period of an MSPB–PAC HH QRP episode in the 30 days post-treatment. One possible scenario occurs where a HHA discharges a beneficiary who is then admitted to a SNF within 30 days. The SNF claim would be included once as an associated service for the attributed provider of the first MSPB–PAC HH QRP episode and once as a treatment

service for the attributed provider of the second MSPB-PAC SNF episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare. Even within the HH setting, one MSPB-PAC HH QRP episode may begin in the associated services period of another MSPB-PAC HH QRP episode in the 30 days post-treatment. The second HH claim would be included once as an associated service for the attributed HHA of the first MSPB-PAC HH QRP episode and once as a treatment service for the attributed HHA of the second MSPB-PAC HH QRP episode. Again, this ensures that HHAs have the same incentives throughout both MSPB-PAC HH QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB-PAC HH QRP episode were excluded from the second HHA's MSPB-PAC HH QRP measure, that HHA would not share the same incentives as the first HHA of the first MSPB-PAC HH QRP episode. The MSPB-PAC HH QRP measure is designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As discussed further below, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

b. Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB-PAC HH QRP episodes, defined according to the methodology previously discussed, are used to calculate the MSPB-PAC HH QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator. The measure calculation is performed separately for MSPB-PAC HH QRP standard, PEP, and LUPA episodes to ensure that they are compared only to other standard, PEP, and LUPA episodes, respectively. The final MSPB-PAC HH QRP measure would combine

the three ratios above to construct one HHA score as described below.

(1) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC HH QRP measure to ensure that the MSPB–PAC HH QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between HHAs. The proposed episode-level exclusions are as follows:

- Any episode that is triggered by a HH claim outside the 50 states, DC, Puerto Rico, and U.S. territories.
- Any episode where the claim(s) constituting the attributed HHA provider's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where a beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed HHA provider's treatment include at least one related condition code indicating that it is not a prospective payment system bill.

(2) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB-PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the MSPB-PAC HH QRP measure are payment-standardized and riskadjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We propose to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and

other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).⁴¹

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed HHA. To assist with risk adjustment for MSPB-PAC HH QRP episodes, we create mutually exclusive and exhaustive clinical case mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB-PAC HH QRP episode. The beneficiaries in these clinical case mix categories have a greater degree of clinical similarity than the overall HHA patient population, and allow us to more accurately estimate Medicare spending. Our proposed MSPB–PAC HH QRP model, adapted for the HH setting from the NQF-endorsed hospital MSPB measure, uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. During the public comment period that ran from January 13 to February 5, 2016 discussed above, we sought and considered public comment regarding the treatment of hospice services occurring within the MSPB-PAC HH QRP episode window. Given the comments received, we propose to include the Medicare spending for hospice services but risk adjust for them, such that MSPB-PAC HH QRP episodes with hospice are compared to a benchmark reflecting other MSPB-PAC HH QRP episodes with hospice. We believe that this provides a balance between the measure's intent of evaluating Medicare spending and

ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

As noted previously, we understand the important role that sociodemographic status, beyond age, plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as required under the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC HH QRP risk-adjustment model, we are not proposing to adjust the MSPB–PAC HH measure for socioeconomic and demographic factors at this time. As this MSPB–PAC HH QRP measure will be submitted to the NQF for consideration of

endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic and demographic factors. We will monitor the results of the trial, studies, and recommendations. We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB-PAC HH QRP measure.

(3) Measure Numerator and Denominator

The MPSB–PAC HH QRP measure is a payment-standardized, risk-adjusted ratio that compares a given HHA's Medicare spending against the Medicare spending of other HHAs within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB-PAC HH QRP measure is calculated as the ratio of the MSPB-PAC Amount for each HHA divided by the episode-weighted median MSPB-PAC Amount across all HHAs. To calculate the MSPB-PAC Amount for each HHA, one calculates the average of the ratio of the standardized spending for HHA standard episodes over the expected spending (as predicted in risk adjustment) for HHA standard episodes, the average of the ratio of the standardized spending for HHA PEP episodes over the expected spending (as predicted in risk adjustment) for HHA PEP episodes, and the average of the ratio of the standardized spending for HHA LUPA episodes over the expected spending (as predicted in risk adjustment) for HHA LUPA episodes. This quantity is then multiplied by the average episode spending level across all HHAs nationally for standard, PEP, and LUPA episodes. The denominator for a HHA's MSPB-PAC HH QRP measure is the episode-weighted national median of the MSPB-PAC Amounts across all HHAs. An MSPB-PAC HH QRP measure of less than 1 indicates that a given HHA's Medicare spending is less than that of the national median HHA during a performance period. Mathematically, this is represented in equation (A) below:

⁴¹ QualityNet, "CMS Price (Payment) Standardization—Detailed Methods" (Revised May 2015) https://qualitynet.org/dcs/ ContentServer?c=Page&pagename=QnetPublic% 2FPage%2FQnetTier4&cid=1228772057350.

$(A) \textit{MSPB-PAC HHA Measure}_j = \frac{\textit{MSPB-PAC Amount}_j}{\textit{National Median MSPB-PAC Amount}}$

$$= \frac{\left(\frac{1}{n_{j}}\sum_{i \in \{I_{j}\}} \frac{Y_{ij}}{\widehat{Y_{i,j}}}\right) \left(\frac{1}{n}\sum_{j}\sum_{i \in \{I_{j}\}} Y_{ij}\right)}{Episode-Weighted Median of}$$
HHA Providers' MSPB-PAC Amount

Where:

- Y_{ij} = attributed standardized spending for episode i and provider j
- \hat{Y}_{ij} = expected standardized spending for episode i and provider j, as predicted from risk adjustment
- n_j = number of episodes for provider j
- n = total number of episodes nationally
- $i \in \{I_j\}$ = all episodes i in the set of episodes attributed to provider j.

a. Data Sources

The MSPB–PAC HH QRP resource use measure is an administrative claimsbased measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

b. Cohort

The measure cohort includes Medicare FFS beneficiaries with a HHA treatment period ending during the data collection period.

c. Reporting

If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2017. We are proposing a minimum of 20 episodes for reporting and inclusion in the HH QRP. For the reliability calculation, as described in the measure specifications provided above, we used data from FY 2014. The reliability results support the 20 episode case minimum, and 94.27 percent of HHAs had moderate or high reliability (above

We invite public comment on our proposal to adopt the MSPB–PAC HH QRP measure for the HH QRP.

2. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community-Post Acute Care Home Health Quality Reporting Program

Section 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 October 1, 2016 for SNFs, IRFs and LTCHs and January 1,

2017 for HHAs), the Secretary specify a measure to address the domain of discharge to community. We are proposing to adopt the measure, Discharge to Community—PAC HH QRP for the HH QRP, beginning with the CY 2018 payment determination and subsequent years as a Medicare fee-forservice (FFS) claims-based measure to meet this requirement.

This proposed measure assesses successful discharge to the community from a HH setting, with successful discharge to the community including no unplanned hospitalizations and no deaths in the 31 days following discharge from the HH agency setting. Specifically, this proposed measure reports a HHA's risk-standardized rate of Medicare FFS patients who are discharged to the community following a HH episode, do not have an unplanned admission to an acute care hospital or LTCH in the 31 days following discharge to community, and remain alive during the 31 days following discharge to community. The term "community," for this measure, is defined as home/self-care, without home health services, based on Patient Discharge Status Codes 01 and 81 on the Medicare FFS claim.^{42 43} This measure is specified uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many patients for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many patients who are not expected to make functional improvement during their HH episode and for patients who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multidimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community. 44 45

In addition to being an important outcome from a patient and family perspective, patients discharged to community settings, on average, incur lower costs over the recovery episode, compared with patients discharged to institutional settings.⁴⁶ ⁴⁷ Given the high costs of care in institutional settings, encouraging post-acute providers to prepare patients for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.⁴⁸ Also, providers have discovered that successful discharge to the community was a major driver of their ability to achieve savings, where capitated payments for post-acute care were in place.⁴⁹ For patients who

⁴² Further description of patient discharge status codes can be found, for example, at the following Web page: https://med.noridianmedicare.com/web/jea/topics/claim-submission/patient-status-codes.

⁴³ This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of "community" for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and Section 504

⁴⁴ El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a post-acute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388–1393.

⁴⁵ Tanwir S, Montgomery K, Chari V, Nesathurai S. Stroke rehabilitation: Availability of a family member as caregiver and discharge destination. *European journal of physical and rehabilitation medicine*. 2014;50(3):355–362.

⁴⁶ Dobrez D, Heinemann AW, Deutsch A, Manheim L, Mallinson T. Impact of Medicare's prospective payment system for inpatient rehabilitation facilities on stroke patient outcomes. American journal of physical medicine & rehabilitation/Association of Academic Physiatrists. 2010;89(3):198–204.

⁴⁷ Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System Final Report. RTI International;2009.

⁴⁸ Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. Med Care. 2016 Mar;54(3):221–228.

⁴⁹ Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital:

require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for patients' outof-pocket expenditures.⁵⁰

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments associated with discharge from IRFs, SNFs, LTCHs, or HHAs to institutional settings, as compared with payments associated with discharge from these PAC providers to community settings.⁵¹ Average, unadjusted Medicare payments associated with discharge to community settings ranged from \$0 to \$4,017 for IRF discharges; \$0 to \$3,544 for SNF discharges, \$0 to \$4,706 for LTCH discharges, and \$0 to \$992 for HHA discharges. In contrast, payments associated with discharge to noncommunity settings were considerably higher, ranging from \$11,847 to \$25,364 for IRF discharges, \$9,305 to \$29,118 for SNF discharges, \$12,465 to \$18,205 for LTCH discharges, and \$7,981 to \$35,192 for HHA discharges.52

Measuring and comparing agencylevel discharge to community rates is expected to help differentiate among agencies with varying performance in this important domain, and to help avoid disparities in care across patient groups. Variation in discharge to community rates has been reported within and across post-acute settings, across a variety of facility-level characteristics such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), freestanding or hospital-based units, and across patient-level characteristics such as race and gender.^{53 54 55 56 57 58} In

bundles in the real world. The Journal of arthroplasty. 2015;30(3):353–355.

the HH Medicare FFS population, using CY 2013 national claims data, we found that approximately 82 percent of episodes ended with a discharge to the community. A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilatordependent on admission were discharged to home.⁵⁹ A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.60 One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge 61 and a second study noted that between 58 percent and 63 percent of beneficiates were discharged to home with rates varying by admission site.62 However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).63

Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of postacute settings. ⁶⁴ ⁶⁵ ⁶⁶ ⁶⁷ ⁶⁸ Many of these

interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.^{69 70 71 72 73} The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care patients is possible through modifying provider-led processes and interventions.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the proposed measure, Discharge to Community-PAC HH QRP into the HH QRP. 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 reliability and validity. 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.

⁵⁰ Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. Med Care. 2016 Jan 12. Epub ahead of print.

⁵¹ Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report. RTI International;2009.

⁵² Ibid

⁵³ Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. Archives of physical medicine and rehabilitation. 2014;95(1):29–38.

⁵⁴El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a post-acute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388–1393.

⁵⁵ March 2015 Report to the Congress: Medicare Payment Policy. Medicare Payment Advisory Commission:2015.

⁵⁶ Bhandari VK, Kushel M, Price L, Schillinger D. Racial disparities in outcomes of inpatient stroke rehabilitation. Archives of physical medicine and rehabilitation. 2005;86(11):2081–2086.

⁵⁷Chang PF, Ostir GV, Kuo YF, Granger CV, Ottenbacher KJ. Ethnic differences in discharge destination among older patients with traumatic brain injury. Archives of physical medicine and rehabilitation. 2008;89(2):231–236.

⁵⁸ Berges IM, Kuo YF, Ostir GV, Granger CV, Graham JE, Ottenbacher KJ. Gender and ethnic differences in rehabilitation outcomes after hipreplacement surgery. American journal of physical medicine & rehabilitation/Association of Academic Physiatrists. 2008;87(7):567–572.

⁵⁹ Scheinhorn DJ, Hassenpflug MS, Votto JJ, et al. Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study. Chest. 2007;131(1):85–93.

⁶⁰ Thakar CV, Quate-Operacz M, Leonard AC, Eckman MH. Outcomes of hemodialysis patients in a long-term care hospital setting: a single-center study. American journal of kidney diseases: the official journal of the National Kidney Foundation. 2010;55(2):300–306.

⁶¹ Wolff JL, Meadow A, Weiss CO, Boyd CM, Leff B. Medicare home health patients' transitions through acute and post-acute care settings. Medical care. 2008;46(11):1188–1193.

⁶² Riggs JS, Madigan EA. Describing Variation in Home Health Care Episodes for Patients with Heart Failure. Home Health Care Management & Practice 2012; 24(3) 146–152.

⁶³ Ibid

⁶⁴ Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310–1318.

⁶⁵ Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442–448.

⁶⁶ Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. Journal of the American Geriatrics Society. 2011;59(6):1130–1136.

⁶⁷ Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. PM & R: the journal of injury, function, and rehabilitation. 2015;7(4):354–364.

⁶⁸ Parker, E., Zimmerman, S., Rodriguez, S., & Lee, T. Exploring best practices in home health care: a review of available evidence on select innovations. Home Health Care Management and Practice, 2014; 26(1): 17–33.

⁶⁹ Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310–1318.

⁷⁰ Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442–448.

⁷¹ Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. Journal of the American Geriatrics Society. 2011;59(6):1130–1136.

⁷² Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. PM & R: the journal of injury, function, and rehabilitation. 2015;7(4):354–364.

⁷³ Parker, E., Zimmerman, S., Rodriguez, S., & Lee, T. Exploring best practices in home health care: a review of available evidence on select innovations. Home Health Care Management and Practice, 2014; 26(1): 17–33.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015 through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. 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, 2015, and provided input on the use of this proposed Discharge to Community-PAC HH QRP measure in the HH QRP. The MAP encouraged continued development of the proposed measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this proposed measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at http:// www.qualityforum.org/Publications/ 2016/02/MAP 2016 Considerations for Implementing Measures in Federal_Programs_-_PAC-LTC.aspx.

Since the MAP review the measure and recommended continued development, we have continued to refine the risk adjustment model and conduct measure testing for this measure. This proposed measure is consistent with the information submitted to the MAP and is scientifically acceptable for current specification in the HH QRP.

We reviewed the NQF's consensusendorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to the community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the measure, Discharge to Community-PAC HH QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We are proposing to use data from the Medicare FFS claims and Medicare eligibility files to calculate this proposed measure. We are proposing to use data from the "Patient Discharge Status Code" on Medicare FFS claims to determine whether a patient was discharged to a community setting for calculation of this proposed measure. In

all PAC settings, we tested the accuracy of determining discharge to a community setting using the "Patient Discharge Status Code" on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the HH setting, using 2013 data, we found 97 percent agreement in discharge to community codes when comparing "Patient Discharge Status Code" from claims and Discharge Disposition (M2420) and Inpatient Facility (M2410) on the OASIS C discharge assessment, when the claims and OASIS assessment had the same discharge date. We further examined the accuracy of "Patient Discharge Status Code" on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by followup acute care claims. We found that 50 percent of HH claims with acute care discharge status codes were followed by an acute care claim in the 31 days after HH discharge. We believe these data support the use of the "Patient Discharge Status Code" for determining discharge to a community setting for this measure. In addition, the proposed measure has high feasibility because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to us.

Based on the evidence discussed above, we are proposing to adopt the measure entitled, "Discharge to Community-PAC HH QRP", for the HH QRP for the CY 2018 payment determination and subsequent years. This proposed measure is calculated utilizing 2 years of data as defined below. We are proposing a minimum of 20 eligible episodes in a given HHA for public reporting of the proposed measure for that HHA. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, HHAs will not be required to report any additional data to CMS for calculation of this measure. The proposed measure denominator is the risk-adjusted expected number of discharges to community. The proposed measure numerator is the risk-adjusted estimate of the number of home health patients who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain

alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, and ESRD status among other variables. For technical information about this proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we refer readers the document titled Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule, available at https://www.cms.gov/ Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ HomeHealthQualityInits/ HHQIQualityMeasures.html.

If this proposed measure is finalized, we intend to provide initial confidential feedback to home health agencies, prior to the public reporting of this measure, based on Medicare FFS claims data from discharges in CYs 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CYs 2016 and 2017. We plan to submit this proposed measure to the NQF for consideration for endorsement.

We invite public comment on our proposal to adopt the measure, Discharge to Community—PAC HH QRP for the HH QRP.

3. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Post-Acute Care Home Health Quality Reporting Program

Section 1899B(d)(1)(C) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is October 1, 2016 for SNFs, IRFs and LTCHs and January 1, 2017 for HHAs), the Secretary specify measures to address the domain of allcondition risk-adjusted potentially preventable hospital readmission rates. We are proposing the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP as a Medicare FFS claims-based measure to meet this requirement beginning with the CY 2018 payment determination.

The proposed measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries that take place within 30 days of a HH discharge. The HH admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay, which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital

readmissions include readmissions to a short-stay acute-care hospital or a LTCH, with a diagnosis considered to be unplanned and potentially preventable. This proposed measure is claims-based, requiring no additional data collection or submission burden for HHAs. Because the measure denominator is based on HH admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning two days after HH discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.74 75 The MedPAC estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered "potentially preventable." ⁷⁶ In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be \$12 billion for 30-day, \$8 billion for 15-day, and \$5 billion for 7-day readmissions. 77 For hospital readmissions from one post-acute care setting, SNFs, MedPAC deemed 76 percent of these readmissions as 'potentially avoidable''—associated with \$12 billion in Medicare expenditures.78 Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission

rate from SNFs, associated with \$4.3 billion in expenditures.⁷⁹ An analysis of data from a nationally representative sample of Medicare FFS beneficiaries receiving home health services in 2004 show that home health patients receive significant amounts of acute and postacute services after discharge from home health care. Within 30 days of discharge from home health, 29 percent of patients were admitted to a hospital.80 Focusing on readmissions, Madigan and colleagues studied 74,580 Medicare home health patients with a rehospitalization within 30 days of the index hospital discharge. The 30-day rehospitalization rate was 26 percent with the largest proportion related to a cardiac-related diagnosis (42 percent).81 Fewer studies have investigated potentially preventable readmission rates from other post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting as well as in PAC. For example, we developed the following measure: Rehospitalization During the First 30 Days of Home Health (NQF #2380), as well as similar measures for other PAC providers (NQF #2502 for IRFs, NQF #2510 for SNFs NOF #2512 for LTCHs).82 These measures are endorsed by the NQF, and the NQF-endorsed measure (NQF #2380) was adopted into the HH QRP in the CY 2014 HH PPS final rule (80 FR 68691 through 68692). Note that these NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3MTM algorithm for Potentially Preventable Readmissions. 83 84 85 Recent

work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations. ^{86 87} Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC. ^{88 89 90}

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR

⁷⁴ Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. Med. Care Res. Rev. 61(2):225–240, 2004. doi:10.1177/1077558704263799.

⁷⁵ Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. N. Engl. J. Med. 360(14):1418–1428, 2009. doi:10.1016/j.jvs.2009.05.045

⁷⁶ MedPAC: Payment policy for inpatient readmissions, in Report to the Congress: Promoting Greater Efficiency in Medicare. Washington, DC, pp. 103–120, 2007. Available from http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf.

⁷⁷ ibid.

⁷⁸ ibid

 $^{^{79}\,\}mathrm{Mor},$ V., Intrator, O., Feng, Z., et al. The revolving door of rehospitalization from skilled nursing facilities. Health Aff. 29(1):57–64, 2010. doi:10.1377/hlthaff.2009.0629.

⁸⁰ Wolff, J. L., Meadow, A., Weiss, C.O., Boyd, C.M., Leff, B. Medicare Home Health Patients' Transitions Through Acute And Post-Acute Care Settings.' Medicare Care 11(46) 2008; 1188–1193.

⁸¹ Madigan, E. A., N. H. Gordon, et al. "Rehospitalization in a national population of home health care patients with heart failure." Health Serv Res 47(6): 2013; 2316–2338.

⁸² National Quality Forum: All-Cause Admissions and Readmissions Measures. pp. 1–319, April 2015. Available from http://www.qualityforum.org/ Publications/2015/04/All-Cause Admissions_and_ Readmissions_Measures_-Final_Report.aspx.

⁸³ Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al. Identifying potentially preventable readmissions. Health Care Finan. Rev. 30(1):75–91,

^{2008.} Available from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/.

⁸⁴ National Quality Forum: Prevention Quality Indicators Overview. 2008.

⁸⁵ MedPAC: Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly. pp. 1– 12, prepared for Chapter 4, 2011. Available from http://www.medpac.gov/documents/reports/Mar11_ Ch04_APPENDIX.pdf?sfvrsn=0.

⁸⁶ Kramer, A., Lin, M., Fish, R., et al. Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement. pp. 1–42, 2015. Available from http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0.

⁸⁷ Kramer, A., Lin, M., Fish, R., et al.
Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures.
pp. 1–75, 2014. Available from http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0.

⁸⁸ Allaudeen, N., Vidyarthi, A., Maselli, J., et al. Redefining readmission risk factors for general medicine patients. J. Hosp. Med. 6(2):54–60, 2011. doi:10.1002/jhm.805.

 ⁸⁹ Gao, J., Moran, E., Li, Y.-F., et al. Predicting potentially avoidable hospitalizations. Med. Care 52(2):164–171, 2014. doi:10.1097/
 MLR.00000000000000041.

⁹⁰ Walsh, E.G., Wiener, J.M., Haber, S., et al. Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. J. Am. Geriatr. Soc. 60(5):821–829, 2012. doi:10.1111/j.1532–5415.2012.03920.

conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and

Inadequate management of other

unplanned events

Àdditional details regarding the definition for potentially preventable readmissions are available in the document titled Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule available at https://www.cms.gov/ Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ HomeHealthQualityInits/ HHQIQualityMeasures.html.

This proposed measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the Rehospitalization During the First 30 Days of Home Health measure (NQF #2380), this proposed measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at http://www.cms.gov/ Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ HospitalQualityInits/Measure-Methodology.html. In addition to the CMS Planned Readmission Algorithm, this proposed measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for postacute care, can be found in the document titled Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule available at https://www.cms.gov/ Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ HomeHealthQualitvInits/ HHQIQualityMeasures.html.

The proposed measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates an agency-specific effect, common to patients treated in each agency. This proposed measure is

calculated for each HHA based on the ratio of the predicted number of riskadjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after an HH discharge, including the estimated agency effect, to the estimated predicted number of risk-adjusted, unplanned hospital readmissions for the same patients treated at the average HHA. A ratio above 1.0 indicates a higher than expected readmission rate (worse), while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all HH episodes. The resulting rate is the riskstandardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible HH episode is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted

in the measure rate.

This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the riskadjustment model for HHAs accounts for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, comorbidities, length of stay during the patient's prior proximal hospital stay, intensive care and coronary care unit (ICU and CCU) utilization, ESRD status, and number of acute care hospitalizations in the preceding 365 days.

The proposed measure is calculated using 3 consecutive calendar years of FFS data, in order to ensure the statistical reliability of this measure for smaller agencies. In addition, we are proposing a minimum of 20 eligible episodes for public reporting of the proposed measure. For technical information about this proposed measure including information about the measure calculation, risk adjustment, and exclusions, we refer readers to our Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/HomeHealthOualitvInits/ HHQIQualityMeasures.html.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report 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. We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also 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 encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at http:// www.qualityforum.org/Publications/ 2016/02/MAP 2016 Considerations for Implementing Measures in Federal Programs - PAC-LTC.aspx.

At the time of the MAP, the riskadjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the Rehospitalization During the First 30 Days of Home Health Measure (NQF #2380) adopted into the HH QRP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures focused on potentially preventable

hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the HH QRP for the CY 2018 payment determination and subsequent years given the evidence previously discussed above.

We plan to submit the proposed measure to the NQF for consideration of endorsement. If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this proposed measure, based on 3 calendar years of claims data from discharges in CYs 2014, 2015 and 2016. We intend to publicly report this proposed measure using claims data from CYs 2015, 2016 and 2017.

We are inviting public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP.

4. Proposal To Address the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post-Acute Care Home Health Quality Reporting Program

Section 1899B(c)(1)(C) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(i) is October 1, 2018 for SNFs, IRFs and LTCHs and January 1, 2017 for HHAs), the Secretary specify quality measures to address the domain of medication reconciliation. We are proposing to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP for the HH QRP as a patientassessment based, cross-setting quality measure to meet this requirement with data collection beginning January 1, 2017, beginning with the CY 2018 payment determination.

This proposed measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified.

Specifically, the proposed quality measure reports the percentage of patient episodes in which a drug regimen review was conducted at the start of care or resumption of care and timely follow-up with a physician occurred each time potential clinically significant medication issues were

identified throughout that episode. For this proposed quality measure, a drug regimen review is defined as the review of all medications or drugs the patient is taking in order to identify potential clinically significant medication issues. This proposed quality measure utilizes both the processes of medication reconciliation and a drug regimen review in the event an actual or potential medication issue occurred. The proposed measure informs whether the PAC agency identified and addressed each clinically significant medication issue and if the agency responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.⁹¹ This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs). Medication discrepancies occur when there is conflicting information documented in the medical records.

The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in patient care and in identifying preventable ADEs. 92 The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.93 The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.94 There is universal

agreement that medication reconciliation directly addresses patient safety issues that can result from medication miscommunication and unavailable or incorrect information.⁹⁵ 96 97 98

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs, 99 100 including subsequent emergency room visits and re-hospitalizations. ADEs are associated with an estimated \$3.5 billion in annual health care costs and 7,000 deaths annually. 101

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical error and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE. 102 103 104 105 106 107

⁹¹Institute of Medicine. Preventing Medication Errors. Washington, DC: National Academies Press; 2006.

⁹² Leotsakos A., *et al.* Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

⁹³ The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

⁹⁴ Greenwald, J.L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: A consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

⁹⁵ IHI. Medication Reconciliation to Prevent Adverse Drug Events [Internet]. Cambridge, MA: Institute for Healthcare Improvement; [cited 2016 Jan 11]. Available from: http://www.ihi.org/topics/adesmedicationreconciliation/Pages/default.aspx. Leotsakos A., et al. Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

⁹⁶ The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

⁹⁷ Greenwald, J.L., Halasyamani, L., Greene, J., LaCivita, C., *et al.* (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: A consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

⁹⁸ The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

⁹⁹ Jha A.K., Kuperman G.J., Rittenberg E., *et al.* Identifying hospital admissions due to adverse drug events using a computer-based monitor. Pharmacoepidemiol Drug Saf. 2001;10(2):113–119.

¹⁰⁰ Hohl C.M., Nosyk B., Kuramoto L., *et al.* Outcomes of emergency department patients presenting with adverse drug events. Ann Emerg Med. 2011;58:270–279.

¹⁰¹ Kohn L.T., Corrigan J.M., Donaldson M.S., "To Err Is Human: Building a Safer Health System," National Academies Press, Washington, DC 1999

¹⁰² Institute of Medicine. To err is human: Building a safer health system. Washington, DC: National Academies Press; 2000.

¹⁰³ Lesar T.S., Briceland L., Stein D.S. Factors related to errors in medication prescribing. JAMA. 1997:277(4): 312–317.

¹⁰⁴ Bond C.A., Raehl C.L., & Franke T. Clinical pharmacy services, hospital pharmacy staffing, and medication errors in United States hospitals. Pharmacotherapy. 2002:22(2): 134–147.

¹⁰⁵ Bates D.W., Cullen D.J., Laird N., Petersen L.A., Small S.D., *et al.* Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995:274(1): 29–34.

Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly \$7.2 billion annually. 108 109

There is strong evidence that medication discrepancies can occur during transfers from acute care facilities to post-acute care facilities. Discrepancies can occur when there is conflicting information documented in the medical records. Almost one-third of medication discrepancies have the potential to cause patient harm. 110 Potential medication problems upon admission to HHAs have been reported as occurring at a rate of 39 percent of reviewed charts 111 and mean medication discrepancies between 2.0 ± 2.3 and 2.1 ± 2.4 . Similarly, medication discrepancies were noted as patients transitioned from the hospital to home health settings. 113 An estimated fifty percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals. 114

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. PAC facilities report gaps in medication information between the acute care hospital and the receiving post-acute care setting when performing

medication reconciliation. 115 116 Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy. 117 118 119 120 121 122 Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay. 123 124 With respect to older patients who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,125 and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge. 126 The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, provides an important component of care coordination for PAC settings and would affect a large proportion of the Medicare population who transfer from hospitals into PAC settings each year. For example, in 2013, 3.2 million Medicare FFS beneficiaries had a home health episode.

A TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for crosssetting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Video 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.

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this proposed measure. 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, 2015, and provided input on the use of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP. The MAP encouraged continued development of the proposed quality measure for the HH QRP to meet the mandate of the IMPACT Act. The MAP agreed with the measure gaps identified by CMS including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAPs recommendations for this measure is available at http:// www.qualityforum.org/Setting Priorities/Partnership/MAP Final Reports.aspx.

Since the MAP's review, we have continued to refine this proposed

¹⁰⁶ Barker K.N., Flynn E.A., Pepper G.A., Bates D.W., & Mikeal R.L. Medication errors observed in 36 health care facilities. JAMA. 2002: 162(16):1897– 1903.

¹⁰⁷ Bates D.W., Boyle D.L., Vander Vliet M.B., Schneider J, & Leape L. Relationship between medication errors and adverse drug events. J Gen Intern Med. 1995:10(4): 199–205.

¹⁰⁸ Institute of Medicine. To err is human: Building a safer health system. Washington, DC: National Academies Press; 2000

¹⁰⁹ Greenwald, J.L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: A consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

¹¹⁰ Wong, J.D.., *et al.* "Medication reconciliation at hospital discharge: Evaluating discrepancies." Annals of Pharmacotherapy 42.10 (2008): 1373–

¹¹¹ Vink J., Morton D., Ferreri S. Medication-Related Problems in the Home Care Setting. The Consultant Pharmacist. Vol 26 No 7 2011 478–484

¹¹² Setter S.M., Corbett C.F., Neumiller J.J., Gates B.J., *et al.* Effectiveness of a pharmacist-nurse intervention on resolving medication discrepancies for patients transitioning from hospital to home health care, Am J Health-Syst Pharm, vol. 66, pp. 2027–2031, 2009

¹¹³ Zillich A.J., Snyder M.E., Frail C.K., Lewis J.L. et al. A Randomized, Controlled Pragmatic Trial of Telephonic Medication Therapy Management to Reduce Hospitalization in Home Health Patient, Health Services Research, vol. 49, no. 5, pp. 1537–1554, 2014.

¹¹⁴ Kripalani, Sunil, *et al.* "Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized trial. "Annals of internal medicine 157.1 (2012): 1–10.

¹¹⁵ Gandara, Esteban, et al. "Communication and information deficits in patients discharged to rehabilitation facilities: An evaluation of five acute care hospitals." Journal of Hospital Medicine 4.8 (2009): E28–E33.

¹¹⁶Gandara, Esteban, *et al.* "Deficits in discharge documentation in patients transferred to rehabilitation facilities on anticoagulation: Results of a system wide evaluation." Joint Commission Journal on Quality and Patient Safety 34.8 (2008): 460–463.

¹¹⁷ Coleman E.A., Smith J.D., Raha D., Min S.J. Post hospital medication discrepancies: Prevalence and contributing factors. Arch Intern Med. 2005 165(16):1842–1847.

¹¹⁸ Wong J.D., Bajcar J.M., Wong G.G., *et al.* Medication reconciliation at hospital discharge: Evaluating discrepancies. Ann Pharmacother. 2008 42(10):1373–1379.

¹¹⁹ Hawes E.M., Maxwell W.D., White S.F., Mangun J., Lin F.C. Impact of an outpatient pharmacist intervention on medication discrepancies and health care resource utilization in post hospitalization care transitions. Journal of Primary Care & Community Health. 2014; 5(1):14– 18.

¹²⁰ Foust J.B., Naylor M.D., Bixby M.B., Ratcliffe S.J. Medication problems occurring at hospital discharge among older adults with heart failure. Research in Gerontological Nursing. 2012, 5(1): 25–33.

¹²¹Pherson E.C., Shermock K.M., Efird L.E., *et al.* Development and implementation of a post discharge home-based medication management service. Am J Health Syst Pharm. 2014; 71(18): 1576–1583.

 $^{^{122}}$ Pronovosta P., Weasta B., Scwarza M., et al. Medication reconciliation: A practical tool to reduce the risk of medication errors. J Crit Care. 2003; 18(4): 201–205.

¹²³ Bates D.W., Cullen D.J., Laird N., Petersen L.A., Small S.D., *et al.* Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995:274(1): 29–34.

¹²⁴ Himmel, W., M. Tabache, and M.M. Kochen. "What happens to long-term medication when general practice patients are referred to hospital?. "European journal of clinical pharmacology 50.4 (1996): 253–257

¹²⁵ Chhabra, P.T., *et al.* (2012). "Medication reconciliation during the transition to and from long-term care settings: A systematic review." Res Social Adm Pharm 8(1): 60–75.

¹²⁶ Hume K., Tomsik E. Enhancing Patient Education and Medication Reconciliation Strategies to Reduce Readmission Rates. Hosp Pharm; 2014; 49(2):112–114.

measure in compliance with the MAP's recommendations. The proposed measure is both consistent with the information submitted to the MAP and supports its scientific acceptability for use in the HH QRP. Therefore, we are proposing this measure for implementation in the HH QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQFendorsed cross-setting and quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HH settings of care: Care for Older Adults (COA) (NQF #0553). The quality measure, Care for Older Adults (COA) (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA) (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, which reports the percentage of patient episodes in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician or physician-designee occurred each time one or more potential clinically significant medication issues were identified throughout that episode.

After careful review of both quality measures, we have decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for the

following reasons:

 The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, employs three standardized patient-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings;

The proposed quality measure,
 Drug Regimen Review Conducted with
 Follow-Up for Identified Issues-PAC HH

QRP, requires the identification of clinically potential medication issues at the beginning, during and at the end of the patient's episode to capture data on each patient's complete HH episode; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population;

- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee) as well as resolution of the issue(s) within a rapid time frame (by midnight of the next calendar day); whereas, the Care for Older Adults (COA) (NQF #0553) quality measure does not include any follow-up or time frame in which the follow-up would need to occur;
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, does not have age exclusions; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure limits the measure's population to patients aged 66 and older; and
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, would be reported to HHAs quarterly to facilitate internal quality monitoring and quality improvement in areas such as patient safety, care coordination and patient satisfaction; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, for the HH QRP for CY 2018 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration of endorsement.

The calculation of the proposed quality measure would be based on the data collection of three standardized items that would be added to the OASIS. The collection of data by means of the standardized items would be obtained at start or resumption of care

and end of care. For more information about the data submission required for this proposed measure, we refer readers to Section I. Form, Manner, and Timing of OASIS Data Submission and OASIS Data for Annual Payment Update.

The standardized items used to calculate this proposed quality measure will replace existing items currently used for data collection within the OASIS. The proposed measure denominator is the number of patient episodes with an end of care assessment during the reporting period. The proposed measure numerator is the number of episodes in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Start or resumption of care; and (2) end of care with a look back through the home health patient episode with all potential clinically significant medication issues identified during the course of care and followedup with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this proposed measure, including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, we refer readers to the document titled Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule available at https://www.cms.gov/ Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ HomeHealthQualityInits/ HHQIQualityMeasures.html.

Data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP, would be collected using the OASIS with submission through the QIES ASAP system.

We invite public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP for CY 2018 APU determination and subsequent years.

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

We invite public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 33 for use in future years in the HH QRP.

TABLE 33: HH ORP Quality Measures under Consideration for Future Years

TABLE 33. HII QK	A Quanty Measures under Consideration for Future Years
IMPACT Act Domain	Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions
IMPACT Act Measure	Transfer of health information and care preferences when an individual transitions
IMPACT Act Domain	Incidence of major falls
IMPACT Act Measure	Application of NQF #0674 - Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)
IMPACT Act Domain	Functional status, cognitive function, and changes in function and cognitive function
IMPACT Act Measure	Application of NQF #2631 - Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function
NQS Priority	Patient- and Caregiver-Centered Care
Measures	 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 Application of NQF #2636 - Discharge Mobility Score for Medical Rehabilitation Patients Application of NQF #2630 - Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)

We are developing a measure related to the IMPACT Act domain, "Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions." We are also considering application of two IMPACT Act measures to the HH QRP, to assess the incidence of falls with major injury and functional assessment and goals setting. We are additionally considering application of four standardized functional measures to the HH QRP; two that would assess change in function

across the HH episode and two that would assess actual function at discharge relative to expected function. Finally, we are considering a measure related to health and well-being, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).

Based on input from stakeholders, we have identified additional concept areas for potential future measure development for the HH QRP. These include "efficacy" measures that pair processes, such as assessment and care planning, with outcomes, such as emergency treatment for injuries or increase in pain. The prevalence of mental health and behavioral problems

was identified as an option to address outcomes for special populations. In addition, CMS is considering development of measures that assess if functional abilities were maintained during a care episode and composite measures that combine multiple evidence-based processes. CMS invites feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

I. Form Manner and Timing of OASIS Data Submission and OASIS Data for Annual Payment Update

1. Regulatory Authority

The HH conditions of participation (CoPs) at § 484.55(d) require that the

comprehensive assessment be updated and revised (including the administration of the OASIS) no less frequently than: (1) The last 5 days of every 60 days beginning with the start of care date, unless there is a beneficiary-elected transfer, significant change in condition, or discharge and return to the same HHA during the 60-day episode; (2) within 48 hours of the patient's return to the home from a hospital admission of 24-hours or more for any reason other than diagnostic tests; and (3) at discharge.

It is important to note that to calculate quality measures from OASIS data, there must be a complete quality episode, which requires both a Start of Care (initial assessment) or Resumption of Care OASIS assessment and a Transfer or Discharge OASIS assessment. Failure to submit sufficient OASIS assessments to allow calculation of quality measures, including transfer and discharge assessments, is a failure to comply with the CoPs.

HHAs are not required to submit OASIS data for patients who are excluded from the OASIS submission requirements as described in the December 23, 2005, final rule "Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies" (70 FR 76202).

As set forth in the CY 2008 HH PPS final rule (72 FR 49863), HHAs that become Medicare certified on or after May 31 of the preceding year are not subject to the OASIS quality reporting requirement nor any payment penalty for quality reporting purposes for the following year. For example, HHAs certified on or after May 31, 2014, are not subject to the 2 percentage point reduction to their market basket update for CY 2015. These exclusions only affect quality reporting requirements and payment reductions, and do not affect the HHA's reporting responsibilities as announced in the December 23, 2005 OASIS final rules (70 FR 76202).

2. Home Health Quality Reporting Program Requirements for CY 2017 Payment and Subsequent Years

In the CY 2014 HH PPS final rule (78 FR 72297), we finalized a proposal to consider OASIS assessments submitted by HHAs to CMS in compliance with HH CoPs and Conditions for Payment for episodes beginning on or after July 1, 2012, and before July 1, 2013, as fulfilling one portion of the quality reporting requirement for CY 2014.

In addition, we finalized a proposal to continue this pattern for each

subsequent year beyond CY 2014. OASIS assessments submitted for episodes beginning on July 1 of the calendar year 2 years prior to the calendar year of the Annual Payment Update (APU) effective date and ending June 30 of the calendar year one year prior to the calendar year of the APU effective date; fulfill the OASIS portion of the HH QRP requirement.

3. Previously Established Pay-for-Reporting Performance Requirement for Submission of OASIS Quality Data

Section 1895(b)(3)(B)(v)(I) of the Act states that for 2007 and each subsequent year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points if a home health agency does not submit quality data to the Secretary in accordance with subclause (II) for such a year. This pay-for-reporting requirement was implemented on January 1, 2007. In the CY 2016 HH PPS final rule (80 FR 68703 through 68705), we finalized a proposal to define the quantity of OASIS assessments each HHA must submit to meet the pay-forreporting requirement. We designed a pay-for-reporting performance system model that could accurately measure the level of an HHA's submission of OASIS data. The performance system is 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.

Section 80 of Chapter 10 of the Medicare Claims Processing Manual states, "If a Medicare beneficiary is covered under an MA Organization during a period of home care, and subsequently decides to change to Medicare FFS coverage, a new start of care OASIS assessment must be completed that reflects the date of the beneficiary's change to this pay source." We wish to clarify that the SOC OASIS assessment submitted when this change in coverage occurs will not be used in our determination of a quality assessment for the purpose of determining compliance with data submission requirements. In such a circumstance, the original SOC or ROC assessment submitted while the Medicare beneficiary is covered under an MA Organization would be considered a quality assessment within the pay-for-reporting, APU, Quality Assessments Only methodology. 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). 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) or be subject to a 2 percentage point reduction to their market basket update for that reporting period.

In this proposed rule we are not proposing any additional policies related to the pay-for-reporting performance requirement.

4. Proposed Timeline and Data Submission Mechanisms for Measures Proposed for the CY 2018 Payment Determination and Subsequent Years

a. Claims Based Measures

The MSPB-PAC HH QRP, Discharge to Community-PAC HH QRP, and Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, which we have proposed in this proposed rule, are Medicare FFS claimsbased measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection will be required from HHAs. As previously discussed in V.G., for the Discharge to Community—PAC HH QRP measure we propose to 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 propose to 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. For the MSPB-PAC HH QRP measure, we propose to 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.

b. Assessment-Based Measures Using OASIS Data Collection

As discussed in section V.G of this proposed rule, for the proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP, affecting CY 2018 payment determination and subsequent years, we are proposing that HHAs would submit data by completing data elements on the OASIS and then submitting the OASIS to CMS through the QIES ASAP system beginning January 1, 2017. For more information on HH QRP reporting through the QIES ASAP system, refer to CMS Web site at https://www.cms.gov/ Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ HomeHealthQualityInits/ HHQIOASISUserManual.html.

We propose to use standardized data elements in OASIS C2 to calculate the proposed measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP. The data elements necessary to calculate this measure using the OASIS are available on our Web site at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.

We invite public comments on the proposed HH QRP data collection requirements for the proposed measure affecting CY 2018 payment determination and subsequent years.

5. Proposed Timeline and Data Submission Mechanisms for the CY 2018 Payment Determination and Subsequent Years for New HH QRP Assessment-Based Quality Measure

In the CY 2016 HH PPS final rule (80 FR 68695 through 68698) for the FY 2018 payment determination, we finalized that HHAs must submit data on the quality measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) using CY 2017 data, for example, patients who are admitted to the HHA on and after January 1, 2017, and discharged from the HHA up to and including December 31, 2017. However, for CY 2018 APU purposes this timeframe would be impossible to achieve, given the processes we have established associated with APU determinations, such as the opportunity for providers to seek reconsideration for determinations of non-compliance. Therefore, for both the measure NQF #0678 Percent of

Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP, we propose that we would collect two quarters of data for CY 2018 APU determination to remain consistent with the January release schedule for the OASIS and to give HHAs sufficient time to update their systems so that they can comply with the new data reporting requirements, and to give us a sufficient amount of time to determine compliance for the CY 2018 program. The proposed use of two quarters of data for the initial year of quality reporting is consistent with the approach we have used to implement new measures in a number of other QRPs, including the LTCH, IRF, and Hospice QRPs in which only one quarter of data was used.

We invite public comments on our proposal to adopt a calendar year data collection time frame, using an initial 6-month reporting period from January 1, 2017, to June 30, 2017 for CY 2018 payment determinations, for the application of measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP.

6. Data Collection Timelines and Requirements for the CY 2019 Payment Determinations and Subsequent Years

In CY 2014 HH PPS final rule (78 FR 72297), we finalized our use of a July 1-June 30 time frame for APU determinations. In alignment with the previously established timeframe data collection for a given calendar year APU determination time period, beginning with the CY 2019 payment determination, we propose for both the finalized measure, NOF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay), and the proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP, to use 12 months of data collection, specifically assessments submitted July 1, 2017 through June 30, 2018, for the CY 2019 payment determination. We further propose to continue to use the same 12-month timeframe of July 1-June 30 for these

measures for subsequent years for APU determinations.

We invite comment on these proposals for the data collection timelines and requirements.

7. Proposed Data Review and Correction Timeframes for Data Submitted Using the OASIS Instrument

In addition, to remain consistent with the SNF, LTCH and IRF QRPs, as well as to comply with the requirements of section of section 1899B(g) of the Act, we are also proposing to implement calendar year provider review and correction periods for the OASIS assessment-based quality measures implemented into the HH ORP in satisfaction of the IMPACT Act, that is, finalized NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) and the proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP. More specifically, we are proposing that HHAs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessmentbased data (that appear on the CASPER generated Quality Measure reports) to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, HHAs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, once the quarterly submission deadline occurs, the data is "frozen" and calculated for public reporting and providers can no longer submit any corrections. As laid out in Table 34, the first calendar year reporting quarter is January 1, 2017 through March 31, 2017. The final deadline for submitting corrected data would be August 15, 2017 for CY Quarter 1, and subsequently and sequentially, November 15, 2017 for CY 2017 Quarter 2, February 15, 2018 for CY 2017 Quarter 3 and May 15, 2018 for CY 2017 Quarter 4. We note that this proposal to review and correct data does not replace other requirements associated with timely data submission. We would encourage HHAs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

TABLE 34: Proposed CY Data Collection/Submission Quarterly Reporting Periods and Data Submission Deadlines* Affecting Finalized and Proposed Assessment-based Measures

Quality Measures	Data Collection Source	Proposed Data Collection/ Ssubmission Quarterly Reporting Period*	Proposed Quarterly Review and Correction Periods and Data Submission Quarterly Deadlines *
NQF # 0678:Application of Percent of Patients or Residents with Pressure Ulcers that are New or Worsened	OASIS	CY 17 Q1 1/1/2017-3/31/2017 CY 17 Q2 4/1/2017-6/30/17	CY 2017 Q1 Deadline: August 15, 2017 CY 2017 Q2 Deadline: November 15, 2017
Drug Regimen Review Conducted with Follow- Up for Identified Issues- PAC HH QRP	OASIS	CY 17 Q3 7/1/2017-9/30/2017 CY 17 Q4 10/1/2017-12/31/2017	CY 2017 Q3 Deadline: February 15, 2018 CY 2017 Q4 Deadline May 15, 2018

^{*}We note that the submission deadlines provided pertain to the correction of data and that the submission of OASIS data must continue to adhere to all submission deadline requirements as imposed under the Conditions of Participation.

We invite public comments on our proposal to adopt a calendar year data collection time frame, with a 4.5 month period of time for review and correction beginning with CY 2017 for the measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed

measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for the HH QRP.

Further, we propose that the OASIS assessment-based measures already finalized for adoption into the HH QRP follow a similar CY schedule of data reporting using quarterly data collection/submission reporting periods

followed by 4.5 months during which providers will have an opportunity to review and correct their data up until the quarterly data submission deadlines as provided in Table 35 for all reporting years unless otherwise specified. This policy would apply to all proposed and finalized assessment-based measures in the HH QRP.

TABLE 35—PROPOSED CY DATA COLLECTION SUBMISSION QUARTERLY REPORTING PERIODS, QUARTERLY REVIEW AND CORRECTION PERIODS AND DATA SUBMISSION DEADLINES FOR MEASURES SPECIFIED IN SATISFACTION OF THE IMPACT ACT IN SUBSEQUENT YEARS

Proposed CY data collection quarter	Proposed data collection/submission quarterly reporting period	Proposed quarterly review and correction periods and data submission quarterly deadlines*	Proposed correction deadlines *
Quarter 1	April 1–June 30	April 1–August 15	November 15. February 15.

*We note that the submission deadlines provided pertain to the correction of data and that the submission of OASIS data must continue to adhere to all submission deadline requirements as imposed under the Conditions of Participation.

We invite public comment on our use of CY quarterly data collection/submission reporting periods with quarterly data submission deadlines that follow a period of approximately 4.5 months of time to enable the review and correction of such data for OASIS assessment-based measures.

J. Public Display of Quality Measure Data for the HH QRP and Procedures for the Opportunity To Review and Correct Data and Information

Medicare home health regulations, as codified at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey® (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. 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 2 years after the applicable specified application date. In future rulemaking, we intend to propose a policy to publicly display performance information for individual HHAs on IMPACT Act measures, as required under the Act. In addition, sections 1895(b)(3)(B)(v)(III) and 1899B(g) of the Act require the Secretary to establish procedures for making data submitted under subclause (II) available to the

public. Under section 1899B(g)(2), such procedures 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 IQR Program, that a home health agency 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 through a process consistent with the Hospital Inpatient Quality Reporting Program (Hospital IQR). 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 requires should be constructed from data collected in a standardized and uniform manner. In this proposed rule, we are proposing procedures that would 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.

1. Proposals for the Review and Correction of Data Used To Calculate the Assessment-Based Measures Prior to Public Display

As provided in section V.I.7., and in Table 34, for assessment-based measures, we are proposing to provide confidential feedback reports to HHAs that contain performance information that the HHAs can review, during the review and correction period, and correct the data used to calculate the measures for the HH QRP that the HHA submitted via the QIES ASAP system. In addition, during the review period, the HHA would be able to request correction of any errors in the assessment-based measure rate calculations.

We propose that these confidential feedback reports would be available to each HHA using the Certification and Survey Provider Enhanced Reporting (CASPER) System. We refer to these reports as the HH Quality Measure (QM) Reports. We intend to provide monthly updates to the data contained in these reports that pertain to assessment-based data, as data become available. The reports will contain both agency- and patient-level data used to calculate the assessment-based quality measures. The CASPER facility level QM reporting would include the numerator, denominator, agency rate, and national rate. The CASPER patient-level QM

Reports would also contain individual patient information that HHAs can use to identify patients that were included in the quality measures so as to identify any potential errors. In addition, we would make other reports available to HHAs through the CASPER System, including OASIS data submission reports and provider validation reports, which would contain information on each HHA's data submission status including details on all items the HHA submitted in relation to individual assessments and the status of the HHA's assessment (OASIS) records that they submitted. When available, additional information regarding the content and availability of these confidential feedback reports would be provided on the HH QRP Web site https:// www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/ index.html.

As previously proposed in section V.I.7., for those measures that use assessment-based data, HHAs would have 4.5 months after the conclusion of each reporting quarter to review and update their reported measure data for the quarter, including correcting any errors that they find on the CASPERgenerated Review and Correct, QM reports pertaining to their assessmentbased data used to calculate the assessment-based measures. However, at the conclusion of this 4.5 month review and correction period, the data reported for that quarter would be "frozen" and used to calculate measure rates for public reporting. We would encourage HHAs to submit timely assessment data during each quarterly reporting period and to review their data and information early during the 4.5 month review and correction period so they can identify errors and resubmit data before the data submission deadline.

We believe that the proposed data submission period along with a review and correction period, consisting of the reporting quarter plus approximately 4.5 months, is sufficient time for HHAs to submit, review and, where necessary, correct their data and information. We also propose that, in addition to the data submission/correction and review period, HHAs will have a 30-day preview period prior to public display during which they can preview the performance information on their measures that will be made public. We also propose to provide this preview report using the Certification and Survey Provider Enhanced Reporting (CASPER) System because HHAs are familiar with this system. The CASPER preview reports for the reporting quarter would be available after the 4.5 month

review and correction period ends, and would be refreshed quarterly or annually for each measure, depending on the length of the reporting period for that measure. We propose to give HHAs 30 days to review this information, beginning from the date on which they can access the preview report. Corrections to the underlying data would not be permitted during this time; however, HHAs would be able to ask for a correction to their measure calculations during the 30-day preview period. If we determine that the measure, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure and publish the corrected rate at the time of the next scheduled public display date. This process is consistent with informal processes used in the Hospital IQR program. If finalized, we intend to utilize a subregulatory mechanism, such as our HH QRP Web site, to explain the technical details for how and when providers may contest their measure calculations. We further propose to increase the current preview period of 15 days to 30 days beginning with the public display of the measures finalized for the CY 2018 payment determination. This preview period would include all measures that are to be publicly displayed under the current quarterly refresh schedule used for posting quality measure data on the Medicare.gov Home Health Compare

We invite public comment on these proposals.

2. Proposals for Review and Correction of Data Used To Calculate Claims-Based Measures Prior To Public Display

In addition to assessment-based measures, we have also proposed claims-based measures for the HH QRP. As noted previously, section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR program. Under the Hospital IQR Program's procedures, for claims-based measures, we give hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We propose to adopt a similar process for the HH QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC and Hospital VBP programs, we propose to make available through the CASPER system a confidential preview report that will contain information pertaining

to their claims-based measure rate calculations, including agency and national rates. This information would be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the rates.

We propose to create data extracts using claims data for these claims based measures, at least 90 days after the last discharge date in the applicable period (12 calendar months preceding), which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017, for data collection January 1, 2017, through December 31, 2017, we would create the data extract on approximately March 31, 2018, at the earliest, and use that data to calculate the claims-based measures for the 2017 reporting period. We propose that beginning with data for measures that will be publicly displayed by January 1, 2019, and for which will need to coincide with the quarterly refresh schedule on Home Health Compare, the claims-based measures will be calculated at least 90 days after the last discharge date using claims data from the applicable reporting period. This timeframe allows us to balance the need to provide timely program information to HHAs with the need to calculate the claims-based measures using as complete a data set as possible. Since HHAs would not be able to submit corrections to the underlying claims snapshot or add claims (for those measures that use HH claims) to this data set, at the conclusion of the 90-day period following the last date of discharge used in the applicable period, we would consider the HH claims data to be complete for purposes of calculating the claims-based measures. We wish to convey the importance that HHAs ensure the completeness and correctness of their claims prior to the claims "snapshot". We seek to have as complete a data set as possible. We recognize that the proposed approximately 90 day "run-out" period is less than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed approximately 90 day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted, and/or episodebased measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to HHAs sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay, both for HHAs and for us to deliver timely calculations to HHAs for quality improvement.

As noted, under this proposed procedure, during the 30-day preview period, HHAs would not be able to submit corrections to the underlying claims data or add new claims to the data extract. This is for two reasons. First, for certain measures, some of the claims data used to calculate the measure are derived not from the HHA's claims, but from the claims of another provider. For example, the proposed measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP uses claims data submitted by the hospital to which the patient was readmitted. HHAs are not able to make corrections to these hospital claims, although the agency could request that the hospital reconfirm that its submissions are correct. Second, even where HHA claims are used to calculate the measures, it would not be not possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static "snapshot" of the claims in order to perform the necessary measure calculations.

As noted previously, we propose to provide HHAs a 30-day preview period to review their confidential preview reports. HHAs would have 30 days from the date the preview report is made available to review this information. The 30-day preview period would be the only time when HHAs would be able to see their claims-based measure rates before they are publicly displayed. HHAs could request that we correct our measure calculation during the 30-day preview period if the HHA believes the measure rate is incorrect. If we agree that the measure rate, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure, and publish the corrected measure rate at the time of the next scheduled public display date. If finalized, we intend to utilize a subregulatory mechanism, such as our HH QRP Web site, to explain the technical details regarding how and when providers may contest their

measure calculations. We refer readers to the discussion in V.I.2 for additional information on these preview reports.

In addition, because the claims-based measures used for the HH QRP are recalculated on an annual basis, these confidential CASPER QM preview reports for claims-based measures would be refreshed annually. An annual refresh is being utilized to ensure consistency in our display of claims based measures, and it will include both claims-based measures that satisfy the IMPACT Act, as well as all other HH QRP claims-based measures.

We invite public comment on these proposals for the public display of quality measure data.

K. Mechanism for Providing Feedback Reports to HHAs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback measure reports to post-acute care providers on their performance on the measures specified under paragraphs (c)(1) and (d)(1), beginning 1 year after the specified application date that applies to such measures and PAC providers. We propose to build upon the current confidential quality measure reports we already generate for HHAs so as to also provide data and information on the measures implemented in satisfaction of the IMPACT Act. As a result. HHAs could review their performance on these measures, as well as those already adopted in the HH QRP. We propose that these additional confidential feedback reports would be made available to each HHA through the CASPER System. Data contained within these CASPER reports would be updated, as previously described, on a monthly basis as the data become available except for claims-based measures, which will only be updated on an annual basis.

We intend to provide detailed procedures to HHAs on how to obtain their new confidential feedback reports in CASPER 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 also propose to use the QIES ASAP system to provide these new confidential quality measure reports in a manner consistent with how HHAs have obtained such reports to date. The QIES ASAP system is a confidential and secure system with access granted to providers, or their designees.

We invite public comment on this proposal to satisfy the requirement to provide confidential feedback reports to HHAs specific to the requirements of the Act.

L. Home Health Care CAHPS® Survey (HHCAHPS)

In the CY 2016 HH PPS final rule (80 FR 68623), we stated that the home health quality measures reporting requirements for Medicare-certified agencies includes the Home Health Care CAHPS® (HHCAHPS) Survey for the CY 2017 and 2018 Annual Payment Update (APU) periods. We are continuing to maintain the stated HHCAHPS data requirements for CY 2017 and CY 2018 that were stated in CY 2016 and in previous HH PPS rules, for the continuous monthly data collection and quarterly data submission of HHCAHPS data.

1. Background and Description of HHCAHPS

As part of the HHS Transparency Initiative, we implemented a process to measure and publicly report patient experiences with home health care, using a survey developed by the Agency for Healthcare Research and Quality's (AHRQ's) Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program and endorsed by the National Quality Forum (NQF) in March 2009 (NQF Number 0517) and NQF reendorsed in 2015. The HHCAHPS Survey is approved under OMB Control Number 0938-1066. The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The Home Health Care CAHPS® (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.

Prior to this survey, there was no national standard for collecting information about patient experiences that enabled valid comparisons across all HHAs. The history and development process for HHCAHPS has been described in previous rules and is also available on the official HHCAHPS Web site at https://homehealthcahps.org and in the annually-updated HHCAHPS Protocols and Guidelines Manual, which is downloadable from https://homehealthcahps.org.

Since April 2012, for public reporting purposes, we report five measures from the HHCAHPS Survey—three composite measures and two global ratings of care that are derived from the questions on the HHCAHPS survey. The publicly reported data are adjusted for differences in patient mix across HHAs. We update the HHCAHPS data on Home Health Compare on www.medicare.gov

quarterly. Each HHCAHPS composite measure consists of four or more individual survey items regarding one of the following related topics:

• Patient care (Q9, Q16, Q19, and Q24);

• Communications between providers and patients (Q2, Q15, Q17, Q18, Q22, and Q23); and

• Specific care issues on medications, home safety, and pain (Q3, Q4, Q5, Q10, Q12, Q13, and Q14).

The two global ratings are the overall rating of care given by the HHA's care providers (Q20), and the patient's willingness to recommend the HHA to family and friends (Q25).

The HHCAHPS survey is currently available in English, Spanish, Chinese, Russian, and Vietnamese. The OMB number on these surveys is the same (0938–1066). All of these surveys are on the Home Health Care CAHPS® Web site, https://homehealthcahps.org. We continue to consider additional language translations of the HHCAHPS in response to the needs of the home health patient population.

All of the requirements about home health patient eligibility for the HHCAHPS survey and conversely, which home health patients are ineligible for the HHCAHPS survey are delineated and detailed in the HHCAHPS Protocols and Guidelines Manual, which is downloadable at https://homehealthcahps.org. Home health patients are eligible for HHCAHPS if they received at least two skilled home health visits in the past 2 months, which are paid for by Medicare or Medicaid.

Home health patients are ineligible for inclusion in HHCAHPS surveys if one of these conditions pertains to them:

- Are under the age of 18;
- Are deceased prior to the date the sample is pulled;
 - Receive hospice care;
 - Receive routine maternity care only;
- Are not considered survey eligible because the state in which the patient lives restricts release of patient information for a specific condition or illness that the patient has; or
- Are "No Publicity" patients, defined as patients who on their own initiative at their first encounter with the HHAs make it very clear that no one outside of the agencies can be advised of their patient status, and no one outside of the HHAs can contact them for any reason.

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 also must provide on a monthly basis a list of their patients served to their respective HHCAHPS survey vendors. Agencies are not allowed to influence at all how their patients respond to the HHCAHPS survey.

As previously required, HHCAHPS survey vendors are required to attend introductory and all update trainings conducted by CMS and the HHCAHPS Survey Coordination Team, as well as 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://hhomehealthcahps.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).

3. HHCAHPS Requirements for the CY 2017 APU

For the CY 2017 APU, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2017, APU includes the second quarter 2015 through the first quarter 2016 (the months of April 2015 through March 2016). HHAs are required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2015 by 11:59 p.m., EST on October 15, 2015; for the third quarter 2015 by 11:59 p.m., EST on January 21, 2016; for the fourth quarter 2015 by 11:59 p.m., EST on April 21, 2016; and for the first quarter 2016 by 11:59 p.m., EST on July 21, 2016. These deadlines are firm; no exceptions are permitted.

For the CY 2017 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2014, through March 31, 2015, are exempt from the HHCAHPS data collection and submission requirements for the CY 2017 APU, upon completion of the CY 2017 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, 2014, through March 31, 2015, are required to submit their patient counts on the CY 2017 HHCAHPS Participation Exemption Request form posted on https://homehealthcahps.org from April 1, 2015, to 11:59 p.m., EST to March 31, 2016. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicarecertification on or after April 1, 2015, are exempt from the HHCAHPS reporting requirement for the CY 2017 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2017 APU.

4. HHCAHPS Requirements for the CY 2018 APU

For the CY 2018 APU, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2018, APU includes the second quarter 2016 through the first quarter 2017 (the months of April 2016 through March 2017). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2016 by 11:59 p.m., EST on October 20, 2016; for the third quarter 2016 by 11:59 p.m., EST on January 19, 2017; for the fourth quarter 2016 by 11:59 p.m., EST on April 20, 2017; and for the first quarter 2017 by 11:59 p.m., EST on July 20, 2017. These deadlines are firm; no exceptions will be permitted.

For the CY 2018 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2015 through March 31, 2016, are exempt from the HHCAHPS data collection and submission requirements for the CY 2018 APU, upon completion of the CY 2018 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPŠ-eligible, unduplicated or unique patients in the period of April 1, 2015, through March 31, 2016, are required to submit their patient counts on the CY 2018 HHCAHPS Participation Exemption Request form posted on https://homehealthcahps.org from April 1, 2016, to 11:59 p.m., EST to March 31, 2017. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicarecertification on or after April 1, 2016, are exempt from the HHCAHPS reporting requirement for the CY 2018 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2018 APU.

5. HHCAHPS Requirements for the CY 2019 APU

For the CY 2019 APU, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2018, APU 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., EST on October 19, 2017; for the third quarter 2017 by 11:59 p.m., EST on January 18, 2018; for the fourth quarter 2017 by 11:59 p.m., EST on April 19, 2018; and for the first quarter 2018 by 11:59 p.m., EST on July 19, 2018. These deadlines are firm; no exceptions will be permitted.

For the CY 2019 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2016 through March 31, 2017, are exempt from the HHCAHPS data collection and submission requirements for the CY 2019 APU, upon completion of the CY 2019 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, 2016, through March 31, 2017, are required to submit their patient counts on the CY 2019 HHCAHPS Participation Exemption Request form posted on https://homehealthcahps.org from April 1, 2017, to 11:59 p.m., EST to March 31, 2018. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicarecertification on or after April 1, 2017, are exempt from the HHCAHPS reporting requirement for the CY 2019 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2019 APU.

6. HHCAHPS Requirements for the CY 2020 APU

For the CY 2020 APU, we require continued monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2020, APU 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., EST on October 18, 2018; for the third quarter 2018 by 11:59 p.m., EST on January 17, 2019; for the fourth quarter 2018 by 11:59 p.m., EST on April 18, 2019; and for the first quarter 2019 by 11:59 p.m., EST on July 19, 2019. These deadlines are firm; no exceptions will be permitted.

For the CY 2020 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2017, through March 31, 2018, are exempt from the HHCAHPS data collection and submission requirements for the CY 2020 APU, upon completion of the CY 2020 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, 2017, through March 31, 2018, are required to submit their patient counts on the CY 2020 HHCAHPS Participation Exemption Request form posted on https://homehealthcahps.org from April 1, 2018, to 11:59 p.m., EST to March 31, 2019. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicarecertification on or after April 1, 2018 are exempt from the HHCAHPS reporting requirement for the CY 2020 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2020 APU.

7. HHCAHPS Reconsiderations and Appeals Process

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 continue the OASIS and HHCAHPS reconsiderations and appeals process that we have finalized and that we have used for prior all periods cited in the previous rules, and utilized in the CY 2012 to CY 2016 APU determinations. We have described the HHCAHPS reconsiderations and appeals process requirements in the APU Notification Letter that we send to the affected HHAs annually in September. HHAs have 30 days from their receipt of the letter informing them that they did not meet the HHCAHPS requirements to reply to us with documentation that supports their requests for reconsideration of the annual payment update to us. It is important that the affected HHAs send in comprehensive information in their reconsideration letter/package because we will not contact the affected HHAs to request additional information or to clarify incomplete or inconclusive information. If clear evidence to support a finding of compliance is not present, then the 2 percent reduction in the annual payment update will be upheld. If clear evidence of compliance is present, then the 2 percent reduction for the APU will be reversed. We notify affected HHAs by December 31 of the decisions that affects payments in the annual year beginning on January 1. If we determine to uphold the 2 percent reduction for the annual payment update, the affected HHA may further appeal the 2 percent reduction via the Provider Reimbursement Review Board (PRRB) appeals process, which is described in the December letter.

8. Summary

We did not propose 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 APU years. We again strongly encourage HHAs to keep up-todate 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. Collection of Information Requirements

While this proposed rule contains information collection requirements, this rule does not add new, nor revise

any of the existing information collection requirements, or burden estimate. The information collection requirements discussed in this rule for the OASIS-C1 data item set had been previously approved by the Office of Management and Budget (OMB) on February 6, 2014 and scheduled for implementation on October 1, 2014. The extension of OASIS-C1/ICD-9 version was reapproved under OMB control number 0938-0760 with a current expiration date of March 31, 2018. This version of the OASIS will be discontinued once the OASIS-C1/ICD-10 version is approved and implemented. In addition, to facilitate the reporting of OASIS data as it relates to the implementation of ICD-10 on October 1, 2015, CMS submitted a new request for approval to OMB for the OASIS-C1/ICD-10 version under the Paperwork Reduction Act (PRA) process. CMS is requesting a new OMB control number for the proposed revised OASIS item as announced in the 30-day Federal Register notice (80 FR 15797). The new information collection request is currently pending OMB approval.

VII. Response to 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.

VIII. 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)(3)(A) 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, 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 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 vears 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.

Section 421(a) of the MMA requires that HH services furnished in a rural area, for episodes and visits ending on or after April 1, 2010, and before January 1, 2016, receive an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act. Section 210 of the MACRA amended section 421(a) of the MMA to extend the 3 percent increase to the payment amounts for serviced furnished in rural areas for episodes and visits ending before January 1, 2018.

Section 3131(a) of the Affordable Care Act mandates that starting in CY 2014, the Secretary must apply an adjustment to the national, standardized 60-day episode payment rate and other amounts applicable under section 1895(b)(3)(A)(i)(III) of the Act to 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. In addition, section 3131(a) of the Affordable Care Act mandates that rebasing must be phased-in over a 4year period in equal increments, not to exceed 3.5 percent of the amount (or

amounts) as of the date of enactment (2010) under section 1895(b)(3)(A)(i)(III) of the Act, and be fully implemented in CY 2017.

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. The HHVBP Model was implemented in January 2016 as described in the CY 2016 HH PPS final rule.

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), and the Congressional Review Act (5 U.S.C. 804(2)).

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 impacts related to the changes in payments under the HH PPS for CY 2017 are estimated to be -\$180 million. The savings impacts related to the

HHVBP model are estimated at a total projected 5-year gross savings of \$378 million assuming a very conservative savings estimate of a 6 percent annual reduction in hospitalizations and a 1.0 percent annual reduction in SNF admissions. Therefore, 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 accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The net transfer impacts related to the changes in payments under the HH PPS for CY 2017 are estimated to be -\$180 million. The savings impacts related to the HHVBP Model are estimated at a total projected 6-year gross savings of \$378 million assuming a very conservative savings estimate of a 6 percent annual reduction in hospitalizations and a 1.0 percent annual reduction in SNF admissions.

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 2016, that threshold is approximately \$146 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 \$146 million or more.

1. HH PPS

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2017. Accordingly, the

following analysis describes the impact in CY 2017 only. We estimate that the net impact of the policies in this rule is approximately \$180 million in decreased payments to HHAs in CY 2017. 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 2017 wage index and the recalibration of the case-mix weights for 2017 is zero. The -\$180 million impact reflects the distributional effects of the 2.3 percent HH payment update percentage (\$420 million increase), the effects of the fourth year of the four-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit payment rates, and the NRS conversion factor for an impact of -2.3percent (\$420 million decrease), the effects of the -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 (\$160 million decrease), and the effects of the proposed change to the FDL ratio of 0.45 to 0.56 for an impact of -0.1 percent (\$20 million decrease). The \$180 million in decreased payments is reflected in the last column of the first row in Table 36 as a 1.0 percent decrease in expenditures when comparing CY 2016 payments to estimated CY 2017 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 Medicarepaid 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 39,

by HHA type and location.

With regards to options for regulatory relief, we note that in the CY 2014 HH PPS final rule we finalized rebasing adjustments to the national, standardized 60-day episode rate, nonroutine supplies (NRS) conversion factor, and the national per-visit payment rates for each year, 2014 through 2017 as described in section II.C and III.C.3 of this proposed rule. Since the rebasing adjustments are mandated by section 3131(a) of the Affordable Čare Act, we cannot offer HHAs relief from the rebasing adjustments for CY 2017. For the 0.97 percent reduction to the national, standardized 60-day episode payment amount for CY 2017 described in section III.C.3 of this proposed rule, we believe it is appropriate to reduce the national, standardized 60-day episode payment amount 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. In the alternatives considered section for the CY 2016 HH PPS proposed rule (80 FR 39839), we note that 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 finalized a reduction to the 60day episode rate over a three-year period (CY 2016, CY 2017, and CY 2018) to account for estimated nominal case-mix growth between CY 2012 and CY 2014 in order to lessen the impact on HHAs in a given year (80 FR 68646).

Executive Order 13563 specifies, to the extent practicable, agencies should assess the costs of cumulative regulations. However, given potential utilization pattern changes, wage index changes, changes to the market basket forecasts, and unknowns regarding future policy changes, we believe it is neither practicable nor appropriate to forecast the cumulative impact of the rebasing adjustments on Medicare payments to HHAs for future years at this time. 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 would make it difficult to predict accurately the full scope of the impact upon HHAs for future years beyond CY 2017. We note that the rebasing adjustments to the national, standardized 60-day episode payment rate and the national per-visit rates are capped at the statutory limit of 3.5 percent of the CY 2010 amounts (as described in the preamble in section II.C. of this proposed rule) for each year, 2014 through 2017. The NRS rebasing adjustment will be -2.82 percent in each year, 2014 through 2017.

2. HHVBP Model

Under the HHVBP Model, the first payment adjustment will apply in CY 2018 based on PY1 (CY 2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (CY 2020) data. In the CY 2016 HH PPS final rule, the overall impact of HHVBP Model from CY 2018-CY 2022 was approximately a reduction of \$380 million. That estimate was based on the five performance years of the Model and only two payment adjustment years. We now estimate that this will be approximately a decrease of \$378 million. This estimate represents the five performance years (CY 2016-CY 2020) and applying the payment adjustments from CY 2018 through CY 2021. We assume that the behavior changes and savings will continue into 2021 because HHAs will continue to receive quality reports until July 2021. Although behavior changes and savings could persist into CY 2022, HHAs would not be receiving quality reports so we did not include it in our savings assumptions.

C. Detailed Economic Analysis

1. HH PPS

This rule proposes updates for CY 2017 to the HH PPS rates contained in the CY 2016 HH PPS final rule (80 FR 68624 through 68719). 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-

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 2015. 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.

Table 36 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule. For this analysis, we used an analytic file with linked CY 2015 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2015 (as of March 31, 2016). The first column of Table 36 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 2017 wage index. The fourth column shows the payment effects of the CY 2016 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 effects of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit payment rates, and NRS conversion factor. For CY 2017, the average impact for all HHAs due to the effects of rebasing is an estimated 2.3 percent decrease in payments. The seventh column shows the effects of revising the FDL ratio used to compute outlier payments from 0.45 to 0.56. The eighth column shows the effects of the change to the outlier methodology. The ninth column shows the effects of the CY 2017 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 2017 would decrease by 1.0 percent. As illustrated in Table 36, 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 2017 wage index, the extent to which HHAs

had episodes in case-mix groups where the case-mix weight decreased for CY 2017 relative to CY 2016, the percentage of total HH PPS payments that were

subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

TABLE 36— ESTIMATED HOME HEALTH AGENCY IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2017

		, talito i i	7.0.0 5	/ (0.12	,	AIILA OI	000	, • .	2017
	Number of Agencies	CY 2017 wage index ¹ %	CY 2017 case-mix weights ²	60-day episode rate nomi- nal case- mix reduct- ion ³ %	Rebas- ing ⁴ %	Revised outlier FDL %	Revised outlier method- ology %	HH payment update percent- age ⁵ %	Total %
All Agencies	11,167	0.0	0.0	-0.9	-2.3	-0.1	0.0	2.3	-1.0
		Fa	cility Type a	nd Control					
F. O. I. (OIL V. IAID	4 007				0.0	0.4	0.0	0.0	
Free-Standing/Other Vol/NP Free-Standing/Other Proprietary Free-Standing/Other Government Freaility-Based Vol/NP Facility-Based Proprietary Facility-Based Government Subtotal: Freestanding Subtotal: Facility-based	1,087 8,715 362 690 109 204 10,164 1,003	-0.2 0.1 0.1 -0.1 0.0 -0.3 0.0 -0.1	-0.1 0.0 0.1 -0.1 0.0 0.0 0.0	-0.9 -0.9 -0.9 -0.9 -0.9 -0.9 -0.9	-2.2 -2.3 -2.2 -2.2 -2.2 -2.3 -2.3 -2.2	-0.1 -0.1 -0.1 -0.1 -0.1 -0.1 -0.1	0.9 -0.3 0.3 0.8 0.4 0.8 -0.1	2.3 2.3 2.3 2.3 2.3 2.3 2.3	- 0.3 - 1.2 - 0.4 - 0.3 - 0.5 - 0.5 - 1.1 - 0.2
Subtotal: Vol/NP Subtotal: Proprietary	1,777 8,824	- 0.2 0.1	-0.1 0.0	- 0.9 - 0.9	-2.2 -2.3	- 0.1 - 0.1	0.9 -0.3	2.3 2.3	-0.3 -1.2
Subtotal: Government	566	-0.1	0.1	-0.9	-2.3	-0.1	0.5	2.3	-0.5
		Facili	ty Type and	Control: Rura	al				
Free-Standing/Other Vol/NP	279	0.1	0.1	-0.9	-2.2	-0.1	0.8	2.3	0.1
Free-Standing/Other Proprietary Free-Standing/Other Government Facility-Based Vol/NP Facility-Based Proprietary Facility-Based Government	873 261 333 54 152	0.1 0.0 0.2 0.3 -0.1 0.1	-0.1 0.0 0.1 0.1 0.2	-0.9 -0.9 -0.9 -0.9 -0.9	-2.2 -2.3 -2.4 -2.2 -2.3 -2.2	-0.1 -0.1 -0.1 -0.1 -0.1	0.6 0.2 -0.2 0.5 0.5 0.4	2.3 2.3 2.3 2.3 2.3 2.3	-0.9 -1.1 0.0 -0.5 -0.2
		Facilit	y Type and (Control: Urba	n				
Free-Standing/Other Vol/NP Free-Standing/Other Proprietary Free-Standing/Other Government Facility-Based Vol/NP Facility-Based Proprietary Facility-Based Government	807 7,837 101 357 55 52	-0.3 0.1 0.0 -0.2 0.1 -0.6	-0.2 0.0 0.0 -0.1 -0.1	- 0.9 - 0.9 - 0.9 - 0.9 - 0.9 - 0.9	-2.2 -2.3 -2.3 -2.2 -2.2 -2.3	-0.1 -0.1 -0.1 -0.1 -0.1	0.9 -0.4 0.2 0.9 0.3 1.1	2.3 2.3 2.3 2.3 2.3 2.3	-0.5 -1.3 -0.8 -0.3 -0.6 -0.6
		Facilit	y Location: l	Urban or Rura	al				
RuralUrban	1,952 9,209	0.2 0.0	0.0 0.0	-0.9 -0.9	-2.3 -2.3	-0.1 -0.1	0.0 0.0	2.3 2.3	-0.8 -1.0
		Facility Lo	ocation: Reg	ion of the Co	untry				
Northeast	848 2,992 5,310 1,968 49 41	-0.4 0.0 -0.1 0.6 -0.3 -0.5	0.0 0.0 0.0 0.0 0.1 0.1	-0.9 -0.9 -0.9 -0.9 -0.9	-2.1 -2.4 -2.3 -2.3 -2.2 -2.2	-0.1 -0.1 -0.1 -0.1 -0.1	0.8 0.4 -0.6 0.3 0.9	2.3 2.3 2.3 2.3 2.3 2.3	-0.4 -0.7 -1.7 -0.1 -0.2 -0.7
	Facilit	ty Location:	Region of the	e Country (Ce	ensus Regior	1)			
New England Mid Atlantic East North Central West North Central South Atlantic East South Central West South Central Mountain Pacific	347 501 2,271 721 1,791 426 3,093 672 1,296	-0.7 -0.3 0.0 0.0 -0.3 -0.1 0.3 0.2 0.7	0.1 -0.1 0.1 -0.1 -0.1 0.0 0.0 0.1	-0.9 -0.9 -0.9 -0.9 -0.9 -0.9 -0.9 -0.9	-2.1 -2.1 -2.4 -2.3 -2.3 -2.4 -2.3 -2.3 -2.3	-0.1 -0.1 -0.1 -0.1 -0.1 -0.1 -0.1 -0.1	0.3 1.1 0.4 0.6 -0.6 0.0 -0.8 -0.2 0.6	2.3 2.3 2.3 2.3 2.3 2.3 2.3 2.3 2.3	- 1.1 - 0.1 - 0.6 - 0.5 - 2.0 - 1.1 - 1.5 - 0.9 0.3
		Facility S	Size (Number	of 1st Episo	des)				
<100 episodes	3,177 2,733 2,342 1,597 1,318	0.0 0.1 0.1 0.0 0.0	0.3 0.2 0.0 0.0 -0.1	- 0.9 - 0.9 - 0.9 - 0.9 - 0.9	-2.3 -2.4 -2.3 -2.3 -2.3	-0.1 -0.1 -0.1 -0.1 -0.1	0.4 0.1 0.0 -0.1 0.0	2.3 2.3 2.3 2.3 2.3	- 0.3 - 0.7 - 0.9 - 1.1 - 1.1

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of December 31, 2015) for which we had a linked OASIS assess-

nent.

1 The impact of the CY 2017 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 2017 home health case-mix weights reflects the recalibration of the case-mix weights as outlined in section III.B of this proposed rule offset by the case-mix weights budget neutrality factor described in section III.C.3 of this proposed rule.

3 The 0.97 percent reduction to the national, standardized 60-day episode payment amount in CY 2017 is estimated to have a 0.9 percent impact on overall HH PPS expenditures

⁴ The impact of rebasing includes the rebasing adjustments to the national, standardized 60-day episode payment rate (-2.74 percent after the CY 2017 payment rate was adjusted for the wage index and case-mix weight budget neutrality factors and the nominal case-mix reduction), the national per-visit rates (+2.9 percent), and the NRS conversion factor (-2.82 percent). The estimated impact of the NRS conversion factor rebasing adjustment is an overall -0.01 percent decrease in esti-

and the first conversion tactor (2.52 percent). The estimated impact of the first estresion tactor restaining adjustment is all overall of percent accrease in estimated payments to HHAs

4 The CY 2017 home health payment update percentage reflects the home health market basket update of 2.8 percent, reduced by a 0.5 percentage point multi-factor productivity (MFP) adjustment as required under section 1895(b)(3)(B)(vi)(I) of the Act, 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. HHVBP Model

Table 37 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 2013 and 2014 OASIS measures, hospitalization measure and Emergency Department (ED) measure from QIES, and Home Health CAHPS data. The impacts below also account for the proposals to change the smaller-volume cohort size determination, calculate achievement threshold and benchmark proposals at the state level, and revise the applicable measures. We determined the distribution of possible payment adjustments based on ten (10) OASIS quality measures, two (2) claims-based measures in QIES, the three (3)New Measures (with the assumption that all HHAs reported on all New Measures and received full points), and OIES Roll Up File data in the same manner as they would be in the Model. The five (5) HHCAHPS measures are based on archived data. The size of the cohorts were determined using the 2014 Quality Episode File based on OASIS assessments (the Model will use the year before each performance year), whereby the HHAs reported at least five measures with over 20 observations. The basis of the payment adjustment was derived from complete 2014 claims data. We note that this impact analysis is based on the aggregate value of all nine (9) selected states.

Table 38 displays our analysis of the distribution of possible payment adjustments based on the same 2013-2014 data used to calculate Table 37, providing information on the estimated impact of this proposed rule. We note that this impact analysis is based on the aggregate value of all nine (9) selected states. 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. Value-based incentive payment adjustments for the estimated 1,900 plus HHAs in the selected states that compete in the HHVBP Model are stratified by size as described in this proposed rule. Under the proposal described, 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 small HHAs would not have a smaller-volume cohort and thus there would only be one cohort that would include all the HHAS in that state. As indicated in Table 38, under this proposal, Massachusetts, Maryland, North Carolina, Tennessee and Washington would only have one cohort and Florida, Arizona, Iowa, Nebraska would have a smaller-volume cohort and a larger-volume cohort. For example, Iowa has 29 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 in 2013. Therefore, those 29 HHAs would be competing in Iowa's smaller-volume cohort if the performance year was 2014.

Using 2013-2014 data and the payment adjustment of 5-percent (as applied in CY 2019), based on the ten (10) OASIS quality measures, two (2) claims-based measures in QIES, the five (5) HHCAHPS measures (based on the archived data), and the three (3) New Measures (with the assumption that all HHAs submitted data), Table 38 illustrates that smaller-volume HHAs in Iowa would have a mean payment adjustment of positive 0.62 percent and the payment adjustment ranges from -2.3 percent at the 10th percentile to +3.8 percent at the 90th percentile. As a result of using the OASIS quality and

claims-based measures, the same source data (from QIES rather than archived data) that the Model will use for implementation, and adding the assumption that all HHAs will submit data for each of the New Measures when calculating the payment adjustments, the range of payment adjustments for all cohorts in this proposed rule is lower than that was included in HH PPS 2016 rule. This difference is largely due to the lowered variation in TPS caused by the assumption that all HHAs will submit data for each of the New Measures.

Table 39 provides the payment adjustment distribution based on proportion of dually-eligible beneficiaries, average case mix (using HCC scores), proportion that reside in rural areas, as well as HHA organizational status. Besides the observation that higher proportion of dually-eligible beneficiaries serviced is related to better performance, the payment adjustment distribution is consistent with respect to these four categories.

The payment adjustment percentages were calculated at the state and size level so that each HHA's payment adjustment was calculated as it would be in the Model. Hence, the values of each separate analysis in the tables are representative of what they would be if the baseline year was 2013 and the performance year was 2014. There were 1,839 HHAs in the nine selected states out of 1,991 HHAs that were found in the HHA data sources that yielded a sufficient number of measures to receive a payment adjustment in the Model. It is expected that a certain number of HHAs will not be subject to the payment adjustment because they may be servicing too small of a population to report on an adequate number of measures to calculate a TPS.

TABLE 37—HHVBP MODEL: 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 5% Payment Adjustment For Performance year 2 of the Model 6% Payment Adjustment For Performance year 3 of the Model 7% Payment Adjustment For Performance year 4 of the Model 8% Payment Adjustment For Performance year 5 of the Model		-1.23 -2.04 -2.45 -2.86 -3.27	-0.87 -1.45 -1.74 -2.03 -2.32	-0.56 -0.94 -1.13 -1.32 -1.50	-0.30 -0.50 -0.61 -0.71 -0.81	-0.02 -0.03 -0.04 -0.04 -0.05	0.27 0.46 0.55 0.64 0.73	0.61 1.01 1.21 1.42 1.62	1.11 1.85 2.22 2.59 2.96	1.85 3.08 3.70 4.32 4.93

TABLE 38—HHVBP MODEL: HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT [Based on a 5-percent payment adjustment]

COHORT	# of HHA	Average payment adj. (%)	10%	20%	30%	40%	Median	60%	70%	80%	90%
HHA Cohort in States with no small cohorts (percent)											
MA	127 53 172 135 59	0.00 0.56 0.16 0.36 0.71	-2.20 -1.50 -1.90 -2.00 -1.70	-1.50 -1.10 -1.50 -1.30 -0.70	-1.10 -0.80 -1.00 -0.80 -0.30	-0.70 -0.10 -0.50 -0.40 0.20	-0.30 0.20 0.10 -0.10 0.50	0.00 0.50 0.50 0.30 0.80	0.80 1.40 0.90 0.90 1.70	1.40 2.00 1.70 2.00 2.30	2.70 3.60 2.40 3.10 2.90
Smaller-volume HHA Cohort in states with small cohort (percent)											
AZ small FL small IA small NE small	9 130 29 16	0.53 - 0.14 0.62 0.48	-1.20 -2.20 -2.30 -1.70	-0.70 -1.70 -1.10 -1.60	-0.70 -1.20 -0.80 -1.20	-0.50 -0.60 0.00 -0.60	-0.30 -0.20 0.30 -0.40	-0.10 0.10 0.90 1.30	0.60 0.40 1.70 2.20	0.90 1.20 2.30 2.40	5.00 1.80 3.80 4.00
Larger-volume HHA Cohort in states with small cohorts (percent)											
AZ large	112 889 107 49	-0.06 0.37 -0.21 0.31	-2.20 -2.10 -2.30 -1.80	-1.50 -1.50 -1.60 -1.20	-1.10 -0.90 -1.30 -0.90	-0.70 -0.40 -0.70 -0.60	-0.30 0.00 -0.20 -0.10	0.10 0.60 0.10 0.30	0.50 1.30 0.50 0.70	1.30 2.20 1.00 1.80	2.30 3.30 1.80 3.70

TABLE 39—PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS

[Based on a 5-percent payment adjustment]

[]											
COHORT	# of HHA	Average payment adj. (%)	10%	20%	30%	40%	Median	60%	70%	80%	90%
Low % Dually-eligible	621	0.18	- 1.80	- 1.30	-0.90	-0.50	0.00	0.40	0.90	1.50	2.50
Medium % Dually-eligible	841	-0.15	-2.20	-1.70	-1.20	-0.80	-0.40	0.00	0.50	1.20	2.20
High % Dually-eligible	416	1.21	-1.80	-0.80	-0.20	0.50	1.10	1.80	2.60	3.30	4.20
Low acuity	459	0.97	-1.70	-1.00	-0.40	0.10	0.70	1.30	2.10	2.90	4.00
Mid acuity	1089	0.83	-2.10	- 1.50	- 1.00	-0.60	-0.10	0.30	0.80	1.50	2.60
High acuity	338	-0.16	-2.10	- 1.60	-1.30	-0.90	-0.50	-0.10	0.50	1.30	2.40
All non-rural	989	0.57	-2.10	- 1.50	-0.90	-0.40	0.10	1.00	1.80	2.70	3.80
Up to 35% rural	141	0.01	-2.10	- 1.50	-1.10	-0.60	-0.20	0.20	0.70	1.40	2.30
Over 35% rural	172	0.54	-1.80	-1.30	-0.90	-0.50	0.00	0.50	1.10	1.70	2.90
Church	62	0.80	-1.70	-0.90	-0.80	0.10	0.40	1.10	1.70	2.60	3.70
Private NP	168	0.22	-1.90	- 1.30	-0.90	-0.30	0.10	0.50	0.90	1.70	2.50
Other	84	0.40	-1.60	-1.10	-0.70	-0.40	0.20	0.60	1.00	1.80	2.60
Private FP	1315	0.20	-2.10	- 1.50	- 1.00	-0.60	-0.10	0.30	1.00	1.90	3.10
Federal	72	0.37	-2.20	- 1.60	-1.10	-0.40	0.20	0.60	1.40	2.10	2.80
State	5	-0.39	-2.50	- 1.90	-1.40	-0.50	0.30	0.50	0.60	0.80	1.00
Local	57	0.50	- 1.50	-1.10	-0.70	0.00	0.30	0.60	0.90	1.40	2.40

D. Alternatives Considered

As described in the CY 2016 HH PPS proposed rule (80 FR 39911), we considered proposing to reduce the national, standardized 60-day episode payment rate by 3.41 percent in CY 2016 to account for nominal case-mix growth between CY 2012 and CY 2014. If we were to reduce the national, standardized 60-day episode payment

rate by 3.41 percent, we estimated that the aggregate impact would have been a decrease of \$600 million in payments to HHAs. However, instead of implementing a one-time reduction in the national, standardized 60-day episode payment rate of 3.41 percent in CY 2016 to account for nominal casemix growth from CY 2012 through CY 2014, we finalized a reduction to the

national, standardized 60-day episode payment rate of 0.97 percent in CY 2016, CY 2017, and CY 2018 to account for nominal case-mix growth from CY 2012 through CY 2014 (80 FR 68646). Since the 0.97 percent reduction to the national, standardized 60-day episode payment rate to account for nominal case-mix growth from 2012 to 2014 was finalized in the CY 2016 HH PPS final

rule, we did not consider alternatives to implementing this reduction for CY 2017.

Section 3131(a) of the Affordable Care Act mandates that starting in CY 2014, the Secretary must apply an adjustment to the national, standardized 60-day episode payment rate and other amounts applicable under section 1895(b)(3)(A)(i)(III) of the Act to 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. In addition, section 3131(a) of the Affordable Care Act mandates that rebasing must be phased-in over a 4year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment (2010) under section 1895(b)(3)(A)(i)(III) of the Act, and be fully implemented in CY 2017. Therefore, in the CY 2014 HH PPS final rule (78 FR 77256), we finalized rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor. As we noted in the CY 2014 HH PPS final rule, because section 3131(a) of the Affordable Care Act requires a four year phase-in of rebasing, in equal increments, to start in CY 2014 and be fully implemented in CY 2017, we do not have the discretion to delay, change, or eliminate the rebasing adjustments once we have determined that rebasing is necessary (78 FR 72283).

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2016 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. For CY 2016, section 3401(e) of the Affordable Care Act, requires that, in CY 2015 (and in subsequent calendar years), the market basket update 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. Beginning in CY 2015, section 1895(b)(3)(B)(vi)(I) of the Act, as amended by section 3401(e) of the Affordable Care Act, requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the HHA PPS for CY 2015 and each subsequent CY. The -0.5 percentage point productivity adjustment to the proposed CY 2017 home health market basket update (2.8 percent), is discussed in the preamble of this rule and is not discretionary as it is a requirement in

section 1895(b)(3)(B)(vi)(I) of the Act (as amended by the Affordable Care Act).

With regards to payments made under the HH PPS for high-cost "outlier" episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care), we did not consider maintaining the fixeddollar loss (FDL) ratio at 0.45 in section III.D.3 of this proposed rule because simulations using CY 2015 utilization data (that is, home health claims data) the proposed CY 2017 HH PPS payment rates resulted in an estimated 2.58 percent of total HH PPS payments being paid as outlier payments using the existing methodology (cost-per-visit) for calculating the cost of an episode of care. Likewise, simulations using CY 2015 utilization data (that is, home health claims data) the proposed CY 2017 HH PPS payment rates resulted in an estimated 3.10 percent of total HH PPS payments being paid as outlier payments using the proposed methodology (cost-per-unit) for calculating the cost of an episode of care. The FDL ratio and the loss-sharing ratio must be selected so that the estimated outlier payments do not exceed the 2.5 percent of total HH PPS payments (as required by section 1895(b)(5)(A) of the Act). We did not consider proposing a change to the losssharing ratio (0.80) in order for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.)

With regards to the methodology used to calculate the cost of an episode of care in order to determine the payment amount under the HH PPS for high-cost "outliers" (that is, episodes of care with unusual variations in the type or amount of medically necessary care), in section III.D.2, we considered maintaining the current methodology used to calculate the cost of an episode of care (cost-per-visit). However, due to the findings from the home health study required as a result of section 3131(d) of the Affordable Care Act (as discussed in section III.D.2 of this proposed rule and in the CY 2016 HH PPS proposed rule (80 FR 39864), we believe that the proposed methodology change (cost-perunit) helps to alleviate financial disincentives for providers to treat medically complex beneficiaries who require longer visits. Since the projection of the percentage of outlier dollars is the same as before the change, the impact of this proposal is budget neutral.

As described in Section III.E of this proposed rule, the Consolidated Appropriations Act of 2016 (Pub. L 114–113) amends both Section 1834 of the

Act (42 U.S.C. 1395m) and Section 1861(m)(5) of the Act (42 U.S.C. 1395x(m)(5)), requiring a separate payment to a HHA for an applicable disposable device when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit. Therefore, we do not have the discretion to delay or eliminate the implementation of a separate payment amount for NPWT performed using a disposable device and thus we did not consider any alternatives regarding this proposal.

We invite comments on the alternatives discussed in this analysis.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 40, 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 40 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.

TABLE 40—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTI-MATED TRANSFERS AND COSTS, FROM THE CYS 2016 TO 2017*

Category	Transfers
Annualized Monetized Transfers.	-\$180 million.
From Whom to Whom?	Federal Government to HHAs.

Table 41 provides our best estimate of the decrease in Medicare payments under the HHVBP Model as a result of the proposed changes presented in this proposed rule for the HHVBP Model.

TABLE 41—ACCOUNTING STATEMENT: HHVBP MODEL CLASSIFICATION OF ESTIMATED COST SAVINGS FOR CY 2016–2021

Category	Savings
6-Year Gross Savings	-\$378 million.
Medicare Payments	Hospitals and SNFs.

F. Conclusion

1. HH PPS

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is a decrease of 1.0 percent, or \$180 million, in Medicare payments to HHAs for CY 2017. The -\$180 million impact reflects the effects of the 2.3 percent CY 2017 HH payment update percentage (\$420 million increase), 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 2016 to account for nominal case-mix growth from 2012 through 2014 (\$160 million decrease), the 0.1 percent decrease in payments due to the change to the FDL ratio (\$20 million decrease), and a 2.3 percent decrease in in payments due to the third year of the 4-year phase-in of the rebasing adjustments required by section 3131(a) of the Affordable Care Act (\$420 million decrease).

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 2017. 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. The financial estimates were based on the analysis of hospital, home health and skilled nursing facility claims data from nine states using the most recent 2014 Medicare claims data. A study published in 2002 by the Journal of the American Geriatric Society (JAGS), "Improving patient outcomes of home health care: findings from two demonstration trials of outcome-based quality improvement," formed the basis for CMMI's projections.127 That study observed a hospitalization relative rate of decline of 22-percent to 26-percent over the 3-year and 4-year demonstration periods (the 1st year of each being the base year) for the national and New York trials. CMMI assumed a conservative savings estimate of up to a 6-percent ultimate annual reduction in hospitalizations and up to a 1.0-percent ultimate annual reduction in SNF admissions and took into account costs incurred from the beneficiary remaining in the HHA if the hospitalization did not occur; resulting in total projected six performance year

gross savings of \$378 million. Based on the JAGS study, which observed hospitalization reductions of over 20percent, the 6-percent ultimate annual hospitalization reduction assumptions are considered reasonable.

IX. 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.

List of Subjects

42 CFR part 409

Health facilities, Medicare

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 409.50 is revised to read as follows:

§ 409.50 Coinsurance for durable medical equipment (DME) and applicable disposable devices furnished as a home health service.

The coinsurance liability of the beneficiary or other person for DME or applicable disposable devices (as defined in section 1834(s)(2)) furnished as a home health service is 20 percent of the customary (insofar as reasonable) charge for the services.

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 484.240 is amended by revising paragraph (d) to read as follows:

§ 484.240 Methodology used for the calculation of the outlier payment.

* * * * * *

(d) CMS imputes 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 imputed cost for all disciplines.

■ 5. Section 484.305 is amended by revising the definition of "Benchmark" and removing the definition of "Starter Set" and to read as follows:

§ 484.305 Definitions.

* * * * * *

*

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.

*

■ 6. Section 484.315 is amended by revising paragraph (a) to read as follows:

§ 484.315 Data reporting for measures and evaluation under the Home Health Value-Based Purchasing (HHVBP) Model.

(a) Competing home health agencies will be evaluated using a set of quality measures.

§ 484.320 [Amended]

- 7. Section 484.320 is amended by:
- a. Amending paragraphs (a), (b), and (c) by removing the phrase "in the starter set,".
- b. Amending paragraph (d) by removing the phrase "in the starter set".
- 8. Section 484.335 is added to read as follows:

§ 484.335 Appeals Process for the Home Health Value-Based Purchasing (HHVBP) Model.

- (a) Requests for recalculation—(1) Matters for recalculation. Subject to the limitations on review under section 1115A of the Act, a HHA may submit a request for recalculation under this section if it wishes to dispute the calculation of the following:
 - (i) Interim performance scores.
 - (ii) Annual total performance scores.
- (iii) Application of the formula to calculate annual payment adjustment percentages.
- (2) Time for filing a request for recalculation. A recalculation request must be submitted in writing within 15 calendar days after CMS posts the HHA-specific information on the HHVBP Secure Portal, in a time and manner specified by CMS.
- (3) Content of request. (i) The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).

¹²⁷ Shaughnessy, et al. "Improving patient outcomes of home health care: findings from two demonstration trials of outcome-based quality improvement," available at http://www.ncbi.nlm.nih.gov/pubmed/12164991.

- (ii) The basis for requesting recalculation to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.
- (iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).
- (iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.
- (4) Scope of review for recalculation. In conducting the recalculation, CMS will review the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the home health agency. CMS may also review any other evidence it believes to be relevant to the recalculation.
- (5) Recalculation decision. CMS will issue a written notification of findings. A recalculation decision is subject to the request for reconsideration process in

- accordance with paragraph (b) of this section.
- (b) Requests for reconsideration—(1) Matters for reconsideration. A home health agency may request reconsideration of the recalculation of the annual total performance score and payment adjustment percentage following a recalculation request submitted under § 484.335(a) or the decision to deny a HHA's recalculation request submitted under paragraph (a) of this section.
- (2) Time for filing a request for reconsideration. The request for reconsideration must be submitted via the HHVBP Secure Portal within 15 calendar days from CMS' notification to the HHA contact of the outcome of the recalculation process.
- (3) Content of request. (i) The name of the HHA, address associated with the services delivered, and CMS Certification Number (CCN).
- (ii) The basis for requesting reconsideration to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.
- (iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

- (iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.
- (4) Scope of review for reconsideration. In conducting the reconsideration review, CMS will review the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the reconsideration. The HHA must prove its case by a preponderance of the evidence with respect to issues of fact
- (5) Reconsideration decision. CMS reconsideration officials will issue a written determination.

Dated: June 2, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 23, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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