DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 484

[CMS–1648–F]

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: Final rule.

SUMMARY: This final rule updates the Home Health Prospective Payment System (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor; effective for home health episodes of care ending on or after January 1, 2017. This 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 case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014; finalizes changes to the methodology used to calculate payments made under the HH PPS for high-cost ''outlier'' episodes of care; implements changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care; discusses our efforts to monitor the potential impacts of the rebasing adjustments; includes an update on subsequent research and analysis as a result of the findings from the home health study; and finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model, which was implemented on January 1, 2016; and updates to the Home Health Quality Reporting Program (HH QRP).

DATES: These regulations are effective on January 1, 2017.

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 Home Health Care CAHPS® Survey (HHCAHPS).

SUPPLEMENTARY INFORMATION:

Table of Contents

Acronyms

In addition, because of the many terms to which we refer by abbreviation in this 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
CASPER Certification and Survey Provider Enhanced Reports
CBSA Core-Based Statistical Area
CBWI Commuting-based Wage Index
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
HHRG 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 (P.L. 113–185)
IRF Inpatient Rehabilitation Facility
LEF Linear Exchange Function
LTCH Long-Term Care Hospital
LUPA Low-Utilization Payment Adjustment
MEPS Medical Expenditures Panel Survey
MFP Multifactor productivity
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, enacted December 8, 2003
MSA Metropolitan Statistical Area
MSPB–PAC Medicare Spending Per Beneficiary-Post Acute Care
MSS Medical Social Services
NPWT Negative Pressure Wound Therapy
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
OPPS Outpatient Prospective Payment System
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
SNF Skilled Nursing Facility
TPS Total Performance Score
TPN Total Parenteral Nutrition
UMRA Unfunded Mandates Reform Act of 1995.
VBP Value-Based Purchasing

I. Executive Summary

A. Purpose

This final rule updates 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 update reflects the final year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit 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 final rule also updates 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 finalizes 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) of the Act, as amended by the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), this rule implements changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act. Additionally, this rule finalizes changes to the Home Health Value-Based Purchasing (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 changes to the home health quality reporting program requirements under the authority of section 1895(b)(3)(B)(v) 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 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 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 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 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 update the payment rates under the HH PPS by the home health payment update percentage of 2.5 percent (using the 2010-based Home Health Agency (HHA) market basket update of 2.8 percent, minus 0.3 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 update the CY 2017 home health wage index using more current hospital wage data. In section III.D, we are finalizing a change to 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 rule, as a result of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), we are implementing changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for a patient under a home health plan of care 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 rule, we provide an update a process for grouping the HH PPS claim centrally during claims processing.

In section IV of this rule, we are finalizing changes to the HHVBP Model that was implemented January 1, 2016. We are finalizing: the removal of the definition of ''starter set''; a revised definition for ''benchmark''; calculation of benchmarks and achievement thresholds at the state level; a minimum requirement of eight HHAs in a cohort; an increased timeframe for submitting New Measure data; removal of four measures from the set of applicable measures; an annual reporting period and submission date for one of the New Measures; and an appeals process that includes a recalculation and reconsideration process. We are also providing an update on the progress towards developing public reporting of performance under the HHVBP Model.

This final rule also include updates to the Home Health Quality Reporting Program in section V, including removing six quality measures, adopting four new quality measures, mentioning future measures under consideration, following a calendar year schedule for measure and data submission requirements, and aligning quarterly reporting timeframes and quarterly review and correction periods.

C. Summary of Costs and Transfers

The preliminary complete set of benchmarks

TABLE 1—SUMMARY OF COSTS AND TRANSFERS

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 −$130 million (−0.7 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.

In accordance with section 1895(b)(3)(A) of the Act, the computation of a standard prospective payment amount must be computed to include all costs for covered HH services paid on a reasonable cost basis and such amounts must be initially based on the most recent reported cost report data. Additionally, section 1895(b)(3)(A) of the Act requires the standardized prospective payment amount to 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, 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 cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (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 in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016. Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (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 post-acute care (PAC) providers, including HHAs. New section 1899B of the Act is titled, ''Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment, and Discharge Planning''. Under section 1899B(a)(1) of the Act, certain post-acute care (PAC) providers (defined in section 1899B(a)(2)(A) of the Act to include 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 sets out specified application dates for each of the measures. The Secretary must specify the quality, resource use, and other measures no later than the applicable specified application date defined 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 III.C.3.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 case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed. In the CY 2012 HH PPS final rule (76 FR 68526), we updated the 60-day national episode rates and the national per-visit rates. In addition, as discussed in the CY 2012 HH PPS final rule (76 FR 68528), our analysis indicated that there was a 22.59 percent increase in overall case-mix from 2000 to 2009 and that only 15.76 percent of that overall observed case-mix percentage increase was due to real

case-mix change. As a result of our analysis, we identified a 19.03 percent nominal increase in case-mix. At that time, to fully account for the 19.03 percent nominal case-mix growth identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013.

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented a 1.32 percent reduction to the payment rates for CY 2013 to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from 2000 to 2010 (0.2390 * (1 − 0.1597) = 0.2008). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. Although we considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, we finalized the 1.32 percent payment reduction to the national, standardized 60-day episode rates in the CY 2012 HH PPS final rule (76 FR 68532).

Section 3131(a) of the Affordable Care Act requires that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we must phase in any adjustment over a 4 year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. The statute specifies that the maximum rebasing adjustment is to be no more than 3.5 percent per year of the CY 2010 rates. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of $80.95 per year, increases to the national per-visit payment rates per year 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, section 421(a) of the MMA, as amended by section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), extended the payment increase of 3 percent for HH services provided in rural areas (as defined in section 1886(d)(2)(D) of the Act) to episodes or visits ending before January 1, 2018.

III. Provisions of the Proposed Rule and Analysis of and Responses to Comments

We received 83 timely comments from the public, including comments from home health agencies, national provider associations, patient and other advocacy organizations, nurses, and device manufacturers. The following sections, arranged by subject area, include a summary of the public comments received, and our responses.

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

In the CY 2017 proposed rule (81 FR 43714), we provided a summary of analysis on FY 2014 HHA cost report data and how such data, if used, would impact our estimate of the percentage difference between Medicare payments and HHA costs used to calculate the Affordable Care Act rebasing adjustments. In addition, we presented information on Medicare home health utilization that included HHA claims data through CY 2015. We will continue to monitor the impacts due to the rebasing adjustments and other future policy changes and will provide the industry with periodic updates on our analysis in future rulemaking and/or announcements on the HHA Center Web page at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html*.

B. CY 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 case-

mix weights—adjusting the weights relative to one another—using the most current, complete data available. To recalibrate the HH PPS case-mix weights for CY 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. For this final rule, we used CY 2015 home health claims data (as of June 30, 2016) with linked OASIS data to generate the final CY 2017 HH PPS case-mix weights. These data are the most current and complete data available at this time. The tables below have been revised to reflect the results using the updated data. The process we used to calculate the HH PPS case-mix weights are also 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 Bureau of Labor Statistics national hourly wage (covering May 2015) plus fringe rates (covering December 2015) for the six home health disciplines and the visit length (reported in 15-minute units) from the claim. The points for each of the variables for each leg of the model, updated with CY 2015 data, are shown in Table 3. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

TABLE 3—CASE-MIX ADJUSTMENT VARIABLES AND SCORES

Case-Mix adjustment variables and scores				
Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
Therapy visits	0–13	14+	0–13	14+
Equation:	*1*	*2*	*3*	*4*
Clinical Dimension				
1. Primary or Other Diagnosis = Blindness/Low Vision.				
2. Primary or Other Diagnosis = Blood disorders	.....	2		
3. Primary or Other Diagnosis = Cancer, selected benign neoplasms	.....	5	.....	5
4. Primary Diagnosis = Diabetes	.....	4	.....	2
5. Other Diagnosis = Diabetes	1			
6. Primary or Other Diagnosis = Dysphagia AND Primary or Other Diagnosis = Neuro 3—Stroke	2	18	2	12
7. Primary or Other Diagnosis = Dysphagia AND M1030 (Therapy at home) = 3 (Enteral)	2	6	.....	6
8. Primary or Other Diagnosis = Gastrointestinal disorders.				
9. Primary or Other Diagnosis = Gastrointestinal disorders AND M1630 (ostomy) = 1 or 2	.....	7		
10. Primary or Other Diagnosis = Gastrointestinal disorders AND Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis, OR Neuro 2—Peripheral neurological disorders, OR Neuro 3—Stroke, OR Neuro 4—Multiple Sclerosis.				
11. Primary or Other Diagnosis = Heart Disease OR Hypertension	1	2	.....	2
12. Primary Diagnosis = Neuro 1—Brain disorders and paralysis	2	12	7	12
13. Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis AND M1840 (Toilet transfer) = 2 or more	.....	3	.....	3
14. Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis OR Neuro 2—Peripheral neurological disorders AND M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3	2	3	1	3
15. Primary or Other Diagnosis = Neuro 3—Stroke	3	12	2	5
16. Primary or Other Diagnosis = Neuro 3—Stroke AND M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3.				
17. Primary or Other Diagnosis = Neuro 3—Stroke AND M1860 (Ambulation) = 4 or more.				
18. Primary or Other Diagnosis = Neuro 4—Multiple Sclerosis AND AT LEAST ONE OF THE FOLLOWING: M1830 (Bathing) = 2 or more OR M1840 (Toilet transfer) = 2 or more OR M1850 (Transferring) = 2 or more OR M1860 (Ambulation) = 4 or more	3	7	6	11
19. Primary or Other Diagnosis = Ortho 1—Leg Disorders or Gait Disorders AND M1324 (most problematic pressure ulcer stage) = 1, 2, 3 or 4	8	1	7	
20. Primary or Other Diagnosis = Ortho 1—Leg OR Ortho 2—Other orthopedic disorders AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	3	.....	3	4
21. Primary or Other Diagnosis = Psych 1—Affective and other psychoses, depression.				
22. Primary or Other Diagnosis = Psych 2—Degenerative and other organic psychiatric disorders.				
23. Primary or Other Diagnosis = Pulmonary disorders	.....	.....	.....	1
24. Primary or Other Diagnosis = Pulmonary disorders *AND* M1860 (Ambulation) = 1 or more	.....	1		
25. Primary Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications	4	20	7	18
26. Other Diagnosis = Skin 1—Traumatic wounds, burns, post-operative complications	7	15	8	15
27. Primary or Other Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications OR Skin 2—Ulcers and other skin conditions AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	3			
28. Primary or Other Diagnosis = Skin 2—Ulcers and other skin conditions	2	17	8	17
29. Primary or Other Diagnosis = Tracheostomy	4	17	4	17

TABLE 3—CASE-MIX ADJUSTMENT VARIABLES AND SCORES—Continued

Case-Mix adjustment variables and scores				
Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
Therapy visits	0–13	14+	0–13	14+
Equation:	*1*	*2*	*3*	*4*
30. Primary or Other Diagnosis = Urostomy/Cystostomy	.....	18	.....	13
31. M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	.....	17	6	17
32. M1030 (Therapy at home) = 3 (Enteral)	.....	16	.....	9
33. M1200 (Vision) = 1 or more.				
34. M1242 (Pain) = 3 or 4	3	.....	2	
35. M1311 = Two or more pressure ulcers at stage 3 or 4 [1]	5	10	5	10
36. M1324 (Most problematic pressure ulcer stage) = 1 or 2	4	19	7	16
37. M1324 (Most problematic pressure ulcer stage) = 3 or 4	9	32	11	26
38. M1334 (Stasis ulcer status) = 2	4	15	8	15
39. M1334 (Stasis ulcer status) = 3	7	17	10	17
40. M1342 (Surgical wound status) = 2	2	7	5	11
41. M1342 (Surgical wound status) = 3	.....	6	4	9
42. M1400 (Dyspnea) = 2, 3, or 4.				
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.				
Functional Dimension				
46. M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3	1	.....	1	
47. M1830 (Bathing) = 2 or more	6	5	5	2
48. M1840 (Toilet transferring) = 2 or more	1	2		
49. M1850 (Transferring) = 2 or more	3	1	2	
50. M1860 (Ambulation) = 1, 2 or 3	7	.....	4	.....
51. M1860 (Ambulation) = 4 or more	8	9	6	8

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of June 30, 2016) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with SCIC or 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.

In updating the four-equation model for CY 2017, using complete 2015 data as of June 30, 2016 (the last update to the four-equation model for CY 2016 used 2014 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 2014 and 2015. The CY 2017 four-equation model resulted in 119 point-giving variables being used in the model (as compared to the 124 point-giving variables for the 2016 recalibration). Of those 119 variables, the CY 2017 four-equation model had 113 variables that were also present in the CY 2016 four-equation model. Of those 113 variables, the points for 33 variables increased in the CY 2017 four-equation model compared to CY 2016 and the points for 33 variables decreased in the CY 2017 4-equation model compared to CY 2016. There were 47 variables with the same point values between CY 2016 and CY 2017. There were 6 variables that were added to the model in CY 2017 that weren't in the model in CY 2016. Also, 11 variables were in the model in CY 2016 but dropped in CY 2017 due to the absence of additional resources associated with these variables. In other words, these variables are not associated with additional resources beyond what is captured by the other case-mix adjustment variables in the regression model.

Step 2: Re-define 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.
- 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 to guide where we placed our thresholds. We tried to group 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

[1] M1308 'Current Number of Unhealed Pressure Ulcers at Each Stage or Unstageable' will be changed to M1311 'Current Number of Unhealed Pressure Ulcers at Each Stage' under the new OASIS C2 format, effective January 1, 2017.

[2] For Step 1, 49.2 percent of episodes were in the medium functional level (All with score 14).

For Step 2.1, 70.7 percent of episodes were in the low functional level (Most with score 5 and 6).

For Step 2.2, 78.7 percent of episodes were in the medium functional level (Most with score 2).

For Step 3, 51.0 percent of episodes were in the medium functional level (Most with score 10).

For Step 4, 51.2 percent of episodes were in the medium functional level (Most with score 5 and 6).

thresholds, based off of the CY 2017 four-equation model points are shown in Table 4.

TABLE 4—CY 2017 CLINICAL AND FUNCTIONAL THRESHOLDS

		1st and 2nd episodes		3rd+ episodes		All episodes
		0 to 13 therapy visits	14 to 19 therapy visits	0 to 13 therapy visits	14 to 19 therapy visits	20+ therapy visits
Grouping Step:		1	2.1	3	2.2	4
Equation(s) used to calculate points: (see Table 3)		1	2	3	4	(2&4)
Dimension	Severity Level					
Clinical	C1	0 to 1	0 to 1	0 to 1	0 to 1	0 to 3
	C2	2 to 3	2 to 7	2	2 to 9	4 to 16
	C3	4+	8+	3+	10+	17+
Functional	F1	0 to 13	0 to 6	0 to 6	0 to 1	0 to 2
	F2	14	7 to 13	7 to 10	2 to 9	3 to 6
	F3	15+	14+	11+	10+	7+

Step 3: Once the clinical and functional thresholds are determined and each episode is assigned a clinical and functional level, the payment regression is estimated with an episode's wage-weighted minutes of care as the dependent variable. Independent variables in the model are indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 5 shows the regression coefficients for the variables in the payment regression model updated with CY 2015 data. The R-squared value for the payment regression model is 0.4929 (an increase from 0.4822 for the CY 2016 recalibration).

TABLE 5—PAYMENT REGRESSION MODEL

Variable description	New payment regression coefficients
Step 1, Clinical Score Medium	$22.81
Step 1, Clinical Score High	53.36
Step 1, Functional Score Medium	70.51
Step 1, Functional Score High	108.77
Step 2.1, Clinical Score Medium	32.34
Step 2.1, Clinical Score High	146.99
Step 2.1, Functional Score Medium	11.24
Step 2.1, Functional Score High	64.89
Step 2.2, Clinical Score Medium	42.88
Step 2.2, Clinical Score High	193.55
Step 2.2, Functional Score Medium	0.00
Step 2.2, Functional Score High	57.18
Step 3, Clinical Score Medium	11.50
Step 3, Clinical Score High	91.93
Step 3, Functional Score Medium	53.82
Step 3, Functional Score High	85.08
Step 4, Clinical Score Medium	76.81
Step 4, Clinical Score High	256.77
Step 4, Functional Score Medium	35.45
Step 4, Functional Score High	81.20
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	498.79
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	506.90
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	−72.76
Step 4, All Episodes, 20+ Therapy Visits	903.44
Intercept	397.53

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of June 30, 2016) for which we had a linked OASIS assessment.

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

Step 5: The weights associated with 0 to 5 therapy visits are then increased by 3.75 percent, the weights associated with 14–15 therapy visits are decreased by 2.5 percent, and the weights associated with 20+ therapy visits are decreased by 5 percent. These adjustments to the case-mix weights were finalized in the CY 2012 HH PPS final rule (76 FR 68557) and were done to address concerns that the HH PPS 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

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

6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) are constant. This interpolation is the identical to the process finalized in the CY 2012 HH PPS final rule (76 FR 68555).

Step 7: The interpolated weights are then adjusted so that the average case-mix for the weights is equal to 1.0000.[4] This last step creates the CY 2017 case-mix weights shown in Table 6.

TABLE 6—FINAL 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)	Final CY 2017 case-mix weights
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5857
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.7168
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8479
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9790
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.1100
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.6896
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.8030
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9164
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0298
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1433
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7460
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8630
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9800
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.0970
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2140
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.6193
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7526
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8860
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0193
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1526
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.7232
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8389
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9545
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0702
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1858
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.7796
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.8988
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	1.0181
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1373
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2565
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6643
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.8204
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9765
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.1325
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2886
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7682
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.9066
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0450
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.1834
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3218
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.8246
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9666
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1086
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.2505
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.3925
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2411
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4125
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5838
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2567
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4388
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6209
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3310
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5089
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6868
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2859
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4769
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6679
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3014
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5032

[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 6—FINAL 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)	Final CY 2017 case-mix weights
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7049
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3757
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5733
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7708
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4446
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6636
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8826
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4602
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6899
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9197
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5345
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.7601
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	1.9856
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2523
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4200
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5876
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2523
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4359
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6195
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3315
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5093
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6870
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3117
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4941
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6765
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3117
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5100
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7083
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3909
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5834
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7759
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.5203
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.7141
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9079
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5203
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7300
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9398
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5995
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8034
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0073
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4785
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6333
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7880
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9428
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0976
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5578
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.6967
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8356
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9745
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1134
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6039
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7494
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.8949
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0405
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1860
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4955
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6587
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8220
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	0.9852
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1485
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5748
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7222
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8695
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0169
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1643
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6208
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7748
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9288

TABLE 6—FINAL 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)	Final CY 2017 case-mix weights
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.0829
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2369
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6140
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.7953
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9765
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1578
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3391
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.6933
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8587
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0241
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.1895
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3549
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7393
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.9114
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0834
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.2554
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4275
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.7552
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.8030
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.8648
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.8588
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.9067
40231	All Episodes, 20+ Therapy Visits	C2F3S1	1.9684
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.1016
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.1495
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.2112

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we apply a case-mix budget neutrality factor to the CY 2017 national, standardized 60-day episode payment rate (see section III.C.3. of this final rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when the CY 2017 HH PPS grouper and case-mix weights (developed using CY 2015 claims data) are applied to CY 2015 utilization (claims) data to total payments when the CY 2016 HH PPS grouper and case-mix weights (developed using CY 2014 claims data) are applied to CY 2015 utilization data. Using CY 2015 claims data as of June 30, 2016, we calculated the case-mix budget neutrality factor for CY 2017 to be 1.0214.

The following is a summary of the comments and our responses to comments on the CY 2017 case-mix weights.

Comment: One commenter implied that the recalibration should be based on trends or standards for the type of care Medicare and providers collectively agree are appropriate for Medicare beneficiaries, rather than a single year of data, and that CMS should recognize innovations in the home health industry. Another commenter stated that current home health resource use does not accurately reflect what the resource use should be and Medicare law provides. The commenter stated that under this payment structure, patients with clinically complex and long-term chronic conditions are often either unable to gain access to legally covered care, or they are provided with limited care relative to what their plan of care orders or their OASIS indicates they should receive. One commenter stated that CMS' 2015 decision, to decrease case-mix weights for the third and later episodes of care with 0 to 19 therapy visits due to the CY 2015 recalibration of the case-mix weights (81 FR 43722), is contrary to Medicare coverage law and that a decrease in case-mix weights for later episodes creates broad-based, practical access problems to HHAs for those who qualify for Medicare home health benefit. One commenter suggested that the case-mix weight recalibration can be easily manipulated to cause industry reimbursement to be much less than projected and/or necessary. The commenter stated that CMS eliminated scoring variables from the case-mix system one year, but then added the variables back into the system the subsequent year. The commenter stated that CMS may not be able to identify what patient characteristics may require additional resources and stated that a committee comprised of CMS and industry representatives should be established to oversee the annual changes to the home health case-mix weights.

Response: We note that we did not change the recalibration methodology from previous years. In CY 2015, we proposed and finalized annual recalibration and the methodology to be used for each recalibration. The recalibration determines the points associated with the case-mix variables and the weights associated with the HHRGs based on resource use (estimated using the Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the visit length (reported in 15-minute units) from the home health claim). The points in the model are taken directly from a regression of resource use and reflect the most current, complete utilization data available. Any decreases in the points associated with the case-mix variables or decreases in the case-mix weights reflect fewer resources being furnished in those episodes than what was previously furnished. We update the recalibration weights every year to reflect current utilization data. Variables falling out or coming back into the case-mix system are a direct reflection of the

changes in the services being furnished and reported.

As noted in section III.F. of this final rule, we have conducted research and analyses to potentially revise the HH PPS case-mix methodology. We plan to release a more detailed Technical Report in the future on our research and analyses.

Comment: One commenter expressed concern with the use of 15-minute unit data at uniform levels as proxies for cost in the case-mix weight recalibration. The commenter stated that there are certain fixed costs that do not vary by visit length, including, but not limited to, transportation and administrative costs, and that using a 15 minute time increment as a cost proxy is inaccurate unless it is weighted in relation to the fixed costs incurred regardless of visit length. The commenter stated that using a single weighted 15 minute time unit in the case-mix recalibration results in HHRGs with shorter than average visits having a lower case-mix weight than what is appropriate and HHRGs with longer than average visits having a higher case-mix weight than what is appropriate. The commenter stated that CMS should withdraw the case mix weight recalibration proposal and that any future recalibration based on time units should proceed only if CMS can fairly weight the units to account for costs that are incurred without regard to visit length.

Response: We have used wage weighted 15-minute units as our measure of resource use since the inception of the HH PPS. We did not propose any changes to the methodology or method of estimating resource use in the proposed rule. Weighting the first 15-minute unit to account for fixed costs is not appropriate as payment for the fixed costs of an episode, such as transportation, are already accounted for under the national, standardized 60-day episode payment rate. We will continue to conduct ongoing data analysis to monitor resource use patterns.

Comment: Commenters urged CMS to reconsider the proposed CY 2017 HH PPS case-mix weight adjustments. Commenters stated that the reduced scoring in the clinical and functional dimensions will significantly adversely impact the ability of HHAs to care for certain types of patients and listed the types of patients affected. Commenters stated that the new case-mix weight scoring has removed key conditions from the case mix index: Diabetes as a co-morbid diagnosis, heart disease diagnosis, neurological diagnoses, including their associated functional deficit combination, blood disorder diagnoses, dyspnea as a symptom for which points are attributed, diagnosis combinations, such as the combination of neurological and orthopedic diagnoses with their functional deficits, and reduced points for skin, wound, and ulcer diagnoses. One commenter stated that CMS should ensure access to care for people with these conditions, support high-quality HHAs that care for these populations, and motivate transfer partners, such as hospitals, to seek out HHAs that can care for these populations. The commenter stated that the case-mix weights also reduce payment for clinical and functional domain needs and that their member HHAs which serve patients with complex conditions and high functional needs are disproportionately affected by the changes. Commenters urged CMS to restore justified scoring and weights to ensure that care for patients with these chronic conditions are properly reimbursed.

Another commenter stated that the findings of the home health study required by section 3131(d) of the Affordable Care Act on access to care for vulnerable beneficiaries should be incorporated into the case-mix weights for CY 2017 and that if the current 4-equation case mix model cannot be adapted to account for these beneficiary characteristics, CMS should expedite replacing the current model with one that can more accurately account for variations in patient characteristics and needs.

A commenter stated that these new weights shift payments to HHAs in unpredictable ways related to each individual agency's distribution of patients and expressed concerns that the proposed case-mix weights may cause significant variation in payment depending on an individual HHA's typical case mix. The commenter stated that CMS should produce significantly more detailed impact analyses to assure that the agency specific impacts of these ongoing adjustments to individual case mix weights are not creating unfair impacts on individual agencies that are lost in the aggregate impact analyses. The commenter expressed concerns that the current impact analysis is too broad and masking potential impact issues.

Response: Any changes in the case-mix weights reflect changes in utilization from 2014 (data used for the CY 2016 recalibration) to 2015 (data used for the CY 2017 recalibration). The points table and weights described in the proposed rule are based off of CY 2015 data as of December 31, 2015 and there are changes in the points and weights when using complete 2015 data as of June 30, 2016. Using complete 2015 data, there are 119 variables in the four-equation model versus 110 variables in the CY 2017 proposed rule. In addition, there were fewer variables dropped from the model and more variables with no change in the points when using complete CY 2015 data as of June 30, 2016 than when using 2015 data as of December 31, 2015. A number of the diagnoses that the commenters mentioned now have points associated with the case-mix variables when using complete 2015 data as of June 30, 2016, such as diabetes as a co-morbid diagnosis, heart disease diagnosis, and blood disorder diagnoses. In addition, there were increases in the points for some of the diagnoses mentioned such as ''Other Diagnosis = Skin 1—Traumatic wounds, burns, post-operative complications.'' We encourage commenters to review the updated table of points (Table 3). We note that in 2015, we started the annual recalibration of the case-mix weights. In addition, on October 1, 2015, ICD–10 was implemented. Changes in the point values and case-mix weights may reflect changes due to the transition to ICD–10 as well as changes in the provision of services as a result of the CY 2015 recalibration.

There are five case-mix variables which have had a drop of 4 points from the CY 2016 recalibration (which is based on CY 2014 data) to the CY 2017 recalibration (which is based on CY 2015 data). The total number of visits for episodes with these characteristics decreased from CY 2014 to CY 2015, with decreases ranging from 0.4 to 2.1 visits per episode. Since there are fewer services being provided in CY 2015 than in CY 2014, points associated with these case-mix variables have decreased. It is important to note that we did not propose any changes to the recalibration methodology and we report impact analyses the same way we have done every year, with expenditure effects of policy changes by HHA facility type and area of the country.

In the CY 2017 HH PPS proposed rule, we described our follow-on work to the home health study, providing further information on our research and analyses conducted to potentially revise the HH PPS case-mix methodology to address the home health study findings outlined in the Report to Congress (81 FR 43744 through 43746). In the proposed rule, we stated that we planned to release a more detailed Technical Report in the future on this additional research and analysis conducted on the Home Health Groupings Model (HHGM), an alternative to the current case-mix system. This report will address

vulnerable beneficiaries as identified in the home health study, which include those beneficiaries that have more complex care needs. As noted in section III.F. of this final rule, once the Technical Report is released, we will post a link on our Home Health Agency (HHA) Center Web site at *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html* to receive comments and feedback on the model. While we are not incorporating findings of the section 3131(d) home health study on access to care for vulnerable beneficiaries in the case-mix system for CY 2017, we encourage commenters to provide feedback on our alternate model that may be considered in future rulemaking.

Comment: One commenter stated that CMS has not provided sufficient transparency of the details and methods used to recalibrate the HH PPS case-mix weights in its discussion of the proposed rule and that CMS provides little justification for recalibrating the case-mix weights just one year following the recalibration of case-mix weights in CY 2016 and only four years since the recalibration for the CY 2012 Final Rule. The commenter stated that the proposed recalibration is significant in that their analysis indicates a greater reduction in case weights than the 0.62 percent proposed by CMS as the budget neutrality adjustment. Another commenter requested that CMS describe in detail how the wage index and case-mix weights budget neutrality factors are calculated.

Response: We proposed and finalized annual recalibration to the weights in CY 2015 in order to ensure that the case-mix system reflects current utilization patterns. We use the most current, complete data available at the time of rulemaking. We note that the budget neutrality factor in the proposed rule was based on 2015 claims data as of December 31, 2015. Updating the budget neutrality factor with complete 2015 claims data as of June 30, 2016, data indicated that a budget neutrality factor of 1.0214 is needed. We encourage commenters to review the methodology described in the CY 2015 rule (79 FR 66066) on how the budget neutrality factor is calculated. The method of calculating a budget neutrality factor is similar to the method used in other payment systems.

Final Decision: We are finalizing the recalibrated scores for the case-mix adjustment variables, clinical and functional thresholds, payment regression model, and case-mix weights in Tables 3 through 6. For the final rule, the CY 2017 scores for the case-mix variables, the clinical and functional thresholds, and the case-mix weights were developed using complete CY 2015 claims data as of June 30, 2016. We note that we finalized the recalibration methodology and the proposal to annually recalibrate the HH PPS case-mix weights in the CY 2015 HH PPS final rule (79 FR 66072). No additional proposals were made with regard to the recalibration methodology in the CY 2017 HH PPS proposed rule.

C. CY 2017 Home Health Payment Rate Update

1. 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. 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). The HH market basket percentage increase for CY 2017 is based on IHS Global Insight Inc.'s (IGI) third quarter 2016 forecast with historical data through the second quarter of 2016. The HH market basket percentage increase for CY 2017 is 2.8 percent.

Section 3401(e) of the Affordable Care Act, adding new section 1895(b)(3)(B)(vi) to the Act, requires that the market basket percentage under the HH PPS (as described in section 1895(b)(3)(B) of the Act) be annually adjusted by changes in economy-wide productivity for CY 2015 and each subsequent calendar year. 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. The MFP adjustment for CY 2017 (the projection of the 10-year moving average of MFP for the period ending CY 2017) is 0.3 percent. Therefore, the CY 2017 HH market basket percentage of 2.8 percent will be reduced by the MFP adjustment of 0.3 percent. The resulting HH payment update percentage is equal to 2.5 percent, or 2.8 percent less 0.3 percentage point.

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 0.5 percent (2.5 percent minus 2 percentage points).

2. 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 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).

We will 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, and thus, no hospital wage data on which to base the calculation of the CY 2017 HH PPS wage index. For rural areas that do not have inpatient hospitals, we will 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).

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 core-based 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.''

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 CY 2016 HH PPS wage index was fully based on the revised OMB delineations adopted in 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.

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

3. 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 § 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight (as described in section III.B of this final rule) and a wage index value based on the site of service for the beneficiary.

To account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS payment rates. The labor-related share of the HH PPS payment rates continues to be 78.535 percent and the non-labor-related continues to be 21.465 percent, as set out in the CY 2013 HH PPS final rule (77 FR 67068). The following steps are taken to compute the case-mix and wage-adjusted national, standardized 60-day episode payment amount:

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

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

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

(4) Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments. In accordance with section 1895(b)(3)(B) of the Act, this document 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, standardized 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (b)(2). We 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 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 adjust the episode payment based on the information submitted on the claim to reflect the following:

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

b. CY 2017 National, Standardized 60-Day Episode Payment Rate

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 will 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 HH payment update percentage discussed in section III.C.1 of this final 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 0.9996. Therefore, we will apply the wage index budget neutrality factor of 0.9996 in our calculation of the CY 2017 national, standardized 60-day episode rate.

As discussed in section III.B of the final rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we will apply a case-mix weight budget neutrality factor in our calculation of 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 applied for CY 2017 will be 1.0214 as described in section III.B of this final rule.

Next, as discussed in the CY 2016 HH PPS final rule (80 FR 68646), we will 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 will 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 will update the payment rates by the CY 2017 HH payment update percentage of 2.5 percent as described in section III.C.1 of this final rule. The CY 2017 national, standardized 60-day episode payment rate is calculated in Table 7.

TABLE 7—CY 2017 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	CY 2017 HH payment update	CY 2017 national, standardized 60-day episode payment
$2,965.12	× 0.9996	× 1.0214	× 0.9903	−$80.95	× 1.025	$2,989.97

The CY 2017 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2017 HH payment update (2.5 percent) minus 2 percentage points and is shown in Table 8.

TABLE 8—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	CY 2017 HH payment update minus 2 percentage points	CY 2017 national, standardized 60-day episode payment
$2,965.12	× 0.9996	× 1.0214	× 0.9903	−$80.95	× 1.005	$2,931.63

c. CY 2017 National Per-Visit Rates

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

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

To calculate the 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 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 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 1.0000. We will apply the wage index budget neutrality factor of 1.0000 in calculating the CY 2017 national per-visit rates.

The LUPA per-visit rates are not adjusted by the case-mix relative weights. Therefore, there is no case-mix weight budget neutrality factor needed to ensure budget neutrality for LUPA payments. We then apply the rebasing adjustments finalized in the CY 2014 HH PPS final rule (78 FR 72280) to the per-visit rates for each discipline. Finally, the per-visit rates for each discipline are updated by the CY 2017 HH payment update percentage of 2.5 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2017 national per-visit rates are shown in Tables 9 and 10.

TABLE 9—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	CY 2017 HH payment update	CY 2017 per-visit payment
Home Health Aide	$60.87	× 1.0000	+ $1.79	× 1.025	$64.23
Medical Social Services	215.47	× 1.0000	+ 6.34	× 1.025	227.36

TABLE 9—CY 2017 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA—Continued

HH discipline type	CY 2016 per-visit payment	Wage index budget neutrality factor	CY 2017 rebasing adjustment	CY 2017 HH payment update	CY 2017 per-visit payment
Occupational Therapy	147.95	× 1.0000	+ 4.35	× 1.025	156.11
Physical Therapy	146.95	× 1.0000	+ 4.32	× 1.025	155.05
Skilled Nursing	134.42	× 1.0000	+ 3.96	× 1.025	141.84
Speech-Language Pathology	159.71	× 1.0000	+ 4.70	× 1.025	168.52

The CY 2017 per-visit payment rates for an HHA that does not submit the required quality data are updated by the CY 2017 HH payment update percentage (2.5 percent) minus 2 percentage points and are shown in Table 10.

TABLE 10—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	CY 2017 HH payment update minus 2 percentage points	CY 2017 per-visit rates
Home Health Aide	$60.87	× 1.0000	+ $1.79	× 1.005	$62.97
Medical Social Services	215.47	× 1.0000	+ 6.34	× 1.005	222.92
Occupational Therapy	147.95	× 1.0000	+ 4.35	× 1.005	153.06
Physical Therapy	146.95	× 1.0000	+ 4.32	× 1.005	152.03
Skilled Nursing	134.42	× 1.0000	+ 3.96	× 1.005	139.07
Speech-Language Pathology	159.71	× 1.0000	+ 4.70	× 1.005	165.23

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 $261.71 (1.8451 multiplied by $141.84), subject to area wage adjustment.

e. 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 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 CY 2017 HH payment update percentage (2.5 percent). We do not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The NRS conversion factor for CY 2017 is shown in Table 11.

TABLE 11—CY 2017 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2016 NRS conversion factor	CY 2017 rebasing adjustment	CY 2017 HH payment update	CY 2017 NRS conversion factor
$52.71	× 0.9718	× 1.025	$52.50

Using the CY 2016 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 12.

TABLE 12—CY 2017 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2017 NRS payment amounts
1	0	0.2698	$14.16

TABLE 12—CY 2017 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA—Continued

Severity level	Points (scoring)	Relative weight	CY 2017 NRS payment amounts
2	1 to 14	0.9742	51.15
3	15 to 27	2.6712	140.24
4	28 to 48	3.9686	208.35
5	49 to 98	6.1198	321.29
6	99+	10.5254	552.58

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 the proposed rule (1 − 0.0282 = 0.9718). We then update the NRS conversion factor by the CY 2017 HH payment update percentage (2.5 percent) minus 2 percentage points. The CY 2017 NRS conversion factor for HHAs that do not submit quality data is shown in Table 13.

TABLE 13—CY 2017 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2016 NRS conversion factor	CY 2017 rebasing adjustment	CY 2017 HH payment update percentage minus 2 percentage points	CY 2017 NRS conversion factor
$52.71	× 0.9718	× 1.005	$51.48

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 14.

TABLE 14—CY 2017 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2017 NRS payment amounts
1	0	0.2698	$13.89
2	1 to 14	0.9742	50.15
3	15 to 27	2.6712	137.51
4	28 to 48	3.9686	204.30
5	49 to 98	6.1198	315.05
6	99+	10.5254	541.85

f. Rural Add-On

Section 421(a) of the MMA, as amended by section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), requires that the Secretary increase by 3 percent the payment amount otherwise made under section 1895 of the Act, for HH services furnished in rural areas (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, 2018. Section 421 of the MMA 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 will be increased by 3 percent as mandated by section 421(a) of the MMA, as amended. 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 15 through 18 for these payment rates.

TABLE 15—CY 2017 PAYMENT AMOUNTS FOR 60-DAY EPISODES FOR SERVICES PROVIDED IN A RURAL AREA

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2017 National, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	CY 2017 Rural national, standardized 60-day episode payment rate	CY 2017 National, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	CY 2017 Rural national, standardized 60-day episode payment rate
$2,989.97	× 1.03	$3,079.67	$2,931.63	× 1.03	$3,019.58

TABLE 16—CY 2017 PER-VISIT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

	For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
HH discipline type	CY 2017 per-visit rate	Multiply by the 3 percent rural add-on	CY 2017 rural per-visit rates	CY 2017 per-visit rate	Multiply by the 3 percent rural add-on	CY 2017 rural per-visit rates
HH Aide	$64.23	× 1.03	$66.16	$62.97	× 1.03	$64.86
MSS	227.36	× 1.03	234.18	222.92	× 1.03	229.61
OT	156.11	× 1.03	160.79	153.06	× 1.03	157.65
PT	155.05	× 1.03	159.70	152.03	× 1.03	156.59
SN	141.84	× 1.03	146.10	139.07	× 1.03	143.24
SLP	168.52	× 1.03	173.58	165.23	× 1.03	170.19

TABLE 17—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		
CY 2017 conversion factor	Multiply by the 3 percent rural add-on	CY 2017 rural NRS conversion factor	CY 2017 conversion factor	Multiply by the 3 percent rural add-on	CY 2017 rural NRS conversion factor
$52.50	× 1.03	$54.08	$51.48	× 1.03	$53.02

TABLE 18—CY 2017 NRS PAYMENT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

Severity level	Points (scoring)	For HHAs that DO submit quality data		For HHAs that DO NOT submit quality data	
		Relative weight	CY 2017 NRS payment amounts for rural areas	Relative weight	CY 2017 NRS payment amounts for rural areas
1	0	0.2698	14.59	0.2698	$14.30
2	1 to 14	0.9742	52.68	0.9742	51.65
3	15 to 27	2.6712	144.46	2.6712	141.63
4	28 to 48	3.9686	214.62	3.9686	210.42
5	49 to 98	6.1198	330.96	6.1198	324.47
6	99+	10.5254	569.21	10.5254	558.06

The following is a summary of the comments we received regarding the CY 2017 home health rate update.

Home Health Wage Index

Comment: Several commenters believe that the pre-floor, pre-reclassified hospital wage index is inadequate for adjusting HH costs. The commenters believe that the statute does give CMS the authority to allow HHAs the same reclassification opportunity provided to hospitals and correct some of these inequities. One commenter expressed concern about how the home health wage index is calculated and implemented compared to hospitals within the same CBSA. The commenter believes that the geographic reclassification and rural floor provisions, which are available to hospitals, create inequity for HHAs because CMS does not apply those provisions to the HH wage index. The commenter states that this inequity makes it difficult for HHAs to compete with hospitals in recruiting and retaining nurses and therapists. A few commenters requested that if the rural floor and reclassification provisions that apply to the hospital wage index cannot be applied to the HH wage index, then CMS should develop a HH wage index that is based on home healthcare industry wages.

Response: We continue to believe that the regulations and statutes that govern the HH PPS do not provide a mechanism for allowing HHAs to seek geographic reclassification or to utilize the rural floor provisions that exist for IPPS hospitals. Section 4410(a) of the BBA provides that the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that state. This is the rural floor provision

and it is specific to hospitals. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification. This reclassification provision is only applicable to hospitals as defined in section 1886(d) of the Act.

In addition, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals and may or may not apply to a given HHA. With regard to implementing a rural floor, we do not believe it would be prudent at this time to adopt such a policy. In Chapter 3 of its March 2013 Report to Congress on Medicare Payment Policy, MedPAC recommended eliminating the rural floor policy from the calculation of the IPPS wage index. On page 65 of the report (available at *http://medpac.gov/documents/reports/mar13_entirereport.pdf)* MedPAC states that in 2007, MedPAC had ''. . . recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies.''

We continue to believe that using the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates is appropriate and reasonable.

Comment: Several commenters recommend that CMS include wage data from critical access hospitals (CAHs) in calculating the HH wage index in order to make the wage index more reflective of actual local wage practices.

Response: Although the pre-floor, pre-classified hospital wage index does not include data from CAHs, we believe that it reflects the relative level of wages and wage-related costs applicable to providing HH services. As we stated in the August 1, 2003 IPPS final rule (68 FR 45397), the CAHs represent a substantial number of hospitals with significantly different labor costs in many labor market areas where they exist. We further noted that, ''. . . in 89 percent of all labor market areas with hospitals converted to CAH status sometime after 2000, the average hourly wage for CAHs is lower than the average hourly wage for other short-term hospitals in the area.'' In 79 percent of the labor market areas with CAHs the average hourly wage for CAHs is lower than the average hourly wage for other short-term hospitals by 5 percent or greater. These results suggest that the wage data for CAHs, in general, are significantly different from other short-term hospitals and thus may not adequately represent the relative level of wages and wage-related costs applicable to providing HH services.

Comment: A commenter requested that CMS explore a wholesale revision and reform of the HH wage index. Another commenter states that in 2015, CMS indicated that the entire wage index system was under review and that a move to a commuting-based wage index (CBWI) was being considered. The commenter urges CMS to expedite that review and implement a system that not only recognizes variations between localities, but also treats all provider types within a local market equitably.

Response: Our ''Report to Congress: Plan to Reform the Medicare Wage Index'' was submitted by the Secretary on April 11, 2012 and is available on our Wage Index Reform Web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html.* This report states that implementation of a CBWI may require both statutory and regulatory changes. In addition, we believe other intermediate steps for implementation, including the collection of commuting data, may be necessary.

Comment: One commenter believes that the unpredictable year-to-year swings in wage index values are often based on inaccurate or incomplete hospital cost reports. Another commenter requested that CMS describe in detail how the wage index is calculated.

Response: We believe that the hospital cost report data are accurate. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified wage index which is calculated based on cost report data from hospitals paid under the IPPS. All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, our intermediaries perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. We believe that our review processes result in an accurate reflection of the applicable wages for the areas given. The processes and procedures describing how the inpatient hospital wage index is developed are discussed in the IPPS rule each year, with the most recent discussion provided in the FY 2017 IPPS final rule (81 FR 56762 through 57345). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

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

Response: The MSA delineations as well as the CBSA delineations are determined by the OMB. The OMB reviews its Metropolitan Area definitions preceding each decennial census to reflect recent population changes. We believe that the OMB's CBSA designations reflect the most recent available geographic classifications and are a reasonable and appropriate way to define geographic areas for purposes of wage index values. Over 10 years ago, in our CY 2006 HH PPS final rule (70 FR 68132), we finalized the adoption of the revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). In the December 27, 2000 **Federal Register** (65 FR 82228 through 82238), the OMB announced its new standards for defining metropolitan and micropolitan statistical areas. According to that notice, the OMB defines a CBSA, beginning in 2003, as ''a geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties.'' The general concept of the CBSAs is that of an area containing a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus. The purpose of the standards is to provide nationally consistent definitions for collecting, tabulating, and publishing federal statistics for a set of geographic areas. CBSAs include adjacent counties that have a minimum of 25 percent commuting to the central counties of the area. This is an increase over the minimum commuting threshold for outlying counties applied in the previous MSA definition of 15 percent.

Based on the OMB's current delineations, as described in the July 15, 2015 OMB Bulletin 15–01, the New Jersey counties of Bergen, Hudson, Middlesex, Monmouth, Ocean, and Passaic belong in the New York-Jersey City-White Plains, NY–NJ (CBSA 35614). In addition, other provider types, such as IPPS hospital, hospice, skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and the ESRD program, have used CBSAs to define their labor market areas for more than a decade.

Comment: One commenter noted that the wage index for rural Maine continues to be the lowest in New England.

Response: We believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the costs reports of hospitals in those specific labor market areas. The wage index values are based on data submitted on the inpatient hospital cost reports. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified wage index which is calculated based on cost report data from hospitals paid under the IPPS. All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, Medicare contractors perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. We believe that our review processes result in an accurate reflection of the applicable wages for the areas given. The processes and procedures describing how the inpatient hospital wage index is developed are discussed in the Inpatient Prospective Payment System (IPPS) rule each year, with the most recent discussion provided in the FY 2017 IPPS final rule (81 FR 56761 through 57438). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

Comment: Several commenters raised concerns around evolving minimum wage standards across the country and recommended that we consider ways to compensate certain geographic areas impacted by increasing minimum wage standards into the HH PPS wage index.

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

Comment: One commenter stated that rural areas are adversely impacted by the wage index due to increased travel costs due to time and mileage involved in traveling from patient to patient. The commenter recommends that CMS institute a population density adjustment to the wage index.

Response: We do not believe that a population density adjustment is appropriate at this time. Rural HHAs cite the added cost of traveling from one patient to the next patient. However, urban HHAs cite the added costs associated with needed security measures and traffic congestion. The HH wage index values in rural areas are not necessarily lower than the HH wage index values in urban areas. The HH wage index reflects the wages that inpatient hospitals pay in their local geographic areas. In addition, HHAs already receive rural add-on payments for services provided to beneficiaries in rural areas. Section 421(a) of the MMA, as amended by section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), provides for a payment increase of 3 percent for HH services provided in rural areas for episodes or visits ending on or after April 1, 2010, and before January 1, 2018.

Comment: One commenter urges CMS to adjust the 2017 HH wage index to limit disparity between provider types within a given CBSA to no more than 10 percent.

Response: With regard to issues mentioned about ensuring that the wage index minimizes fluctuations, we note that section 3137(b) of the Affordable Care Act required us to submit a report to the Congress by December 31, 2011 that included a plan to reform the hospital wage index system. This report describes the concept of a Commuting Based Wage Index as a potential replacement to the current Medicare wage index methodology. While this report addresses the goals of broad based Medicare wage index reform, no consensus has been achieved regarding how best to implement a replacement system. These concerns will be taken into consideration while we continue to explore potential wage index reforms. The report that we submitted is available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/WageIndex-Reform.html*.

Affordable Care Act Rebasing Adjustments

Comment: MedPAC stated that the rebasing reduction will not sufficiently reduce home health payments. MedPAC projected that home health agencies will have Medicare margins of 8.8 percent in 2016, and the rebasing adjustment will not lower payments in 2017 due to the offsetting statutory payment update. MedPAC stated that Medicare has overpaid for home health care since the inception of the HH PPS and more reductions are necessary to stop this pattern from continuing. MedPAC recommended in their March 2016 report that Congress eliminate the payment update for CY 2017 and implement a rebasing reduction in the following 2 years to bring payments closer to costs. MedPAC stated that the decline in utilization since 2010 does not unduly raise concerns about beneficiaries' access to home health care and that the base payment for 2017 will not fall due to rebasing and should not have an impact on access to care. MedPAC recognized that the statute limits CMS' ability to reduce payments but reiterated their recommendation that further reductions are appropriate and would not negatively affect access to care.

Response: As noted by MedPAC, we are constrained to comply with the statutory requirements in our rebasing adjustments. Our rebasing adjustments for CY 2014 through CY 2017 are in accordance with the statute.

Comment: Commenters urged CMS to postpone or stop the implementation of the rebasing reductions. Commenters expressed concerns with the rebasing methodology, impact analysis, and process outlined in the CY 2014 HH PPS proposed and final rules and stated that a more comprehensive study is needed to evaluate the rebasing reductions. Commenters suggested alternatives to rebasing or alternate ways to implement the rebasing reductions.

Response: We thank the commenters for their comments. We did not propose changes to the rebasing adjustments for CY 2014 through CY 2017 finalized in the CY 2014 HH PPS final rule. A majority of the comments received regarding the rebasing adjustments were nearly identical to the comments submitted during the comment period for the CY 2014 HH PPS proposed rule. Therefore, we encourage commenters to review our responses to the comments we received on the rebasing adjustments in the CY 2014 HH PPS final rule (78 FR 72282–72294).

Comment: Commenters were concerned that rebasing adjustments are

based on outdated and incomplete data and do not reflect current or future costs and do not take into account operational and financial challenges providers experience and trends in data. Commenters recommended that CMS perform analysis to determine the need for rebasing and include all costs providers incur. Commenters requested that CMS evaluate the rebasing and case-mix adjustments on ''real-time'' data and work toward that goal going forward. Some commenters also recommended that CMS work in collaboration with the home healthcare community in finding and using current data to make assessments about the impact and appropriateness of payment reductions going forward. Commenters urged CMS to update its analysis to include data from 2015 cost reports to capture costs associated with the implementation of the physician face-to-face encounter requirement and therapy reassessment requirements and the implementation of ICD–10 in projecting profit margins. One commenter stated that the rebasing methodology relies too much on the very poor cost report system. Some commenters stated that the rebasing methodology was too complex and that the public could not understand the approach used.

Response: We note that we proposed and finalized the rebasing adjustments in 2014 using the most current, complete data available at the time of rulemaking. We recommend commenters review the description of the calculation of the adjustments described in the CY 2014 final rule (78 FR 72276 through 72282). We also note that for the CY 2017 HH PPS 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 data used in calculating the rebasing adjustments. 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 (81 FR 43719, 43720). Given that 2012 through 2014 cost data has indicated the need for a larger reduction to the national, standardized 60-day episode payment rate than what was calculated with the 2011 cost data, we question whether the 2015 cost data will show that payments are low relative to the costs associated with providing care during a home health episode of care. However, we plan to continue to monitor costs and payments for any unintended effects of rebasing.

As stated in our responses to comments in the 2014 final rule, we disagree with the commenter's claim that home health agencies have no incentives for ensuring the accuracy of their cost reports and that the cost report data are inaccurate and not representative of the costs that agencies actually incur. Each HH cost report is required to be certified by the Officer or Director of the home health agency as complete and accurate. We also note that any misrepresentation or falsification of any information on the cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. As always, we encourage providers to fill out the Medicare cost reports as accurately as possible.

Comment: Commenters were concerned with the impact of the payment reductions on vulnerable populations and on safety net providers and agencies that serve underserved regions and/or vulnerable beneficiaries. Commenters stated that CMS has not accounted for the effect of the rebasing adjustments on access to care for vulnerable populations and the adjustments will threaten the efficiency of the health care system. The commenter urged CMS to consider the potential impact of payment cuts on the patient population, and mitigate these risks where possible. One commenter urged CMS to more carefully and accurately measure access to home health services and to move beyond the consideration of zip code coverage as a measure of access to care. The commenter provided suggestions for the impact and monitoring analyses. Commenters urged CMS to conduct a more thorough analysis examining the cumulative impact of rebasing, rather than assessing only a one-year impact.

Commenters also expressed concerns that the rebasing reductions put access to home care in jeopardy in various parts of the country. A commenter stated that CMS' approach ignores regional differences in operating margins. Commenters were concerned about the impact of the reductions on margins, citing negative margins. One commenter provided their projection of the percentage of agencies with negative margins in 2017 by agency type and by state. Commenters wanted CMS to remove or adjust the rebasing adjustments and consult with Congress before considering additional reductions, including case-mix reductions, or further rebasing suggested by MedPAC.

Response: The rebasing reductions were finalized in the 2014 HH PPS final rule and the statute required us to implement a 4-year phase-in of the rebasing reductions starting in CY 2014 and in equal increments over the 4-year period. As described in the CY 2016 HH PPS proposed rule, section 3131(a) of the Affordable Care Act required MedPAC to assess, by January 1, 2015, the impact of the mandated rebasing adjustments on quality of and beneficiary access to home health care. As part of this assessment, the statute required MedPAC to consider the impact on care delivered by rural, urban, nonprofit, and for-profit home health agencies. MedPAC's Report to Congress noted that the rebasing adjustments are partially offset by the payment update each year and across all 4 years of the phase in of the rebasing adjustments the cumulative net reduction would equal about 2 percent. MedPAC concluded that, as a result of the payment update offsets to the rebasing adjustments, HHA margins were likely to remain high under the current rebasing policy and quality of care and beneficiary access to care were unlikely to be negatively affected (80 FR 39846). In addition, in their March 2016 report to the Congress, MedPAC recommended that the Congress eliminate the payment update for 2017, and implement a rebasing reduction in the following 2 years to bring payments closer to costs in order to align payments with costs in CY 2017.

As we noted in the CY 2014 HH PPS final rule (78 FR 72291), MedPAC's past reviews of access to home health care found that access generally remained adequate during periods of substantial decline in the number of agencies. MedPAC stated that this is due in part to the low capital requirements for home health care services that allow the industry to react rapidly when the supply of agencies changes or contracts. In addition, in the CY 2017 HH PPS proposed rule, we noted 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 (81 FR 43720). Even if some HHAs were to exit the program due to possible payment concerns, the home health market would be expected to remain robust. We plan to continue to monitor for the effects of rebasing as data become available.

In the CY 2017 proposed rule, we also described an alternate case-mix model option, the Home Health Groupings Model (HHGM). If implemented, the Home Health Groupings Model could redistribute payments across the range of home health patients, improve payments for specific vulnerable populations, and help address disincentives to provide services to vulnerable populations. In the proposed rule, we noted that we planned to release a more detailed technical report in the future on this additional research and analysis conducted on the HHGM. Once the technical report is released, we will post a link on our Home Health Agency (HHA) Center Web site at *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html* to receive comments and feedback on the model.

Comment: Commenters stated that CMS' own analysis of 2015 data has shown that the rebasing reductions have had an impact on access to care. Commenters stated that CMS' analysis shows a decrease in the number of home health episodes between 2013 and 2015 and a decrease in the number of Medicare beneficiaries receiving at least one episode of care. Commenters stated that rebasing should be suspended until stakeholders have had an opportunity to conduct a full analysis.

In their comments on the HH PPS proposed rule, MedPAC noted that the decline in the number of episodes continues a trend since 2010, when utilization peaked at 6.8 million episodes. About 70 percent of the decline in volume since the peak has been attributable to lower volume in five states (Florida, Illinois, Louisiana, Tennessee, and Texas). However, even with the recent declines, these five states had levels of per-capita home health utilization greater than double the per-capita rate for the rest of the country.

MedPAC stated that though service volume has declined, policy and economic changes other than Medicare payment policy likely account for a significant portion of this change. The number of hospital discharges, a common source of referrals, has declined since 2009, mitigating the demand for post-acute services. The period has also seen relatively low growth in economy-wide health care spending. In addition, several actions have been taken to curb fraud, waste, and abuse in Medicare home health care. The Department of Justice and other enforcement agencies have launched a number of investigative efforts that have scrutinized Medicare HHAs. The number of agencies declined by 2 percent in 2014, with this decline concentrated in Florida, Michigan, and Texas. These factors likely affected spending and utilization in recent years.

MedPAC stated that this decline follows a period of considerable growth. Home health utilization increased by 67 percent between 2002 and 2010. Given this prior rapid growth, and the reasons for the decline in home health use since 2010, MedPAC believes that the decline in utilization since 2010 does not raise substantive concerns about beneficiaries' access to home health care.

Response: As noted by MedPAC in their comments on the proposed rule, there are various reasons for the decline in home health use since 2010 and policy and economic changes other than Medicare payment policy likely account for a significant portion of this change. We note that we plan to continue to monitor for the effects of rebasing as data become available.

Comment: Some commenters stated that there is an error in CMS's calculation of the proposed CY 2017 national, standardized 60-day episode payment rate that inappropriately inflates the rebasing adjustment. Commenters stated that the Affordable Care Act provision regarding the 4-year phased-in rebasing adjustment strictly limits CMS's authority to impose no more than $80.95 in annual rebasing adjustments from 2014 through 2017. Commenters stated that by subtracting the $80.95 from the rate calculation before adjusting for inflation, CMS has inflated the impact of the rebasing adjustment for CY 2017 from $80.95 to $82.81. Commenters stated that CMS has made this same calculation error for each of the 4 years that the rebasing adjustment has been in place. Commenters stated that compounding the cumulative impact over the 4 years, the proposed CY 2017 national, standardized 60-day episode payment rate is $7.19 less than if CMS had subtracted the rebasing adjustment after adjusting for inflation.

Commenters recommended that CMS correct the calculation methodology, increase the proposed CY 2017 national, standardized 60-day episode payment rate by $7.19, and retroactively adjust the national, standardized 60-day episode payment rates for years 2014 through 2016 to comply with the statutory limitation on the rebasing adjustment.

Response: The last sentence in section 1895(3)(A)(iii)(I) of the Act states that the rebasing adjustment shall be made before the update under subparagraph (B) is applied for the year. Subparagraph (B) describes the home health update percentage. Therefore, the statute requires that the rebasing adjustments be applied before the home health update percentage. The description of the limits is referring to the rebasing adjustments, which must be applied before the home health update percentage. Therefore, no error was made in applying the rebasing adjustment to the national, standardized 60-day episode payment rate before the home health payment percentage and in the CY 2017 national, standardized 60-day episode payment amount or the amounts in CYs 2014 through 2016.

Comment: One commenter stated that instead of the rebasing adjustments, CMS should start the development of a new payment methodology for the therapy component of the HH PPS that accurately bases payment on the severity level of the patient and the necessary resources to treat the condition at the requisite level of intensity.

Response: While a new payment methodology for the therapy component of the HH PPS may redistribute payments for certain patients, the rebasing adjustments are meant to align the national, standardized 60-day episode payment rate, the per-visit LUPA rates, and the NRS conversion factor with the cost of providing care.

Nominal Case-Mix Reduction

Comment: MedPAC stated that they have long held it necessary for CMS to make adjustments to account for nominal case-mix change to prevent additional overpayments. MedPAC stated that the CMS' reduction to account for nominal case-mix growth is consistent with the agency's past findings on trends in case-mix change in the payment system and thus is warranted to ensure the accuracy of payments under the home health PPS. MedPAC stated that a reduction of 0.97 percent should not significantly affect access to care.

Response: We thank MedPAC for their comments.

Comment: Several commenters stated that they wanted CMS to rescind the case-mix reductions for CY 2017 and CY 2018. Some commenters stated that implementation of the nominal case-mix reductions in 2016, 2017, and 2018 violated the limits on payment reductions set out by the Congress and urged CMS to adhere to the statutory limits on home health rate cuts. Commenters expressed concerns with the data and methodology used to develop the proposed case-mix cuts and stated that the annual recalibration should have eliminated any practice of assigning an inaccurate code to increase

reimbursement. Some commenters stated that the nominal case-mix reductions were duplicative of the rebasing reductions. A few commenters stated that the baseline used in calculating the amount of case-mix growth was inappropriate. Commenters stated that the estimate of real case-mix was outdated and needed to be updated. Commenters stated that any analysis of case mix in home care must be put in the context of the current environment and take into account initiatives and trends. Commenters urged CMS to conduct the necessary analyses of 2012 through 2014 nominal case-mix change and share such analyses with stakeholders in the form of a new, evidence-based proposal. Commenters recommended that CMS withdraw the proposed case-mix reductions and consider alternative approaches. Some commenters stated that CMS should implement program integrity measures to control aberrant coding by some providers instead of imposing across-the-board case mix creep adjustments on all providers, and that CMS should not impose adjustments to payments until the completion of rebasing cuts (that is, 2018 or later). Commenters requested that CMS reconsider negative adjustments or spread the adjustments over more years.

Some commenters noted that actual program spending on home health was consistently less than Congressional Budget Office (CBO) estimates and questioned CMS' authority to implement case mix weight adjustments when home health spending was less than these estimates. Commenters stated that there was no increase in aggregate expenditures that warranted the application of this statutory authority, and CMS should withdraw its proposal. One commenter stated that CMS did not perform a detailed analysis of case mix growth for this year's proposed rule.

Response: We thank the commenters for their comments. We finalized the case-mix reductions for CY 2016, CY 2017, and CY 2018 in the CY 2016 HH PPS final rule and did not propose changes to the finalized reduction in the CY 2017 HH PPS proposed rule. The majority of the comments received regarding the payment reductions for nominal case-mix growth were very similar to the comments submitted during the comment period for the CY 2016 HH PPS proposed rule. Therefore, we encourage commenters to review our responses to the comments we received on the payment reductions for nominal case-mix growth in the CY 2016 HH PPS final rule (80 FR 68639–68646). We will continue to monitor real and nominal case-mix growth and may propose additional reductions for nominal case-mix growth, as needed, in the future.

Final Decision: After considering the comments received in response to the CY 2017 HH PPS proposed rule, we are finalizing our proposal to use the pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2017, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013 (FY 2013 cost report data). In addition, we are implementing the final year of the rebasing adjustments and the 0.97 percent payment reduction to account for nominal case-mix growth when finalizing the CY 2017 HH PPS payment rates. We note that the rebasing adjustments were finalized in the CY 2014 HH PPS final rule and the payment reductions to account for nominal case-mix growth from 2012 to 2014 were finalized in the CY 2016 HH PPS final rule. No additional adjustments or reductions were proposed in the CY 2017 proposed rule.

D. Payments for High-Cost Outliers Under the HH PPS

1. Background

In the CY 2017 HH PPS proposed rule (81 FR 43737 through 43742), we described the background and current method for determining outlier payments under the HH PPS. Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the national, standardized 60-day episode payment amount in the case of episodes that incur unusually high costs due to unusual variations in the type or amount of medically necessary care. Outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). Currently, 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 is the episode payment amount for that group, or the partial episode payment (PEP) adjustment amount for the episode, plus a fixed-dollar loss (FDL) amount that is the same for all case-mix groups.

The outlier payment is defined to be a proportion of the wage-adjusted estimated cost beyond the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio, which is currently 0.80.

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, 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. Changes to the Methodology Used To Estimate Episode Cost

In the CY 2017 HH PPS proposed rule, we described that our analysis of outlier episodes, based on preliminary 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. In addition, we also noted in the proposed rule that outlier payments are predominately driven by the provision of skilled nursing services. As a result of the analysis of CY 2015 home health claims data, we stated that we are concerned that 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 if certain interventions are provided. 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

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

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] These complex interventions could include total parenteral nutrition (TPN) therapy and central line catheter care. 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 generally require more intensive and frequent home health surveillance, increased home health care utilization, and costs.[7] [8]

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.'' [9] 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 were ill, permanently disabled beneficiaries, and those beneficiaries with episodes of care that received outlier payments. The study found that only a small fraction of proxy demonstration patients had episodes of care that generated 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 proposed 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. Table 19 shows the cost-per-unit payment rates for the calculation of outlier payments, updated with complete CY 2015 home health claims data (as of June 30, 2016). 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 up to, but no more than, 2.5 percent of total payments as outlier payments in accordance with section 1895(b)(5)(A) of the Act.

TABLE 19—COST-PER-UNIT PAYMENT RATES FOR THE CALCULATION OF OUTLIER PAYMENTS

Visit type	CY 2017 national per-visit payment rates	Average minutes-per-visit	Cost-per-unit (1 unit = 15 minutes)
Home health aide	$64.23	63.0	$15.29
Medical social services	227.36	56.5	60.36
Occupational therapy	156.11	47.1	49.72
Physical therapy	155.05	46.6	49.91
Skilled nursing	141.84	44.8	47.49
Speech-language pathology	168.52	48.1	52.55

In the CY 2017 proposed rule, we stated that 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.

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 proposed 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 proposed 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 noted 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 19. 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

[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,

[7] 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.

[8] 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.

[9] 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.

episode's estimated cost and 3.5 hours of home health aide services would be counted in the episode's estimated cost (8 hours − 4.5 hours = 3.5 hours) since home health aide services has a lower cost-per-unit than skilled nursing services.

Out of approximately 6.47 million episodes in our analytic file for 2015, only 17,505 episodes or 0.3 percent of all home health episodes reported instances where over 8 hours of care were provided in a single day (some episodes of which could have resulted from data entry errors). Of those 17,505 episodes, only 8,305 would be considered outlier episodes under the proposed outlier methodology. Therefore, we estimate that approximately 8,300 episodes, out of 6.47 million episodes, would be impacted due to the proposed 8 hour cap.

3. Proposed Fixed Dollar Loss (FDL) Ratio

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower. The FDL ratio and the loss-sharing ratio must be selected so that outlier payments do not exceed 2.5 percent of total payments (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 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. The national, standardized 60-day episode payment amount is multiplied by the FDL ratio. That amount is wage-adjusted to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

In the CY 2017 HH PPS 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 estimated 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 the CY 2017 HH PPS proposed rule, we stated that we estimate that outlier payments would comprise approximately 2.58 percent of total HH PPS payments in CY 2017 under the current outlier methodology. This 15.7 percent 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 proposed to increase 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 did not propose a change to the loss-sharing ratio (0.80) as a loss-sharing ratio of 0.80 for the HH PPS would remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.). In the CY 2017 HH PPS proposed rule, we stated that under the current outlier methodology, the FDL ratio would need to be increased 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 estimated 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 would need to be increased 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 proposed to increase the FDL ratio from 0.45 to 0.56 for CY 2017. In the CY 2017 HH PPS proposed rule, we stated that we would update our estimate of outlier payments as a percent of total HH PPS payments for the final rule. Using complete CY 2015 claims data as of June 30, 2016, we estimate that the FDL ratio would need to increase from 0.45 to 0.55 for CY 2017 in order to pay up to, but no more than, 2.5 percent of total payments as outlier payments.

In the CY 2017 HH PPS proposed rule, we solicited 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 increase to the FDL ratio. The following is a summary of the comments and our responses.

Comment: MedPAC was supportive of the proposed change to the outlier methodology, stating that the proposed policy improves the targeting of outlier funds and is similar to the method CMS uses when constructing the home health case-mix weights. MedPAC stated that the proposed method will better capture the variability in costs among home health agencies, will better align payments with agencies' actual costs, will reduce vulnerabilities, and will reduce incentives for agencies to not sufficiently treat patients who need longer than average visits under the HH PPS. Other commenters appreciated CMS' effort to develop an outlier policy that better aligns payment with cost and addresses disincentives to provide services to complex patients who need longer visits. A number of commenters requested that CMS finalize the proposed change to the outlier methodology.

Response: We thank MedPAC and other commenters for their support. Our analysis shows that changing the outlier methodology using a 15-minute unit approach better aligns payment with the cost of providing care and may help address some of the findings from the home health study and alleviate potential financial disincentives to treat patients with medically complex needs.

Comment: Several commenters requested specific information or instructions on reporting visits and visit length. A few commenters requested more clarity on how the 15-minute units would be calculated and tracked by the agency. Some commenters expressed concerns that the proposed change in the outlier methodology could result in fraudulent calculation of the time necessary to provide the service. Commenters were concerned that some HHAs may artificially inflate the time spent with patients or misreport the units that were actually delivered. A commenter brought up a concern about the reliability of the paper-based reporting. Commenters were concerned that adjusting payment according to visit length may encourage overutilization and encouraged CMS to put into place screens and checks to prevent potential overestimation of time reporting. A few commenters suggested that CMS consider reimbursing partial 15 minute units on a pro-rata basis to increase payment accuracy and avoid a reporting cliff.

Some commenters expressed concerns about whether HHAs have the data to

accurately capture the length of care provided by each of the six disciplines and whether HHAs and their software vendors will have adequate time to incorporate the proposed changes to their Medicare billing systems. A commenter recommended that CMS delay the particular change to the outlier methodology in order to provide HHAs time to work with their software billing vendors to update their systems and make changes to bill outlier payments correctly. A few commenters stated that the change in the methodology may result in additional costs from their electronic health record vendor to capture the cost per unit as well as staff training to document time in and out when in the home. A commenter stated that the extra expense and time resources should be captured in the estimate of the impact of this proposed change.

Response: We did not propose to change the reporting of visits or visit length in the CY 2017 HH PPS proposed rule. The requirement to report visit length in 15 minute units is a statutory requirement that has been in place since the start of the HH PPS. We encourage providers to continue to bill visits and visit length according to previous guidance. Specifically, see Table 20, which will be added to the Medicare Claims Processing Manual, chapter 11 (Pub. 100–04).

TABLE 20—DEFINITION OF THE 15-MINUTE UNITS

Unit	Time
1	<23 minutes.
2	= 23 minutes to <38 minutes.
3	= 38 minutes to <53 minutes.
4	= 53 minutes to <68 minutes.
5	= 68 minutes to <83 minutes.
6	= 83 minutes to <98 minutes.
7	= 98 minutes to <113 minutes.
8	= 113 minutes to <128 minutes.
9	= 128 minutes to <143 minutes.
10	= 143 minutes to <158 minutes.

Since we are not adding or changing reporting requirements, providers should not have an increase in burden due to this policy. Providers are already required to report visit length, in 15 minute increments, by discipline, on home health claims. We do not have minute data to pay partial 15 minute units on a pro-rated basis. Furthermore, we do not have the statutory authority to require HHAs to report visit lengths in timeframes other than in 15-minute increments in accordance with section 1895(c)(2) of the Act. We will monitor for changes in the reporting of visit lengths and may investigate HHAs with suspect billing patterns. As a reminder, any HHA misreporting information on their home health claims will be in violation of the False Claims Act and could be subject to civil penalties and damages and/or criminal prosecution.

Comment: We received a question asking whether the rural add-on will be used in the calculation of the estimated cost of an episode, when applicable, under the proposed outlier policy.

Response: Yes, the rural add-on will apply in this calculation. We will use rural versus non-rural per unit rates the same way we currently use rural versus non-rural per visit rates to calculate the imputed cost.

Comment: A commenter stated that the outlier proposal rewards quantity, but does not take into account quality. One commenter encouraged CMS to focus on the identified ''bad actor'' agencies and not impose potential administrative burdens on compliant providers.

Response: The proposed change in the outlier methodology is not meant to be punitive, but rather is meant to more accurately calculate the cost of an outlier episode of care and thus better align outlier payments with episode cost than the cost per visit approach. 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 HHAs to accept and care for medically complex beneficiaries who require longer visits. 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 only or primarily patients with less complex needs.

Comment: One commenter urged CMS to release data to allow for a historical comparison of HH visits vs. HH units of service over multiple years and requested that CMS update the rate per unit computations with every year using the latest data available.

Response: In the proposed rule, we described the average number of visits by discipline type for a Medicare home health 60-day episode of care from CY 2001 to CY 2015 (81FR 43739). While the number of visits by discipline has changed since 2001, visit length has been relatively stable from CY 2001 to CY 2015. From CY 2001 to CY 2015, the average number of 15-minute units reported for physical therapy visits and skilled nursing visits increased by .1 unit or 1.5 minutes, the average number of 15-minute units reported for occupational therapy visits decreased by .1 unit or 1.5 minutes, and the average number of 15-minute units reported for home health aide services decreased by .2 units or 3 minutes. From CY 2001 to CY 2015, the average number of 15-minute units reported for speech-language pathology services and medical social services remained stable. We note that the per-unit rates used to estimate an episode's cost will be updated by the home health update percentage each year. While we do not plan to re-estimate the per-unit rates by discipline using new per-unit data every year, we will monitor the visit length by discipline as more recent data become available. If there are significant changes, we may propose to update the rates.

Comment: One commenter supported the 10-percent cap on outlier payments. Another commenter disagreed with CMS' proposal to maintain the 10-percent cap on outlier payments and instead suggested that CMS include a minimum provider-specific number of percent of episodes that result in LUPAs. Some commenters stated that the shift to a bundled payment system as well as the shift to move care out of institutionalized settings and into home and community-based settings will lead to an influx of patients with more severe conditions being treated by HHAs. Commenters requested that CMS consider this when developing the final policy. Some commenters recommended that CMS conduct a more detailed analysis in the near future on whether the total outlier cap of 2.5 percent is adequate or whether it needs to be increased for future years. Another commenter recommended that CMS pay out more than 2.5 percent in outlier payments.

Response: The 2.5 percent target of outlier payments to total payments and the 10 percent cap on outlier payments at the home health agency level are statutory requirements, as described in section 1895(b)(5) of the Social Security Act. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5 percent target amount. In 2015, only about 1 percent of HHAs received 10 percent of their total HH PPS payments as outlier payments, while almost 71 percent of HHAs received less than 1 percent of their total HH PPS payments as outliers. Therefore, the 10 percent agency-level cap does not seem to be significantly impacting a large portion of HHAs.

Comment: Commenters were concerned with the proposal to increase the FDL ratio from 0.45 to 0.56, stating that the increase would reduce the number of episodes that qualify for outlier payment and reduce payments to providers. A commenter implied that the increase in the FDL ratio was solely due to the change in the outlier methodology calculation. The commenter stated that for those HHAs that provide the most outlier care services, Table 26 in the proposed rule (81 FR 43740) shows average minutes per visit jumping from 27.5 to 104.5 to receive outlier payments under the proposed methodology. The commenter stated that this increase drives the fixed dollar loss ratio increase from the current 0.45 to 0.56 in CY 2017, an almost 25 percent increase. Some commenters stated that raising the FDL will cause access issues for certain patients. Another commenter was concerned about the increase in the FDL ratio, stating that CMS has been overly conservative in their outlier projections in the past. The commenter stated that outlier payments have consistently fallen well below the 2.5 percent target the past several years and urged CMS to recalculate the FDL ratio using less conservative projections to ensure outlier payments are closer to the 2.5 percent target amount. A third commenter recommended that CMS retain the current FDL and consider an alternate method to meet the statutory limit placed on outlier payments, such as lowering the outlier payment to total payment cap.

Response: To clarify, Table 26 in the proposed rule (81FR 43740) indicates that for those agencies with 10 percent of their payments as outlier payments, the average minutes per visit under the current methodology is 27.5, while the average number of minutes per visit under the proposed methodology is 104.5. However, as indicated in our response above, only about 1 percent of HHAs received 10 percent of their total HH PPS payments as outlier payments in 2015. The majority of agencies received less than 1 percent of their total HH PPS payments as outlier payments in 2015. As stated in the proposed rule, regardless of the change in the outlier methodology, we would need to raise the FDL in order to target 2.5 percent of total payments as outliers. We project that the percentage of outlier episodes will increase from 2016 to 2017 as a result of the rebasing and nominal case-mix reductions to the national, standardized 60-day episode payment rate as well as increases to the per-visit rates due to the implementation of the fourth and final year of the rebasing adjustments. Since complete CY 2016 or 2017 data are currently not available, we estimate outlier payments for CY 2016 and CY 2017 using 2015 home health utilization data and applying the CY 2016 and CY 2017 payment parameters. Using complete CY 2015 claims data as of June 30, 2016, we estimate that outlier payments will be 2.20 percent of total payments in CY 2016 and that outlier payments will be 2.84 percent of total payments in CY 2017 when applying the CY 2017 payment parameters and the proposed changes to the outlier methodology. Therefore, we are increasing the FDL from 0.45 to 0.55 to target 2.5 percent of payments as outliers, as required by statute. We note that other payment systems with outlier payments, such as the IRF PPS and IPPS, annually re-assess the fixed-loss cost outlier threshold amount. Adjusting the outlier threshold amount in order to target the statutorily required percentage of total payments as outlier payments is standard practice.

Comment: A commenter expressed concerns about the proposed changes to the outlier methodology and urged CMS to withdraw the proposal and retain the current methodology in calculating outlier payments or delay implementation. Another commenter stated that instead of the proposed policy, CMS should keep the existing methodology and add an outlier add-on to pay for individuals with longer than average visits. Several commenters expressed concerns with CMS' proposal to give equal weight to each 15-minute increment of care, stating that there are certain fixed costs that do not vary with visit length. A few commenters stated that the volume of patients who might need longer than average visits is significantly smaller than the volume of patients who need shorter, but more frequent visits for services, such as insulin injections. A commenter also stated that the proposal needs to account for the costs to initiate a visit and that the beginning of the encounter is more resource-intensive than later in the encounter. Commenters stated that short visits would receive substantially less payment for fixed costs that do not vary based on the length of the visit, such as travel time, and the commenters encouraged CMS to refine the proposed policy to give greater weight to the first 15-minute unit of a visit. Commenters also stated that costs outside the actual HH visit, such as but not limited to documentation and back office costs, would not be captured through the proposed approach.

Response: The purpose of the proposed change in the outlier methodology is to more accurately pay for outlier episodes by taking into account both the number of visits and the visit length by discipline when imputing episode cost. We remind commenters that the units of care per discipline will be summed up for each discipline for the entire episode and then multiplied by the cost per unit in order to estimate the estimated episode cost. Therefore, episodes with four 15-minute skilled nursing visits a day for 10 days would receive the same cost estimate as five 2 hour skilled nursing visits in an episode. Episodes with 15-minute visits may still be able to qualify for outlier payments.

We note that payment for the fixed costs of an episode, such as transportation, are already accounted for under the national, standardized 60-day episode payment rate and the national per-visit payment rates. CMS does not track transportation and other administrative costs for each visit or episode. Section 1895(b)(5)(A) of the Social Security Act states that outlier payments are to be made in the case ''of unusual variations in the type or amount of medically necessary care'' and not for unusual variations in fixed costs. Outlier payments are meant to help mitigate the incentive for HHAs to avoid patients that may have episodes of care that result in unusual variations in the type or amount of medically necessary care. Outlier payments serve as a type of ''reinsurance'' whereby, under the HH PPS, Medicare reimburses HHAs 80 percent of their costs for outlier cases once the case exceeds an outlier threshold amount. We have concerns with HHAs that may be developing business models around outlier payments and are trying to make a profit off of these episodes. The goal of this proposal is to more accurately pay for outlier episodes; we noted in the proposed rule that preliminary analysis indicates that a larger percentage of episodes of care for patients with a fragile overall health status will qualify for outlier payments. The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care. Therefore, using a linear relationship between costs and visit length aligns with the premise of the outlier payment system and with the statute.

Comment: One commenter stated that additional information is needed to accurately assess the financial impact and ensure that CMS is paying outliers accurately. Other commenters were concerned that the outlier proposal may adversely impact access to home health

services or may result in inadequate payment for patients who require multiple short visits per day, such as insulin dependent diabetic patients who are unable to self-inject. Commenters stated that these patients may receive more expensive types of care at other settings or have unnecessary hospitalizations. Another commenter expressed concerns that changing the methodology could negatively impact physical therapy practicing in the home health setting. Commenters wanted to learn more about the types of patients that may not receive outlier payments under the proposed methodology and how this change may impact access to care for certain vulnerable patient groups. Another commenter stated that CMS should use current data to better understand the clinical characteristics of patients who are currently receiving outlier payments. A few commenters stated that the effects of any changes to the outlier methodology should be closely monitored.

Response: The purpose of the proposed change in the outlier methodology is to better align outlier payments with the estimated cost per episode, accounting 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 medically less complex patients. As noted in our response above, episodes with short, frequent visits may also qualify for outlier payments. We estimate that over two-thirds of outlier episodes under the current payment system would continue to receive outlier payments under the proposed outlier methodology. We note that it is difficult to identify with absolute certainty, through administrative data, the visits and episodes for which the sole purpose was to provide insulin injections to insulin-dependent diabetics that cannot self-inject and for which there is no able or willing caregiver that can assist with providing such injections. In 2015, about 358,000 episodes or 6.6 percent of episodes had diabetes as the primary diagnosis and 1,241,000 or 22.9 percent of episodes had diabetes as the secondary diagnosis. Even though almost 30 percent of episodes had a diagnosis of diabetes, we cannot parse out the exact services provided during these episodes, as there were a variety of services that HHAs could have been providing to patients with diabetes. Given the limitations in the data, extensive impact analysis of insulin-dependent diabetics is not possible. However, we plan to monitor for any unintended results of this policy on insulin-dependent diabetics. We reiterate that the goal of the proposed change to the outlier methodology is to more appropriately pay for outlier episodes, not to create incentives to provide care only to a certain population of patients.

Comment: Another commenter urged CMS to provide additional information on the methodology used to calculate episode costs and to provide maximum transparency throughout the development and implementation process. A commenter questioned whether the new methodology would be based on the episode end date or the service date for the outlier.

Response: The outlier methodology will be based on the episode end date. Detailed information on our methodology is available in section III.D.1 and in our responses to comments above.

Comment: Some commenters opposed the proposed 8-hour cap and wanted CMS to remove the cap, stating that it could negatively impact certain patient groups and could create disincentives for agencies to take on sicker patients who would be likely to be outlier patients. Commenters stated that the cap could result in patients receiving care in other settings and increase the overall healthcare expenditures. One commenter stated that outlier payments were already controlled for budget neutrality, and therefore the 8-hour cap was not needed. Another commenter stated that CMS should evaluate the medical complexity of the patients whose episodes may be affected by the 8-hour cap to avoid any unintended access barriers for patients who clinically warrant extra home health care and resources. Commenters also stated that CMS should remove the per-week cap of 28 hours. A commenter stated that capping the hours of care at 28 hours per week, with a review process which would allow up to 35 hours per week of care, was (1) inconsistent with the language in the program manual specifying less than eight hours per day OR less than six days per week; and (2) created an undue burden on providers by requiring additional paperwork in order to provide adequate care to outlier patients. A few commenters stated that CMS should modify the language in the program manual to recognize the importance of treating outlier patients and the need to do so outside of the traditional confines of the pre-existing definition of part-time and intermittent services. Another commenter urged CMS to carefully consider eliminating the per day and per week caps for certain vulnerable patient groups.

Response: Where a patient is eligible for coverage of home health services, Medicare covers part-time or intermittent home health aide services and skilled nursing services, subject to statutory limits. Section 1861(m)(7)(B) of the Act states that the term ''part–time or intermittent services'' means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week).'' Therefore, the weekly cap on the amount of skilled nursing and home health aide services combined is a statutory limit, not an additional regulatory requirement. As stated in the proposed rule, outlier payments are predominately driven by the provision of skilled nursing services. The 8-hour daily cap on services aligns with the statute, which requires that skilled nursing and home health aide services be furnished less than 8 hours each day.

As noted earlier, out of approximately 6.47 million episodes in our analytic file for 2015, only 17,505 episodes or 0.3 percent of all home health episodes reported instances where over 8 hours of care were provided in a single day (which also could have resulted from data entry errors, as we currently do not use visit length for payment). Of those 17,505 episodes, only 8,305 would be classified as outlier episodes under the proposed outlier methodology. Therefore, we estimate that only 8,300 episodes or so, out of 6.47 million episodes, would be impacted due to the proposed 8 hour cap and we do not expect a significant impact on patients and providers. We plan to monitor for any unintended results of this policy as data become available.

Comment: One commenter stated that the current outlier policy should be eliminated until CMS and the industry have had time to develop a more reasonable outlier provision. The commenter also stated that cost of medical supplies should be included in the imputed cost for episodes.

Response: We will take this comment into consideration given the history of fraud and abuse associated with outlier payments. We note that there is a separate system that covers NRS costs and payments range from $14.16 to $552.58. We will take into consideration the comment about combining NRS

costs with episode costs. However, we note that in the 2014 HH PPS proposed rule, we stated that during our analysis of NRS costs and payments, we found that a significant number of providers listed charges for NRS on the home health claim, but those same providers did not list any NRS costs on their cost reports. Specifically, out of 6,252 cost reports from FY 2011, 1,756 cost reports (28.1 percent) reported NRS charges in their claims, but listed $0 NRS costs on their cost reports. Given the findings from a sample of cost report audits performed and our analysis of NRS payments and costs, we are exploring possible additional edits to the cost report and quality checks at the time of submission to improve future cost reporting accuracy (78 FR 40290). We encourage providers to provide accurate data on the cost report so NRS cost information can be used in the future.

Final Decision: After consideration of all public comments, we are finalizing the proposed changes to the outlier methodology as proposed, as well as the proposed increase to the FDL ratio and the corresponding proposed changes in the regulations text at § 484.240. The methodology to calculate outlier payments will change for CY 2017 to use a cost-per-unit approach as outlined above. The FDL will be set at 0.55 for CY 2017 based on analysis of complete CY 2015 data (as of June 30, 2016).

E. 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. 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 using a disposable device. A disposable NPWT device is a single-use integrated 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 devices have a preset continuous negative pressure, there is no intermittent setting, they are pocket-sized and easily transportable, and they are generally battery-operated with disposable batteries.[10]

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 care
- 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 a 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.

As described above, 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, as described in section 50.4.1 of Chapter 7 of the Medicare Benefit Policy Manual.[11] 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 reimbursed on an episodic basis for every Medicare home health patient regardless of whether the patient requires medical supplies during the episode. The law requires that all medical supplies (routine and non-routine) be provided by the HHA while the patient is under a home health plan of care. A disposable NPWT device 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 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 Healthcare Common Procedure Coding System or 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 *https://www.cms.gov/Medicare/*

[10] Dumville JC, Land L, Evans D, Peinemann F. Negative pressure wound therapy for treating leg ulcers. Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.: CD011354. DOI: 10.1002/14651858.CD011354.pub2.

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

Billing/TherapyServices/AnnualTherapyUpdate.html.

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 a 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.[12] CPT® codes 97607 and 97608 are subject to the HHA consolidated billing requirements, given that these two codes are considered ''sometimes'' therapy codes and the service can be performed by a therapist or non-physician practitioner and given that these two codes include disposable NPWT devices, which are considered a non-routine supply.

2. The Consolidated Appropriations Act, 2016

As described in the proposed rule, a disposable NPWT device is currently considered a non-routine supply and thus payment for the disposable NPWT device is included in the episodic reimbursement amount. However, the Consolidated Appropriations Act, 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 NPWT 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 1834(s)(3) of the Act, the separate payment amount for a disposable NPWT device 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 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. These 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. 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 proposed 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 proposed that since furnishing NPWT using a disposable device for an individual who receives home health services and for which payment is made under the Medicare home health benefit (that is, 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 as well as furnishing the service, the HHA must bill these visits separately under type of bill (TOB) 34x (used for some 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 disposable device would not be reported on the HH PPS claim (TOB 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 proposed 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 (TOB 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 an integrated, disposable device under TOB 34x along with the appropriate HCPCS code (97607 or 97608). Additionally, this same visit should also be reported on the HH PPS claim (TOB 32x), but only the time spent furnishing the services unrelated to the provision of NPWT using an integrated, disposable device.

As noted in section III.E.1, since these two CPT® codes (97607 and 97608) are considered ''sometimes'' therapy codes, we proposed that NPWT using a disposable device for patients under a home health plan of care can be performed, in accordance with 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 descriptions for CPT® codes 97607 and 97608 include performing a wound assessment, therefore in the proposed rule we stated 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).

As outlined in the proposed rule, since the payment amount for both 97607 and 97608 would be set equal to the amount of the payment that would be made under the OPPS, the payment amount would also be subject to the area wage adjustment policies in place under the OPPS in a given 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, 2016 (Pub. L 114–113) also amends section 1833(a)(1) of the Act, which requires that furnishing NPWT using a disposable device be subject to beneficiary coinsurance in the amount of 20 percent. The amount paid to the HHA by Medicare would be equal to 80 percent of the lesser of the actual charge

[12] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.html.*

or the payment amount as determined by the OPPS for the year.

In the CY 2017 HH PPS proposed rule, we also noted that 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 (81 FR 43744). 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 initial and comprehensive assessments as required by § 484.55, and/or the 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, taking into account the unique medical condition of the patient. 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.[13] 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 solicited public comment on all aspects of the proposed payment policies for furnishing NPWT using a disposable device as articulated in this section as well as the corresponding proposed changes to the regulations at § 409.50 in section VII of the proposed rule.

The following is a summary of the comments we received regarding the proposal for the payment of NPWT using a disposable device.

Comment: Many commenters expressed support of the proposed payment policies for the provision of NPWT using a disposable device.

Response: We appreciate the positive feedback from the provider community as well as other stakeholders.

Comment: Many commenters expressed confusion regarding how to bill for wound care visits that would not include the replacement of a disposable NPWT device and encouraged CMS to provide clarification as to how these wound care visits should be billed. In addition, several commenters requested guidance from CMS on how to track time and services related to NPWT using a disposable device in order to ensure they are complying with billing requirements.

Response: We appreciate commenters' interest in wanting to appropriately track and bill for NPWT using a disposable device. We proposed that, where the sole purpose of a home health visit is to ''furnish NPWT using a disposable device,'' we would not pay for the visit under the HH PPS. Rather, those services would be reported on a TOB 34x and paid for separately outside the HH PPS. Where NPWT is furnished using a disposable device, and other services that are unrelated to the NPWT are also furnished, the NPWT services would be billed and paid for separately outside the HH PPS (using TOB 34x), and the services unrelated to NPWT would be billed and paid for under the HH PPS (using TOB 32x).

We hoped our explanation—that, when NPWT is furnished using a disposable device, both the device and the services associated with furnishing the device are paid for separately based on the OPPS amount (81 FR 43643)—would convey that a new device had to be furnished in order for the service to be separately paid outside the HH PPS. However, based on commenters' questions about which services HHAs must bill using bill types 34x and 32x, we believe we need to be clearer about what we meant by ''furnish NPWT using a disposable device'' in the proposed rule. We are clarifying here that, when a HHA ''furnishes NPWT using a disposable device,'' the HHA is furnishing a new disposable NPWT device. This means the HHA provider is either initially applying an entirely new disposable NPWT device, or removing a disposable NPWT device and replacing it with an entirely new one. In both cases, all the services associated with NPWT—for example, conducting a wound assessment, changing dressings, and providing instructions for ongoing care—must be reported on TOB 34x with the corresponding CPT® code (that is, CPT code 97607 or 97608); they may not be reported on the home health claim (TOB 32x). The reimbursement for all of these services is included in the OPPS reimbursement amount for those two CPT® codes. Any follow-up visits for wound assessment, wound management, and dressing changes where a new disposable NPWT device is not applied must be included on the home health claim (TOB 32x).

We are codifying this definition of ''furnishing negative pressure wound therapy (NPWT) using a disposable device'' in our regulations at § 484.202. This is a technical amendment that reflects the substance of our proposal without changes.

In the interest of providing clarification on potential billing scenarios for HHAs furnishing NPWT using a disposable device, we are providing some examples below:

• *Example #1:*

On Monday, a nurse assesses the patient's condition, assesses the wound, and applies a new disposable NPWT device. The nurse also provides wound care education to the patient and family. On the following Monday, the nurse returns, assesses the wound, and replaces the device that was applied the week before with an entirely new disposable NPWT device. In this scenario, the billing procedures are as follows:

++ For each visit, all the services provided by the nurse were associated with furnishing NPWT using a disposable device because the nurse applied a new disposable NPWT device during each visit. The nurse did not provide any services other than furnishing NPWT using a disposable device. Therefore, all the nursing services for both visits should be reported on TOB 34x with CPT® code 97607 or 97608. None of the services should be reported on TOB 32x.

• *Example #2:*

On Monday, a nurse assesses the wound, applies a new disposable NPWT device, and provides wound care education to the patient and family. The nurse returns on Thursday for wound assessment and replaces the fluid management system (or dressing) for the existing disposable NPWT, but does not replace the entire device. The nurse

[13] Corbett Lisa Q. and Ennis William J., What Do Patients Want? Patient Preferences in Wound Care. Advances in Wound Care. August 2014, 3(8): 537–543. doi:10.1089/wound.2013.0458.

returns the following Monday, assesses the patient's condition and the wound, and replaces the device that had been applied on the previous Monday with a new disposable NPWT device. In this scenario, the billing procedures are as follows:

++ For both Monday visits, all the services provided by the nurse were associated with furnishing NPWT using a disposable device. The nurse did not provide any services that were not associated with furnishing NPWT using a disposable device. Therefore, all the nursing services for both Monday visits should be reported on TOB 34x with CPT® code 97607 or 97608. None of the services should be reported on TOB 32x.

++ For the Thursday visit, the nurse checked the wound, but did not apply a new disposable NPWT device, so even though the nurse provided care related to the wound, those services would not be considered furnishing NPWT using a disposable device. Therefore, the services should be reported on bill type 32x and no services should be reported on bill type 34x.

• *Example #3:*

• On Monday, the nurse applies a new disposable NPWT device. On Thursday, the nurse returns for a scheduled visit to change the beneficiary's indwelling catheter. While there, the nurse assesses the wound and applies a new fluid management system (or dressing) for the existing disposable NPWT device, but does not replace the device entirely. In this scenario, the billing procedures are as follows:

++ For the Monday visit, all the nursing services were associated with furnishing NPWT using a disposable device. The nurse did not provide any services that were not associated with furnishing NPWT using a disposable device. Therefore, the HHA should report the nursing visit on TOB 34x with CPT® code 97607 or 97608; the visit should not be reported on a 32x claim.

++ For the Thursday visit, while the nursing services included wound assessment and application of a component of the disposable NPWT device, the nurse did not furnish a new disposable NPWT device. Therefore, the nurse did not furnish NPWT using a disposable device, so the HHA should report all the nursing services for the visit, including the catheter change and the wound care, on TOB 32x.

• *Example #4:*

On Monday, the nurse applies a new disposable NPWT device, and provides instructions for ongoing wound care. During this same visit, per the HH plan of care, the nurse changes the indwelling catheter and provides troubleshooting information and teaching regarding its maintenance. In this scenario, the billing procedures are as follows:

++ The visit included applying a new disposable NPWT device as well as services unrelated to that NPWT service, which means the HHA will submit both a TOB 34x and a TOB 32x.

++ For furnishing NPWT using a disposable device, that is, the application of the new disposable NPWT device and the time spent instructing the beneficiary about ongoing wound care, the HHA would bill using a TOB 34x with CPT® code 97607 or 97608.

++ For services not associated with furnishing NPWT using a disposable device, that is, for the replacement of the indwelling catheter and instructions about troubleshooting and maintenance, the HHA would bill under TOB 32x.

Comment: Several commenters suggested that CMS' payment proposal for furnishing NPWT using a disposable device was not consistent with the intent of section 504 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), which they believe is to facilitate the use of less expensive disposable devices in place of more costly DME equipment for wound therapy. Commenters maintained that the payment amount required by the statute is only for the disposable NPWT device and does not incorporate the services associated with the device. They stated that, because the statute refers to a separate payment for the NPWT device, the payment amount is meant to be a payment over and above the home health payment for providing the service. Commenters asserted that, by not allowing the reporting of a home health visit associated with the application of a disposable NPWT device, we would be encouraging providers to continue to provide conventional DME equipment for NPWT rather than NPWT using a disposable device, which effectively limits treatment choices and ignores patient preferences, and is therefore inconsistent with the intent of the statute.

Response: Section 1834(s)(3) of the Act, as added by section 504 of the Consolidated Appropriations Act, 2016, specifies that the payment amount for an applicable disposable device must be equal to the amount of payment that would be made under the hospital outpatient PPS for the HCPCS code ''for which the description for a professional service includes the furnishing of such device.'' The OPPS payment amounts associated with CPT® codes 97607 and 97608 include both the device cost and the related services for furnishing the device (including topical application(s), wound assessment, and instruction(s) for ongoing care). Therefore, the payments we will make for furnishing NPWT with a disposable device beginning CY 2017 will include amounts for both the device and the associated services, which we believe is consistent with the statute. We do not believe our policy will necessarily encourage or discourage the continued use of DME as a treatment option.

We are codifying this policy in our regulations at § 484.205(b), where we state that the separate payment described here is not included in the episode payment. This is a technical amendment that reflects our proposed policy without any change.

Comment: Several commenters requested more details regarding the definition of ''non-manual vacuum pump,'' as that term is used in section 1834(s)(2)(A) of the Act. Commenters also questioned if there are any disposable negative pressure wound therapy pumps that would not qualify for the separate payment.

Response: Section 1834(s)(2) of the Act defines ''an applicable disposable device'' as ''a disposable device that, as determined by the Secretary, is—(A) 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; and (B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.'' We interpret the term ''non-manual'' in the definition to mean, not powered by hand, but rather, powered automatically, mechanically, or electronically. Additionally, a disposable NPWT device is one that stimulates tissue growth and does not simply collect wound exudate (for example,. a Jackson-Pratt drain), and is used in lieu of a DME NPWT system.

We recognize that there are various disposable NPWT devices, and the decision to select one of these systems is usually determined by wound characteristics, indications for use, and in collaboration between the patient's physician and the patient to achieve desired outcomes. If the NPWT disposable device meets the statutory definition, as articulated in section 1834(s)(2) of the Act, then it would be eligible for the separate payment for

furnishing NPWT using a disposable device. Conversely, if a disposable NPWT device does not conform to the definition outlined in the Consolidated Appropriations Act, 2016, then it would not be considered an ''applicable disposable device.''

Comment: Several commenters requested clarification on coverage for those patients who qualify for the Medicare home health benefit, but only receive services from a HHA for CPT® code 97607 or 97608 on a 34x claim. One commenter noted that some HHAs believe the proposed policies for furnishing NPWT using a disposable device will prevent them from billing for other skilled visits related to wound care that occur more frequently than once every seven days when the disposable NPWT device is scheduled to be replaced, and they requested clarification.

Response: When a home health beneficiary receives *only* services related to furnishing NPWT using a disposable device, the HHA will submit only a TOB 34x. Although a HHA may not submit a TOB 32x, the beneficiary of those services is still recognized as a Medicare-covered home health patient. This instruction applies when the *only* home health service being provided in a visit is the furnishing of NPWT using a disposable device, that is, the initial application or replacement of the disposable NPWT device in its entirety. This policy will not prevent HHAs from billing for other skilled visits related to wound care that occur when a new device is not being applied or a device is being entirely replaced.

Clinical practice guidelines for disposable NPWT devices recommend topical dressing changes at least one time per week in between those visits where a new disposable NPWT device is applied or replaced in its entirety.[14] Therefore, if clinical practice guidelines are followed, there will be skilled nursing visits pertaining to wound management, other than for applying a disposable NPWT device in its entirety, and those services would be billed for on the HH PPS claim (TOB 32x), when medically reasonable and necessary.

Comment: One commenter questioned how claims will be billed where the only skilled service is billed on a 34x claim but dependent services are also provided.

Response: To ensure appropriate payment for dependent services (for example, home health aide visits, medical social services) dictated by the beneficiary's plan of care, we will permit TOB 32x home health claims to be used to bill dependent services when the only skilled service (furnishing NPWT using a disposable device) is billed on a 34x claim, as the commenter described. Specifically, we will permit those TOB 32x home health claims, as long as both (1) the patient qualified for home health on the basis of intermittent skilled nursing care that consisted of furnishing NPWT using a disposable device, and (2) condition code 54 (effective July 1, 2016) is used. This code indicates that, (1) the HHA provided no skilled services via the TOB 32x during the billing period (that is, the patient ceased to receive the skilled service that qualifies the patient for the home health benefit—skilled nursing (SN), physical therapy (PT), speech-language pathology services (SLP), or a continued need for occupational therapy after such time that the need for SN, PT or SLP, via the TOB 32x ceased), but that, (2) the HHA has documentation on file of an allowable circumstance for the provision of non-skilled services. The official instructions regarding use of condition code 54 can be found on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3553CP.pdf*.

Comment: Several commenters stated that the OPPS payment amounts for CPT® codes 97607 and 97608 do not capture the administrative costs of a home health care plan, and requested clarification on how the HHA will be paid for these costs.

Response: Section 1834(s) of the Act stipulates that payment for a disposable NPWT device must be equal to the amount of the payment that would be made under the OPPS amount for the HCPCS code for which the description for a professional service includes the furnishing of such device. While that payment amount will cover the costs of the device and related services, we understand the commenters are asking how the administrative costs of home health care that are not built into the OPPS payment amounts for CPT® codes 97607 and 97608 will be paid for. We expect that payment for furnishing NPWT using a disposable device will almost always be made in addition to a HH episode payment, which already includes reimbursement for overhead and administrative costs. These administrative costs are reported on HHA cost reports in accordance with § 484.210, which states that one factor in the calculation of the national, standardized 60-day episode payment is ''Medicare cost data on the most recent audited cost report data available.''

Per the home health Conditions of Participation (CoPs) at § 484.18, a Medicare beneficiary receiving services from a Medicare-certified HHA must be under the care of a physician and the services provided must be in accordance with the home health plan of care. A plan of care developed for a patient should cover all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. Therefore, even when a beneficiary requires NPWT furnished using a disposable device, for which payment will be made outside the HH PPS, the beneficiary will also be provided the services and supplies specified in the HH plan of care, and those other services will be paid a HH episode payment under the HH PPS. Additionally, if the HH PPS claim (32x) includes 4 or fewer visits, the national per-visit payment rates paid account for administrative costs, and if the episode is the only episode or the first episode in a sequence of adjacent episodes separated by no more than a 60-day gap, the episode would be eligible for an add-on payment that accounts for the ''front-loading'' of costs incurred in an episode of care (72 FR 49848 and 49849). Therefore, we believe the existing payment policy approach for LUPA episodes represents appropriate payment for episodes that include the furnishing of NPWT using a disposable device as the LUPA payment, and any eligible LUPA add-on, take into account the administrative costs.

Comment: A few commenters inquired as to the low-utilization payment adjustment (LUPA) payment policy as it relates to visits reported on both a 32x and 34x type of bill. Specifically commenters requested clarification on a scenario in which the total number of home health visits provided is more than four, but four or fewer of those visits are billed on a 32x claim, with the remaining visits billed on a 34x claim. Commenters wanted to know whether or not the HHA would receive a LUPA payment or LUPA add-on payment.

Response: If a HHA provides four or fewer visits on the HH PPS claim (32x), the HHA will be paid a standardized per visit payment instead of a 60-day episode payment. This payment adjustment is referred to as a low-

[14] Sandoz H., (2014). Negative pressure wound therapy: clinical utility. Chronic Wound Care Management and Research. Volume 2. 71–79 doi.org/10.2147/CWCMR.S48885.

utilization payment adjustment, or LUPA. For the purposes of determining whether an episode receives the full episode payment amount or a LUPA, only visits on the 32x HH claim will be counted. Visits that are submitted via 34x claims will not count as a visit for purposes of determining whether a HHA receives a full episode payment or a LUPA. Services reported on 34x claims are for certain medical and other health services which are paid from the Part B that are paid outside the HH episode payment. Just as services reported on TOB 34x are not reimbursed under the HH 60-day episode payment, they are also not reimbursed as part of a LUPA.

As indicated in the comment response above, if a LUPA episode is the first episode in a sequence of adjacent episodes or is the only episode of care the beneficiary received, Medicare makes an additional payment called a LUPA add-on payment. Similar to the policy regarding LUPAs, visits for furnishing NPWT using a disposable device will not count as visits for purposes of the LUPA add-on payment. The LUPA add-on payment will still be made for any 32x claim that includes four or fewer visits that is considered the first episode in a sequence of adjacent episodes or is the only episode of care, regardless of whether additional visits are reported for disposable NPWT devices on the TOB 34x.

Comment: Several commenters stated that the implementation of the proposed policies for NPWT using a disposable device would pose a tremendous administrative and operational burden, citing that the policy would necessitate systems changes as well as changes to billing practices. Several commenters noted that they are concerned that the proposed billing approach is overly complicated and will result in both provider and beneficiary confusion.

Response: In accordance with section 1833(a)(1)(AA) of the Act, the Medicare payment amount for furnishing NPWT using a disposable device will be 80 percent of the lesser of the actual charge or the amount equal to the established OPPS amount, and we are requiring HHAs to submit claims for those services on a TOB 34x. We understand some commenters are concerned about the systems and billing changes they may have to make to implement this new policy, but we note that certain services provided under a home health plan of care, but for which reimbursement is not covered under the HH PPS, are currently billed utilizing the TOB 34x (for example, osteoporosis injections and vaccine administration). In addition, certain services provided that are *not* under a home health plan of care are also billed by HHAs on the 34x (for example, diabetes self-management training, smoking and tobacco-use cessation counseling services, bone mass measurements, etc.). Therefore, HHAs should already have familiarity with the procedures for billing as well as the systems requirements necessary for submitting the 34x claim type. However, we recognize the concerns about the education of providers, beneficiaries, and other stakeholders with regard to this new payment policy. We will utilize existing outreach and educational mechanisms such as Open Door Forums, Medicare Learning Network articles, and other products with the goal of educating stakeholders regarding this new payment policy for disposable NPWT devices.

Comment: A few commenters suggested that CMS allow HHAs additional time to make the necessary internal system changes by extending the implementation deadline to July 1, 2017 or another future date. Commenters noted that the postponement would allow time for implementation and appropriate enforcement of the policy.

Response: We acknowledge that some commenters would like additional time to prepare their systems, but section 1834(s)(1) of the Act specifies that the separate payment requirement for applicable disposable devices applies to such devices furnished on or after January 1, 2017.

Comment: Some commenters suggested that requiring separate billing for disposable NPWT devices represents a shift in the benefit away from holistic, interdisciplinary home health care towards a more fragmented benefit.

Response: We appreciate the concern regarding the provision of comprehensive care for home health beneficiaries. HH clinicians should continue to conduct home visits in a comprehensive, holistic manner. The HH plan of care is meant to meet the clinical, psychosocial, and daily living needs of the patient, and should remain focused on the appropriate care. However, accurate accounting of services provided is also an integral part of the provision of home health care through the Medicare benefit. In order for us to provide accurate payment, there must be proper accounting of the services provided by Medicare providers. Therefore, adherence to billing procedures and requirements, including the accurate accounting of services and interventions, is expected in conjunction with the provision of care.

Comment: A few commenters requested clarification regarding which practitioners are permitted to provide NPWT using a disposable device, specifically wanting to know whether licensed practical nurses (LPNs) may do so.

Response: Because specific services can be provided by either a therapist or a non-therapist, CMS created the designation ''sometimes therapy.'' When a code is designated as ''sometimes therapy,'' it may be performed by a qualified therapist (for example, physical therapist or occupational therapist) under a certified therapy plan of care or by another qualified clinician. As we discuss in the proposed rule (81 FR 43743 and 43744), because CPT® codes 97607 and 97608 are considered ''sometimes therapy'' codes (as described in section 200.9 of Chapter 4 of the Medicare Claims Processing Manual),[15] furnishing NPWT using a disposable device for patients under a home health plan of care can be performed by either a physician or a non-physician practitioner, consistent with other CMS guidance. In the proposed rule, we specifically stated that ''sometimes'' therapy can be performed, in accordance with State law, by a registered nurse, physical therapist, or occupational therapist (81 FR 43743). While we believe that the complex nature of furnishing disposable NPWT would best be performed by a registered nurse, physical therapist, or occupational therapist, we recognize that LPNs often provide skilled services, including wound care, to HH beneficiaries in accordance with State law and per agency policies. Per Chapter 7 of CMS's Benefit Policy Manual; section 40.1.2.8, wound care, which would include furnishing NPWT using a disposable device, is considered to be a skilled nursing service, for which the skills of a licensed nurse are usually reasonable and necessary. Skilled nursing services are those provided by skilled, licensed nursing professionals, which includes both LPNs and RNs. Therefore, LPNs also may furnish NPWT using a disposable device in accordance with State law and agency policies.

Comment: One commenter requested clarification regarding the application of the OPPS wage index to the payment amount for a disposable NPWT device.

Response: Since the payment amount for both CPT® codes 97607 and 97608 will be set equal to the amount of the payment that would be made under the

[15] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c04.pdf.*

OPPS, the payment amount would also be subject to the area wage adjustment policies in place under the OPPS in a given year. We note that the wage index that will apply to this payment will be equal to the current OPPS wage index; for example, for CY 2017 payments for disposable NPWT devices, the CY 2017 OPPS wage index will apply.

Comment: A few commenters urged CMS to provide guidance on how this new disposable NPWT device policy will affect clinical documentation requirements in the medical record.

Response: There are no additional documentation requirements for the provision of NPWT using a disposable device. All existing policies and guidelines will still apply. HHAs may also follow their own internal policies and procedures for documenting clinical information in the patient's medical record beyond those required by regulation.

Final Decision: After consideration of all public comments, we are finalizing our proposal as proposed including the corresponding proposed changes to the regulations at § 409.50. A separate payment will be made to a HHA for furnishing NPWT using a disposable device to an individual who receives home health services for which payment is made under the Medicare home health benefit, for services furnished beginning January 1, 2017. The payment amount for furnishing NPWT using a disposable device under a HH plan of care will be equal to the lesser of the actual charges or the OPPS payment amount for CPT® codes 97607 and 97608, and must be billed via the 34x TOB. HHAs may not bill for furnishing NPWT using a disposable device on a TOB 32x. Payment for HH visits related to wound care, but not requiring the furnishing of an entirely new disposable NPWT device, will still be covered by the HH PPS episode payment and must be billed using TOB 32x. Where a home health visit is exclusively for the purpose of furnishing NPWT using a disposable device, the HHA will submit only a TOB 34x. Where, however, the home health visit includes the provision of other home health services in addition to, and separate from, furnishing NPWT using a disposable device, the HHA will submit both a TOB 32x and TOB 34x—the TOB 32x for other home health services and the TOB 34x for furnishing NPWT using a disposable device. Physical therapists, occupational therapists, registered nurses, and licensed practical nurses are permitted to provide NPWT using a disposable device under a home health plan of care.

Additionally, we are making a technical amendment to the language at 42 CFR 409.50 to update the language regarding beneficiary coinsurance liability for DME and applicable disposable devices. We proposed to amend § 409.50 to account for the coinsurance liability of the beneficiary for applicable disposable devices as ''20 percent of the customary (as reasonable) charge for the services.'' In this final rule, consistent with section 1833(a)(1)(AA) of the Act, we are revising that language to specify that the coinsurance liability for an applicable disposable device is 20 percent of the payment amount for furnishing NPWT using a disposable device (as that term is defined in § 484.202). The changes to § 409.50 are found in section VIII. of this final rule.

And, as part of this final rule, we are clarifying that furnishing NPWT using a disposable device means the HHA is furnishing a new disposable NPWT device, that is, the HHA provider is either initially applying an entirely new disposable NPWT device or removing a disposable NPWT device and replacing it with an entirely new one. As such, we are amending § 484.202 to include the definition of ''furnishing NPWT using a disposable device.'' We are also codifying our final policy, in § 484.205(b), that separate payment is made for furnishing NPWT using a disposable device, which is not included in the episode payment. We did not propose to amend the regulations at § 484.202 or § 484.205, but we believe it is appropriate to include the new policy in the regulation text. The specific changes we are making in the regulations simply codify the final policies we described in the proposed rule and do not reflect any additional substantive changes.

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 the CY 2017 HH PPS proposed rule (81 FR 43744), we provided 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 the principal diagnosis based on the expected primary home health interventions that would be required during the episode of care for that diagnosis. 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, including timing of the episode, referral source, functional/cognitive level, and comorbidity adjustment.

While we did not solicit comments on the HHGM in the proposed rule, we received nine comments on the HHGM model. Commenters were generally supportive of the model, but stated that more detailed information is needed before they could provide any substantive comments. As stated in the proposed rule, we will be releasing a Technical Report which will provide more detail as to the research and the analysis conducted on the HHGM. Once the Technical Report is released, we will post a link on our Home Health Agency (HHA) Center Web site at *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html* to receive additional comments and feedback on the model.

G. Update on Future Plans to Group HH PPS Claims Centrally During Claims Processing

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, speech-language pathology, occupational therapy, and medical social services)

and non-routine medical supplies. To adjust for case-mix, the HH PPS uses a 153-category case-mix 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. HHAs enter data collected from their patients' OASIS assessments into a free data collection software tool (JHAVEN) provided by CMS. 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 claim, ultimately enabling our claims processing system to reimburse the HHA for services provided to patients receiving Medicare home health services.

We recently implemented a process where we match the claim and the OASIS assessment in order to validate the HIPPS code on the Medicare claim. In addition, we have conducted an analysis and prototype testing of a java-based grouper with our Fiscal Intermediary Shared System (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 of HIPPS codes on claims and decrease costs and burden to HHAs.

In the CY 2017 HH PPS proposed rule, we solicited public comments on grouping HH PPS claims centrally with the claims processing system (81 FR 43746. If we group 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 will also address current payment vulnerabilities associated with the potential for misreporting HIPPS codes on the claim.

The following is a summary of the comments we received regarding our future plans to group HH PPS claims centrally during claims processing.

Comment: Several commenters supported CMS' proposal to implement centralized grouping of HH PPS claims. These commenters believed that centrally grouping HH claims should simplify and improve the accuracy of HIPPS code assignment and OASIS matching. The commenters would welcome a process that they expect will improve payment accuracy, decrease costs, and reduce administrative burden on providers. One commenter also noted that this proposal would decrease the potential that legitimate claims will be incorrectly identified as fraudulent.

Response: We appreciate the commenters support and agree that grouping claims centrally within the claims processing system will reduce errors associated with reporting incorrect HIPPS codes and OASIS matching. In addition, we also expect that grouping claims centrally will reduce HHA costs and administrative burden. We also believe that it will lead to a more streamlined, efficient claims processing system and improved payment accuracy.

Comment: Several commenters requested that CMS still continue to provide the grouper software and/or algorithm in order for providers to be able to calculate the HIPPS codes so that they can determine the expected reimbursement amount for each claim. The commenters further stated that the ability to value their account receivables is an important business function and necessary for financial reporting purposes.

Response: We understand the importance of HHAs being able to value their account receivables as part of their business processes and planning and we will consider this recommendation as we continue to explore options for grouping HH PPS claims centrally during claims processing.

Comment: One commenter requested that CMS develop an effective and timely communication process to provide the HIPPS codes resulting from the new grouper/claims process.

Response: The HIPPS codes will not change as a result of grouping claims centrally within the claims processing system. We will provide HHAs and other interested parties with sufficient notice and updates regarding our future plans via future rulemaking, our HHA Center page located at *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html*, and our home health, hospice and DME open door forums.

Comment: One commenter requested that CMS provide agencies the ability to review and correct their data submissions similar to what occurs now. If OASIS data corrections cause the assigned HIPPS code to change, the HHA should be able to cancel and resubmit the Request for Anticipated Payment (RAP).

Response: If an OASIS correction results in a new HIPPS code, HHAs would still be able to cancel the RAP and resubmit. A new HIPPS code will be generated within the claims processing system once the new RAP is submitted.

We appreciate the positive feedback and thoughtful comments that we have received regarding this proposal. We continue to believe that this process will increase payment accuracy and will reduce costs and burden to HHAs. We will continue to explore options for grouping HH PPS claims centrally during claims processing.

IV. Provisions of the Home Health Value-Based Purchasing (HHVBP) Model and Analysis of and Responses to Comments

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 Medicare-certified 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 CY 2018 based on performance on applicable measures. Payment adjustments will be increased incrementally over the course

of the HHVBP Model in the following manner: (1) A maximum payment adjustment of 3 percent (upward or downward) in CY 2018; (2) a maximum payment adjustment of 5 percent (upward or downward) in CY 2019; (3) a maximum payment adjustment of 6 percent (upward or downward) in CY 2020; (4) a maximum payment adjustment of 7 percent (upward or downward) in CY 2021; and, (5) a maximum payment adjustment of 8 percent (upward or downward) in CY 2022. Payment adjustments will be based on each HHA's Total Performance Score (TPS) in a given performance year (PY) on (1) a set of measures already reported via OASIS and HHCAHPS for all patients serviced by the HHA and select claims data elements, and (2) three New Measures where points are achieved for reporting data.

B. Smaller- and Larger-Volume Cohorts

As finalized in the CY 2016 HH PPS final rule, 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 into 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 smaller volume 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). As discussed in more detail below, we proposed, and are finalizing, the following changes to this methodology: (1) Calculation of the benchmarks and achievement thresholds at the state level rather than the state and size level and (2) a required minimum of 8 HHAs in a cohort.

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 were calculated for both the larger-volume cohort and for the smaller-volume cohort of HHAs in each state, based on a baseline period running from January 1, 2015 through December 31, 2015. In the CY 2016 HH PPS final rule, 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 year 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 cohort use for benchmarking and threshold purposes because they have been used for several years in other CMS quality initiatives such as 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 OASIS benchmarks and achievement thresholds using 2015 data that was not available when we did the analyses included in the CY 2016 HH PPS final rule. We calculated the benchmarks and achievement thresholds for each OASIS measure for the smaller- and larger-volume 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 smaller-volume 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. 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 were concerned that this high variation was not the result of expected differences, like state regulatory policy, but was instead the result of (1) the cohort being so small that there were not enough HHAs in the cohort to calculate the values using the finalized methodology (mean of the top decile); or (2) the cohort being large enough to calculate the values using the finalized methodology, but there were not enough HHAs in the cohort to generate reliable values.

We are including here Tables 21, 22, and 23, which were included as Tables 28, 29 and 30 in the proposed rule (81 FR 43748–43749), to help illustrate this issue below. 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 when the proposed rule was in development we did 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 21, Table 22 and Table 23 represent the OASIS measure benchmarks for the smaller-volume cohorts, larger-volume cohorts and the state level (which includes HHAs from both smaller- and larger-volume cohorts), respectively.

For example, the differences in benchmark values for Iowa and Nebraska (two of the four states that

have smaller-volume cohorts) for the Improvement in Bed Transferring measure are: 13.1 (72.7 for Iowa and 85.8 for Nebraska) for the smaller-volume cohort (Table 21); 4.1 (78.1 for Iowa to 82.2 for Nebraska) for the larger-volume cohort (Table 22); and 5.5 (77.6 for Iowa to 83.1 for Nebraska) for the state level cohort (Table 23). We believe that the higher range for the smaller-volume cohorts in these states is a result of the smaller number of HHAs in these cohorts.

TABLE 21—SMALLER-VOLUME COHORT BENCHMARKS

Oasis-based measures	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Discharged to Community	77.0	88.8	73.6	82.0	.....	75.1	81.1	79.4	.....
Drug Education on All Medications Provided 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	63.0	74.0	58.4	62.0	.....	62.8	65.8	58.9	.....
Improvement in Pain Interfering with Activity	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	.....
Pneumococcal Polysaccharide Vaccine Ever Received	95.8	91.5	95.8	95.3	.....	83.6	97.0	100.0	.....

TABLE 22—LARGER-VOLUME COHORT BENCHMARKS

Oasis-based measures	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
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 Provided 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 Activity	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 23—STATE LEVEL COHORT BENCHMARKS

Oasis-based measures	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
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 Provided 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 Activity	88.1	96.8	81.5	88.4	84.4	81.5	84.3	81.7	75.5

TABLE 23—STATE LEVEL COHORT BENCHMARKS—Continued

Oasis-based measures	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
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 data available during the development of the proposed rule. The results highlight that there is a greater degree of inter-state 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 compared 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 described above, we are concerned that if we separate the HHAs into smaller- and larger-volume 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 greater than the level of performance that HHAs in the larger-volume cohorts would be required to achieve. For this reason, we proposed 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 requested public comments on this proposal.

Comment: Most of the comments we received supported this proposal. Several commenters supported this policy because it would reduce variability in performance standards. Some commenters stated that state level comparison cohorts would provide a more robust benchmark than the state level and size based cohort. Some commenters expressed some concern about the proposed change. One commenter suggested CMS should conduct ongoing research to determine the effectiveness of using state level and size based cohorts. One commenter, MedPAC, recommended that CMS calculate benchmarks and achievement thresholds at a national level because Medicare is a national program and there is the possibility that a state level focus could reward low quality agencies. Finally, one commenter stated that it does not make sense to compare disparate groups of HHAs whether the comparisons are done at the local, state, or national levels or even, as currently exists in the Model, among HHAs with similarly-sized patient cohorts but did not provide specific reasons for their view.

Response: We appreciate commenters' support for our proposal to calculate benchmarks and achievement thresholds at the state level. Calculating the benchmarks and achievement thresholds at the state level, rather than at the state level and size cohort level, will eliminate the increased variation caused by having too few HHAs in a cohort. In addition, calculating the benchmarks and achievement thresholds at the state level, rather than the national level, is consistent with the factors considered in proposing selection at the state level, as discussed in the CY 2016 HH PPS final rule (81 FR 68659), including that HHAs should be competing within the same market and that the Model should align with other CMS programs like Home Health Compare and Home Health Five Star that report by state. Calculating the benchmarks and achievement thresholds at the state level rather than at the national level also allows the Model to take into account the inter-state variation in quality measurement due to different state regulatory environments. We will continue to monitor and research the effectiveness of using state level cohorts.

Comment: We received comments that were outside of the scope of our proposed change to the benchmark and achievement threshold calculations. Several commenters expressed concern that HHAs will not know what benchmarks are needed to avoid penalty until the end of the 2016 performance year, and recommended that CMS establish prospective benchmarks based on historical performance so it is clear to HHAs the level of achievement necessary to avoid penalties. Commenters stated that agencies may not invest in quality improvement activities if the potential financial return is difficult to determine and recommended that CMS set benchmarks at a level where most providers have a reasonable expectation of achieving them. A few commenters supported 2015 as the baseline year, and suggested providing HHAs with mid-course snapshots of their performance against the benchmarks. A commenter was concerned that using improvement scores was not sufficiently beneficiary-focused because what really matters are the agency's actual levels of performance. Several other commenters were concerned that using 'improvement' scores may create inequities in payment and penalties because agencies with equal or better levels of achievement could score lower than agencies with lower achievement but higher improvement scores. Another commenter expressed concern that the limited state selection will not sufficiently represent the entire Medicare population due to the lack of measures relating to stabilization and maintenance. Finally, one commenter stated that improvement scores should only exist for the first 3 years of the Model.

Response: As noted, these comments are outside of the scope of the proposed methodology change in the CY 2017 HH PPS proposed rule; however, we are clarifying here the calculation of the benchmarks and how HHAs are notified of the benchmarks. The methodology for calculating the achievement thresholds and benchmarks was described in the CY 2016 HH PPS final rule (80 FR 68681). The achievement threshold for each measure used in the Model is calculated as the median of all HHAs' performance on the specified quality measure during the baseline period (CY 2015). The benchmark is calculated as the mean of the top decile of all HHAs' performance on the specified quality measure during the baseline period (CY 2015). As noted above, we are finalizing a change to the methodology as described in the CY 2016 HH PPS final

rule to calculate benchmark and achievement thresholds at the state level, rather than at the state and cohort-size level.

The preliminary complete set of benchmarks was based on 2015 data for all measures in the Model, calculated both at the state and cohort-size level, was made available to competing HHAs on HHVBP *Connect.* HHVBP *Connect* was available beginning February 2016 and allows HHAs to attain general information about the Model, including the initial baseline benchmarks and achievement thresholds. The most current baseline achievement thresholds and benchmarks used 2015 quality data from the Model's OASIS measures (12 months), HHCAHPS measures (9 months), and claims measures (9 months). This data was posted in April 2016 on HHVBP *Connect.* The baseline achievement thresholds and benchmarks that was based on 12 months for the HHCAHPS measures and the claims measures were included in the Interim Performance Report posted in July 2016 on the HHVBP Secure Portal. The HHVBP Secure Portal was available in May 2016, which allows HHAs to view their own specific measures and scores. The quarterly Interim Performance Reports also allow HHAs to monitor their performance on the quality measures used to calculate their TPS. The Interim Performance Reports (IPRs) posted to the HHVBP Secure Portal in July 2016 included performance scores for the OASIS-based measures for the first quarter of CY 2016. The next IPRs, which are to be posted to the HHVBP Secure Portal in October 2016, will include performance scores for HHCAHPS measures and claims-based measures for the first quarter of CY 2016 as well as the performance scores for the OASIS-based measures for the second quarter of CY 2016. HHAs' performance on the 17 initial measures of the Model (as finalized in section IV.C of this final rule) for CY 2016 to CY 2020 will be determined using state-level achievement thresholds and benchmarks, and individual HHA baseline values calculated using data from the 2015 baseline year; consistent with the finalized proposal to calculate benchmarks and achievement thresholds at the state-level. Performance scores to be posted on the HHVBP Secure Portal in October 2016 will be calculated using the state-level cohort baseline benchmarks and achievement thresholds. HHAs will receive points if they achieve performance equal to or above the achievement threshold, calculated as the median of 2015 values.

Final Decision: For the reasons stated above and in consideration of the comments received, we are finalizing our proposal to calculate the benchmarks and achievement thresholds at the state-level rather than the smaller- and larger-volume cohort level.

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 value-based 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 larger-volume 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. 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 37 of the proposed rule, which is also included as Table 37 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, −2.0 percent 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 38 of this rule. Under the payment distribution for the larger-volume cohorts, 80 percent of the HHAs in AZ, IA, FL and NE would receive a payment adjustment ranging from –2.2 percent to +2.2 percent when the maximum payment adjustment is 5 percent (See state level cohort in Table 38). Arizona is a state that has a smaller-volume 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 percent.

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 claims-based 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 + 2.4 percent. As a result of this analysis, we proposed 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 larger-volume cohort. We stated that 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 HHAs.

We also proposed 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. We stated that if finalized, this change would apply to the CY 2018 payment adjustments and thereafter. We further stated that we will continue to analyze and review the most current cohort size data as it becomes available.

We requested public comments on this proposal.

Comment: Most of the commenters supported the proposed requirement for a minimum of eight HHAs in any size cohort. One commenter suggested that eight HHAs in a smaller-volume cohort could still be significantly impacted by an outlier. A commenter requested more information about how the minimum of 8 HHAs in the cohort was determined. Another commenter suggested that we use a minimum of 12 HHAs rather than 8 HHAs as the minimum number of HHAs required in the cohort. Another commenter suggested that CMS implement economies of scale between agencies to account for the business advantages that larger HHAs have over smaller ones but did not provide any more specific detail. Finally, one commenter suggested that CMS should compare HHAs nationally by altering qualification requirements so that states with a smaller number of qualified agencies can benchmark against national requirements.

Response: We believe that a minimum of 8 HHAs per cohort represents a figure significant enough to mitigate the effect of outliers. As we discussed in the proposed rule, we analyzed performance results related to OASIS and claim-based measures, as well as HHCAHPS, using 2013 and 2014 data to determine if an HHA in a cohort with a minimum number of HHAs would be at a disadvantage with respect to the impact of outlier HHAs on the payment adjustments, when compared to HHAs in larger size cohorts. With this information, we simulated the impact that outliers would have on cohort sizes ranging from 4 to 12 HHAs. We found that, in contrast to the calculation of the achievement thresholds and the benchmarks, the LEF had lower susceptibility to large variation caused by outliers even with a relatively small number of HHAs in the cohort. By running simulations using the data described above, we found that the distribution of payment adjustments was similar whether the number of HHAs in the cohort was 8, 12 or over 30 HHAs. More specifically, having 8, 12 or over 30 HHAs in the cohort permitted the LEF to distribute payments such that 80 percent of the payment adjustments was between −2.5 percent and + 2.5 percent. Further, we conducted a sensitivity analysis examining the difference in the impact that an outlier HHA would have on a cohort size of 8 HHAs as compared to a cohort size of 12 HHAs. By running simulations of adding an outlier to a cohort with 8 HHAs and a cohort of 12 HHAs, we identified that the difference in impact on the payment adjustment on the non-outlier HHAs in the cohort ranged from 0.1 percent to 0.13 percent. We believe that having a minimum of 8 HHAs in the cohort ensures that there are enough states in the Model with a smaller-volume cohort to analyze the impact on competition at the different cohort size levels, and that this outweighs the marginal difference in the impact of outliers as compared to using a minimum of 12 HHAs.

Although it may be operationally possible to have all the smaller-volume HHAs in the nine states compete against each other in a national pool, having HHAs compete at the state level (that is, all HHAs in a state or a cohort of HHAs in the same state) rather than at the national level enables the Model to address the issue of inter-state variation in quality measurement that could be related to different state regulatory environments. This is especially important when considering that performance incentives could flow from states with lower measure scores to states with higher measures scores because of state regulatory differences rather than the quality of care that HHAs provide.

We will continue to monitor and research the impact of cohort size on different measurements.

Final Decision: For the reasons stated above and in consideration of the comments received, we are finalizing the proposal that there must be a minimum of eight HHAs in any size cohort. Under this final policy, a smaller-volume cohort must have a minimum of eight HHAs in order for the HHAs in that cohort to be compared only against each other, and not against the HHAs in the larger-volume cohort. If a smaller-volume cohort in a state has fewer than eight HHAs, those HHAs will be included in the larger-volume cohort for that state for purposes of calculating the LEF and payment adjustment percentages.

C. Quality Measures

In the CY 2016 HH PPS final rule, we finalized a set of quality measures in Figure 4a: Final PY1 Measures and Figure 4b: Final PY1 New Measures (80 FR 68671 through 68673) for the HHVBP Model to be used in PY1, referred to as the ''starter set''.

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 [16] (80 FR 68668). The NQS domains include six priority areas identified in the CY 2016 HH PPS final rule (80 FR 68668) as the CMS Framework for Quality Measurement Mapping. These areas are: (1) Clinical quality of care, (2) Care coordination, (3) Population & community health, (4) Person- and Caregiver-centered experience and outcomes, (5) Safety, and (6) Efficiency and cost reduction. Figures 4a and 4b (inadvertently referred to as Figures 5 and 6 in the CY 2017 HH PPS proposed rule) 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).

[16] 2015 Annual Report to Congress, *http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm.*

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 proposed 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 October 1 and March 31?; and (4) Reason Pneumococcal Vaccine Not Received. We proposed to remove these four measures, for the reasons discussed below, beginning with the CY 2016 Performance Year (PY1) calculations, and stated that we 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. As discussed later in this section, we are finalizing the proposed revisions to the measure set, as set forth in Table 31 of the proposed rule and Table 24 of this final rule, which will be applicable to each performance year subject to any changes made through future rulemaking.

We proposed 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 CY 2016 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 stated that 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 proposed 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 proposed 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 Model measure ''Influenza Immunization Received for Current Flu Season'' and was not designed as an additional and separate measure of performance.

We proposed 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 proposed 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 also proposed 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 finalized set of applicable measures is presented in Table 24, which excludes the four measures we proposed to remove. For the reasons stated below and in consideration of the comments received, we are finalizing this measure set for 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.

TABLE 24—MEASURE SET FOR THE HHVBP MODEL [17]

NQS Domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care	Improvement in Ambulation-Locomotion.	Outcome	NQF0167	OASIS (M1860)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in ambulation/locomotion at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care	Improvement in Bed Transferring.	Outcome	NQF0175	OASIS (M1850)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bed transferring at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care	Improvement in Bathing	Outcome	NQF0174	OASIS (M1830)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bathing at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.

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

For NQF endorsed measures see The NQF Quality Positioning System available at *http://www.qualityforum.org/QPS*. For non-NQF measures using OASIS see links for data tables related to OASIS measures at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*. For information on HHCAHPS measures see *https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx*.

TABLE 24—MEASURE SET FOR THE HHVBP MODEL [17]—Continued

NQS Domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care	Improvement in Dyspnea	Outcome	NA	OASIS (M1400)	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Communication & Care Coordination.	Discharged to Community	Outcome	NA	OASIS (M2420)	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Efficiency & Cost Reduction	Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health.	Outcome	NQF0171	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Efficiency & Cost Reduction	Emergency Department Use without Hospitalization.	Outcome	NQF0173	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Patient Safety	Improvement in Pain Interfering with Activity.	Outcome	NQF0177	OASIS (M1242)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less frequent pain at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient Safety	Improvement in Management of Oral Medications.	Outcome	NQF0176	OASIS (M2020)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health	Influenza Immunization Received for Current Flu Season.	Process	NQF0522	OASIS (M1046)	Number of home health episodes during which patients a) received vaccination from the HHA or b) had received vaccination from HHA during earlier episode of care, or c) was determined to have received vaccination from another provider.	Number of home health episodes of care ending with discharge, or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health	Pneumococcal Polysaccharide Vaccine Ever Received.	Process	NQF0525	OASIS (M1051)	Number of home health episodes during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV).	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
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 episodes of care during which patient/caregiver was instructed on how to monitor the effectiveness of drug therapy, how to recognize potential adverse effects, and how and when to report problems (since the previous OASIS assessment).	Number of home health episodes of care ending with a discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient & Caregiver-Centered Experience.	Care of Patients	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Communications between Providers and Patients.	Outcome		CAHPS	NA	NA.
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.

TABLE 24—MEASURE SET FOR THE HHVBP MODEL [17]—Continued

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

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. In the CY 2017 HH PPS proposed rule, we proposed 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 proposed 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. We stated that under this proposal, for PY1, HHAs would report on this measure in October 2016 and January 2017. We further stated that HHAs would report on this measure in April 2017 for PY2 and annually in April thereafter. We stated that we believe 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 did not propose 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, ''Advance Care Planning'', and ''Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?''

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

We invited public comment on these proposals.

Comment: Most commenters expressed support for the removal of the four identified quality measures. One commenter disputed the accuracy of the rationale for removing the prior functioning measure on the basis that it has never been collected by HHAs, citing use of AM–PAC [activity measure for post-acute care], which is based on NQF0430, and urged reconsideration or further development of a measure that considers function (ADLs and IADLs) as a focus of occupational therapy services to this population.

Response: We appreciate the support regarding the proposed removal of these four measures. In regard to the one comment on the prior functioning measure, we determined that NQF0430 utilizes data from the AM–PAC (Activity Measure for Post-Acute Care), a proprietary tool that is not currently, and has never been collected by CMS or utilized in its home health quality programs. CMS will continue to consider how a prior functioning measure could inform a patient's potential for improving, along with its measure development work on functional status, caregiving, and other clinical indicators, to determine whether future modifications to the measure set would be appropriate. We are finalizing the removal of the following 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 October 1 and March 31; and (4) Reason Pneumococcal Vaccine Not Received as proposed.

Comment: Another commenter suggested that CMS move quickly to eliminate process measures that weakly correlate with health outcomes, and those that measure basic standards of care on which providers have achieved full performance.

Response: We appreciate the perspective on how process measures may correlate with health outcomes. We believe that the process measures selected for use in this Model, which primarily relate to receiving recommended vaccines, are correlated with positive population health outcomes. Regarding those measures where providers have achieved 'full performance', we are monitoring this and may propose in future rulemaking to remove one or more measures if we conclude that it is no longer appropriate for the Model.

Comment: Multiple commenters expressed support for removing the phrase ''starter set'' in describing the initial quality measures set. One commenter stated that while they had no issues with eliminating the phrase ''starter set'' from the quality measures set, CMS should not imply that it is a static set of measures.

Response: We appreciate the support regarding the proposed deletion of ''starter set'' from §§ 484.305, 484.315, and 484.320. CMS will continue to reexamine and revise the measures as needed to develop a concise set of measures for the HHVBP Model. We are finalizing the deletion of ''starter set'' from §§ 484.305, 484.315, and 484.320 as proposed.

Comment: One commenter urged CMS to align measures included in the HHVBP Model with measures being implemented under the provisions of the IMPACT Act when possible to align HHVBP Model measures with those in the HHQRP.

Response: There is intra-agency collaboration at CMS to ensure that measure selection is aligned among the various CMS post-acute care initiatives. We continue to consider options to effectively align future HHVBP Model measures with other HH measures developed to implement requirements under the IMPACT Act.

Comment: Multiple commenters stated their support to increase the New Measures data submission timeframe from 7 to 15 calendar days. There was no opposition to this change.

Response: We appreciate the support regarding the proposal to increase the New Measures data submission timeframe from 7 to 15 calendar days following the end of each reporting period. For the reasons stated in the proposed rule and in consideration of commenters' support for this modification, we are finalizing the 15-day submission timeframe for the New Measures as proposed.

Comment: We received multiple comments, including from MedPAC that supported changing the reporting requirements for the Influenza Vaccination Coverage for Home Health Personnel New Measure from quarterly to annual, including the suggestion that we not require this information to be reported in January 2017 and instead initiate annual collection in April 2017.

Response: We appreciate the suggestion regarding the revised submission timeframe for this measure and we agree. Because the measure refers to an event (flu vaccination) that usually only on an annual basis, we agree that annual reporting in April for the prior six-month period is appropriate. Given the time frame for release of this final rule, HHAs will already have submitted data on this measure for PY 1 in October 2016. HHAs will not be required to report on this measure in January 2017, as proposed, but will report for PY 2 in April 2017, for the period October 1, 2016 (or when the vaccine became available) through March 31, 2017, and annually in April thereafter, as this timing aligns with the influenza vaccination season.

We are finalizing the annual reporting requirement for the Influenza Vaccination Coverage for Home Health Personnel measure with this modification.

Comment: Several commenters suggested measures, or modifications to measures, to be considered for the HHVBP Model, including (1) pneumococcal vaccine in older adults (NQF#0043); (2) working with and supporting caregiving families; (3) changing the drug education measure from a process to outcome measure (examples: a measure of the HHA efforts regarding health literacy, or caregiver understanding of tasks); and (4) modifying the Acute Care Hospitalization: Unplanned Hospitalization during first 60 Days of Home Health measure.

Response: These comments are outside the scope of our proposed changes to the measure set. In the CY 2016 HH PPS final rule, we delineated the principles for developing and retiring measures (80 FR 68667–68669). We continue to review measure appropriateness in terms of statistical and clinical relevance to patient outcomes and will continue to consider additional applicable measures. We also will continue to seek input from the public on measures for consideration. Suggestions for specific measures that support the guiding principles articulated previously in this section for consideration for inclusion in future HHVBP Model measures sets may be submitted by emailing *HHVBPmeasures@abtassoc.com*. Please include the exact name of the measure(s), the specifications of how the measure is calculated, and the reason(s) why you believe the measure(s) would enhance the HHVBP Model.

Comment: One commenter stated its view that CMS has changed the Model's implementation design, which the commenter described as limiting the performance analysis to traditional Medicare enrollees. The commenter stated that including all patients subject to OASIS, including Medicare Advantage and Medicaid patients, is inconsistent with the CY 2016 HH PPS final rule and inappropriate in a VBP model that only affects traditional Medicare payments, and that Medicare should not penalize or reward HHAs for their performance in other payment programs that are outside of traditional Medicare.

Response: As discussed in the CY 2016 final rule, the majority of the measures finalized for use in the model will use OASIS data currently being reported by CMS–CCNs, to promote consistency and to reduce the data collection burden for providers (80 FR 68668). We explained further that using OASIS (and HHCAHPS) data allows the Model to leverage reporting structures already in place to evaluate performance and identify weaknesses in care delivery. OASIS and HHCAHPS measures are collected for applicable Medicare and Medicaid patients for whom the data is collected. Each of these measures is risk adjusted to take into account wide variation in the data.

OASIS and HHCAHPS performance scores utilize data for patients of HHAs for whom we require completion of these instruments, without separate scoring based on data for Medicare beneficiaries. This is also true of measure rates that are publicly reported on Home Health Compare, as well as the performance scoring under this Model. Consistent with this, the term patient is generally used throughout the section of the CY 2016 HH PPS final rule describing the HHVBP Model applicable measure set.

This is also consistent with our implementation of the Model to date. In December 2015 and January 2016, we

provided webinars to educate the HHAs on the Model design, how the TPS was calculated, how data was collected, as well as the details and use of the quality measures. In July 2016, we posted the Interim Performance Reports for each competing HHA on the HHVBP Secure Portal, reflecting measure performance derived from OASIS and HHCAHPS, as well as claim-based measures. In addition, HHAs are informed when the HHAs log into the HHVBP Secure Portal that the Total Performance Score on a set of measures collected via OASIS and HHCAHPS for all patients serviced by the HHA. We note that we have not received any concerns or recalculation requests relating to the scope of quality measure data used to generate these reports.

Comment: We received several additional comments regarding the measure set that were outside the scope of our proposed changes. Some commenters expressed concern that the performance measures do not reflect the patient population served under the Medicare Home Health benefit as the outcome measures focus on a patient's clinical improvement and do not address patients with chronic illnesses; deteriorating neurological, pulmonary, cardiac, and other conditions; and some with terminal illness. These commenters opined that the value of including stabilization measures in the HHVBP Model is readily apparent as it aligns the Model with the Medicare Home Health benefit. Commenters also expressed concerns that 'improvement' is not always the goal for each patient and that stabilization is a reasonable clinical goal for some. Commenters suggested the addition of stabilization or maintenance measures be considered for the HHVBP Model. However, no specific measures were suggested by commenters. Several commenters cited the *Jimmo* v. *Sebelius* settlement. Many of the commenters objected to the use of improvement measures in the HHVBP Model.

Response: We appreciate the comments on the measures methodology and, as discussed in the CY 2016 HH PPS final rule, acknowledge that skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition, as was clarified through the manual provisions revised as part of *Jimmo* v. *Sebelius* settlement (80 FR 68669). As further stated in that rule, this settlement agreement pertains only to the clarification of CMS's manual guidance on coverage standards, not payment measures like those at issue here, and expressly does not pertain to or prevent the implementation of new regulations, including new regulations pertaining to the HHVBP Model. We refer readers to the CY 2016 HH PPS final rule (80 FR 68669 through 68670) for additional discussion of our analyses of measure selection, including our analyses of existing measures relating to improvement and stabilization. As discussed in that rule, the HHVBP Model is designed such that any measures determined to be good indicators of quality will be considered for use in the HHVBP Model in future years and may be added through the rulemaking process. We will also continue to seek input from the public on the measure set for the HHVBP Model as discussed previously.

Comment: Two commenters stated that OASIS measures can be manipulated and the HHVBP Model should only use claims-based measures because they are more objective. Another commenter suggested that the claim-based measures be weighted greater than OASIS measures for that same reason. Two commenters suggested that CMS use risk adjustment to account for areas where there is ''lack of access to health care or economic disparities''. One commenter posited that data indicates that the margin of error for a sample size of 20 surveys is large when considering typical performance on HHCAHPS measures, and recommends that a minimum of 100 HHCAHPS surveys be established for inclusion within the HHVBP Model.

Response: Although these comments were outside the scope of our proposed changes, we appreciate the issues raised for possible consideration to improve the HHVBP Model in future rulemaking. We conducted extensive testing and consultation in developing the measure set and considered if socioeconomic status could be risk adjusted. OASIS is continuously reviewed and monitored for accuracy in reporting. More information about OASIS can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/Regulations.html.* We will continue to seek input from all stakeholders on the measure set for the HH VBP Model as discussed previously.

Final Decision: For the reasons stated and in consideration of the comments received, we are finalizing the removal of the four measures from the measure set for PY 1 and subsequent performance years, as reflected in Table 24: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31; and (4) Reason Pneumococcal Vaccine Not Received. In addition, we are also finalizing as proposed, the deletion of the reference to starter set in §§ 484.305, 484.315, and 484.320, and the 15-day submission timeframe for New Measures data. We are also finalizing an annual submission of the ''Influenza Vaccination Coverage for Home Health Personnel'' New Measure, with the first annual submission in April 2017 for PY2, for the prior 6-month reporting period of October 1 2016–March 31, 2017 to coincide with the flu season.

D. Appeals Process

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. In the CY 2017 HH PPS proposed rule, we proposed 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 proposed, and a 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.

As 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 Reports were posted to the HHVBP Secure Portal in July 2016 and included performance scores for the OASIS-based measures for the first quarter of CY 2016. See Table 25 for data provided in each report. Table 25 is similar to Table 32 included in the proposed rule (81 FR 43754) except that it has been revised to reflect that every report contains 12 months of rolling data including the quarters identified in Table 32 of the proposed rule. The quarterly Interim Performance Reports 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 proposed 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 Model 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.

We proposed adding 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 the 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 modifications described later in this section. We proposed 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 described later in this section. We stated that 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 and Hospital Value-Based Purchasing Program, as well as the appeals policy for the Comprehensive Care for Joint Replacement Model that is being tested by the Center for Medicare and Medicaid Innovation (Innovation Center).

Under section 1115A(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 25—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	12 months ending 9/30 of previous PY	12 months ending 6/30 of previous PY.
Interim Performance Scores	April	12 months ending 12/31 of previous PY	12 months ending 9/30 of previous PY.
Interim Performance Scores	July	12 months ending 3/31 of current PY	12 months ending 12/31 of previous PY.
Interim Performance Scores	October	12 months ending 6/30 of current PY	12 months ending 3/31 of current PY.
Annual TPS and Payment Adjustment Percentage.	August	Entire 12 months of previous PY [Jan–Dec].	
Annual TPS and Payment Adjustment Percentage (Final).	December	Entire 12 months of previous PY [Jan–Dec] after all recalculations and reconsideration requests processed.	

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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 for the applicable performance year. We invited comments on this proposed timeframe for recalculation requests, as well as any alternatives.

2. Reconsideration

We proposed 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 proposed 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 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 proposed 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 for the applicable performance year.

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. In the CY 2017 HH PPS proposed rule, we proposed 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 solicited 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.

Comment: Many commenters supported the proposed reconsideration process, which would allow a HHA to request reconsideration for the outcome of a recalculation request for its Annual TPS and Payment Adjustment Report.

Response: We appreciate the support to add reconsideration as the second level of review in addition to the recalculation process.

Comment: Many commenters supported the proposed changes to the timeline for submitting recalculation requests. One commenter noted that while they understood the need to shorten the timeframe, they encourage CMS to enforce firm timelines by which HHAs will be notified of the decision of their appeal and for CMS to appropriately staff the appeals team to meet these targets. Another commenter suggested that CMS provide educational tools, such as webinars and/or conference calls, to help HHAs determine inaccuracies in their reports so HHAs can make accurate determinations and submit appeals in a timely manner.

Response: We appreciate the comments supporting the proposed

changes to the timeframes for submitting recalculation requests. We expect to provide timely and transparent adjudication of appeals and notifications to the HHAs. We will continue to offer educational tools, such as webinars and conference calls, to help HHAs in reviewing their performance report so that they may submit any appeals in a timely manner.

Comment: A few commenters disagreed with the proposal to shorten the timeframe for recalculation requests from 30 calendar days to 15 calendar days for both the Interim Performance Reports and the Annual TPS and Payment Adjustment Reports. These same commenters did not agree with the 15-calendar day submission timeline for reconsideration requests. Commenters expressed concern that 15 calendar days does not provide a sufficient amount of time for HHAs to review the reports and determine whether an appeal is needed, collect supporting data, and submit their requests. One commenter also requested that CMS commit to a specific release date for each of the Interim Performance Reports, specifically the 1st day of each publication month, and improve functionality and accessibility of the HHVBP Secure Portal in order for agencies to adequately review the Interim Performance Reports within the 15-calendar day timeframe.

One commenter ''cautiously supports'' the proposal to provide each HHA with its payment adjustment percentage no later than 30 calendar days before the payment adjustment is applied to allow extra time for the appeals process to take place. While the commenter supports more time for HHAs to receive their payment adjustment reports so that they can operationalize the payment adjustments, it stated that it understands this balances additional time for the appeals process. Commenters stated that with this additional time they expect a timely and transparent adjudication of appeals and notification to HHAs.

Response: We proposed to shorten the timeframe for recalculations and reconsiderations to accommodate the time needed to generate and submit the final data file to the FISS to meet the January payment adjustment implementation date for each model year. As described in the proposed rule, we believe that HHAs' ability to review their quarterly Interim Performance Reports and submit recalculation requests provides HHAs with a mechanism to address potential errors in advance of receiving the Annual TPS and Payment Adjustment Report and we expect that in many cases, the reconsideration requests would result in a mechanical review of the application of the formulas for the TPS and LEF. We therefore believe that 15 calendar days is a sufficient amount of time to determine whether an appeal is needed, collect supporting data, and submit a recalculation request following the posting of the Annual TPS and Payment Adjustment Reports. We do not provide dates for the release of the Interim Performance Reports or the Annual TPS and Payment Adjustment Reports because the availability of data varies. We expect to provide timely and transparent adjudication of appeals and notifications to the HHAs and are always looking for ways to improve the functionality and accessibility of the HHVBP Secure Portal.

Comment: One commenter requested that CMS maintain the decision to release final reports no later than 60 calendar days prior to payment adjustments taking effect so that HHAs have enough time to prepare for the impact of the payment adjustment.

Response: We proposed 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 believe that this revised timeframe would provide sufficient notice to HHAs of their payment adjustment in advance of the payment adjustment being applied while at the same time allowing for the proposed second level of appeals. CMS aims to provide the final TPS and payment adjustment percentage to HHAs as far in advance of the payment year as possible following the resolution of the reconsideration process.

Comment: One commenter requested that we clarify whether a successful appeal that changes the performance scores for a particular HHA correspondingly changes the performance rankings of the HHAs in that cohort and whether it would affect their payment adjustments. The commenter also questioned how HHAs will be notified, as well as whether there are further appeal rights.

Response: As noted above, we proposed that if we deny an HHA's 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. After a determination has been made on any such reconsideration requests, a final payment adjustment report will be posted that reflects any changes to the payment adjustments as a result of the reconsideration decisions, both for those HHAs that requested the reconsiderations and all other HHAs, and a system generated notification will go to each HHA. If the TPS score or payment adjustment is recalculated for an HHA as a result of that HHA's reconsideration request, the payment adjustments will have to be recalculated for all HHAs in the same cohort. Figure 9 of the CY 2016 HH PPS final rule (80 FR 68688) provides an illustration of how the LEF is calculated. Columns C1–C5 of Figure 9 demonstrate that the LEF coefficient is dependent on the TPS and volume of service for each HHA in the cohort. As a result, if an HHA's reconsideration request results in a change to that HHA's TPS, all other HHAs in the same cohort may experience a minimal change to their respective payment adjustment. We would expect the change to the other HHAs' payment adjustments to be minimal because the magnitude of change would be divided among all the other HHAs in the cohort. We are finalizing in this rule the process for an HHA to request recalculation or reconsideration, following a decision on that HHA's request for recalculation, if the HHA has concerns that its TPS or payment adjustment is miscalculated. There is no further appeal process under the HHVBP model following a decision on the reconsideration request.

Final Decision: For the reasons stated and in consideration of the comments received, we are finalizing the appeals process as proposed and the associated regulation text at § 484.335, titled ''Appeals Process for the Home Health Value-Based Purchasing Model'', with a modification to § 484.335(a)(3)(iv) to correct an erroneous reference to ''reconsideration'' to ''recalculation'' and modifications to § 484.335(b)(1) for clarity and internal consistency. That is, we are finalizing the reconsideration process; the requirement that recalculation requests be submitted within 15 calendar days of the Interim Performance Report or the Annual TPS and Payment Adjustment Report being posted on the HHVBP Secure Portal; the requirement that reconsideration requests be submitted within 15 days of being notified of the results of the recalculation request; and that the final TPS and payment adjustment percentage is provided to competing HHAs in a final report no later than 30 calendar days in advance of the payment adjustment taking effect.

E. Discussion of the Public Display of Total Performance Scores

In the CY 2016 HH PPS final rule (80 FR 68658), we stated that one of the three goals of the HHVBP Model is to enhance 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 public reports would 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 those beneficiaries 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 commenters 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, webinars, updates to the HHVBP Model Innovation Center Web page (*https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model*), a dedicated help desk, and a web-based forum where regularly frequently asked questions are published. 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, HHAs have been required to collect OASIS data since 1999 and report HHCAHPS data since 2012.

We are considering various public reporting platforms for the HHVBP Model including Home Health Compare (HHC) and the Innovation Center 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 Model data elements 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.

Comment: One commenter suggested that CMS not consider public display until after the Model was evaluated and a decision would be made as to whether or not to scale the Model nationally. The commenter stated that it was not appropriate to report outcomes for some HHAs when only those in the nine designated states could be reported, and not all agencies in the United States, potentially putting the reported agencies at a disadvantage. One commenter favored the public display of the TPS, but urged CMS to: (1) Employ a transparent process and involve stakeholders in deciding what is reported; (2) provide a review period with a process for review and appeal before reporting; and (3) provide a clear explanation of what the TPS does and does not say to ensure appropriate consumer understanding and decision making. Finally, several commenters suggested that CMS post the information on the Innovation Center Web site, and not on the HHC Web site. The commenters suggested that posting this information on the Innovation Center Web site would clearly separate the information from national public reporting of all HHAs and be less likely to confuse consumers from non-participating states.

Response: We support providing the public with information to make an informed decision when choosing a Medicare-certified HHA. Similar to current reporting mechanisms for providing information on home health performance, including Home Health Compare and the Home Health Quality Reporting Program (HHQRP), the HHVBP Model's public display would provide all stakeholders in the selected states with additional information as they identify the home health services that best meet their needs. As we expect stakeholders to access publicly reported information for the state in which they are interested in finding services, we would not expect those stakeholders in non-participating states to utilize this information. We do not believe public display of information regarding performance in the Model would create a disadvantage for participating HHAs in their own states because all HHAs in a selected state must participate.

Current CMS public information Web sites, such as Hospital Compare and Nursing Home Compare, help consumers and others choose among providers based on the quality of care and services. We intend to continue to provide opportunities for stakeholder input as we develop a mechanism for public reporting under the HHVBP Model. We appreciate the commenters' concern about avoiding confusion with other public reporting by HHAs. We believe it is also important to make the information available where it is most likely to be accessed by a variety of stakeholders. We are considering an approach that balances access and reduces the likelihood for confusion by perhaps providing a link from the Home

Health Compare Web site (a site with high visibility that is frequently used by consumers of home health services) to the Innovation Center Web site, where stakeholders in the selected states or others may access it.

We appreciate the comments and will continue to gather information from the public as we consider mechanisms for public reporting under the HHVBP Model.

V. Updates to the Home Health Care Quality Reporting Program (HH QRP) and Analysis of and Responses to Comments

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 post-acute 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 (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,[18] which incorporates the three broad aims of the National Quality Strategy.[19] 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.

We proposed 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 proposed 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 pre-rulemaking 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

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

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

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 proposed 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 these proposed measures in the HH setting.

The following is a summary of the comments we received for general consideration regarding our proposals for the HH QRP.

Comment: One commenter supported the criteria that measures selected for the HH QRP be valid, reliable, and relevant, but noted that these criteria did not address the fact that maintaining function through skilled care was a valid goal for home health.

Response: We appreciate the commenter's support regarding the criteria that measures selected for the HH QRP be valid, reliable, and relevant and confirm that maintenance of function is a valid goal for some home health patients.

Comment: We received several comments regarding NQF endorsement of the measures. Several commenters expressed concern about the lack of NQF endorsement for measures. In addition, several commenters recommended that CMS delay implementing the proposed measures until NQF has completed its review and has endorsed the measures. Several commenters noted the NQF MAP committee did not endorse the proposed measures. Additionally, commenters recommended NQF endorsement prior to finalization of use in public reporting. A number of commenters recommended that CMS test new measures for reliability and validity prior to implementation, and encouraged CMS to analyze data to ensure comparability across post-acute care settings. Commenters also requested that testing results be made available to stakeholders.

Response: We acknowledge the commenters' recommendation to delay implementation of the measures until they are NQF-endorsed. While we appreciate the importance of consensus endorsement and intend to seek such endorsement, we must balance the need to address gaps in quality and adhere to statutorily-required timelines as in the case of the quality and resource use measures proposed in order to meet the requirements of the IMPACT Act. We consider and propose appropriate measures that have been endorsed by the NQF whenever possible. We recognize the importance of consensus endorsement and, where possible in light of the statutory deadlines imposed by the IMPACT Act, have adopted measures for the HH QRP that are endorsed by the NQF. However, when this is not feasible because there is no NQF-endorsed measure, we utilize our statutory authority that allows the Secretary to specify a measure for the HH QRP that is not NQF-endorsed where, as in the case for the proposed measures, we have not been able to identify other measures that are endorsed or adopted by a consensus organization.

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the HH QRP, we proposed for the HH QRP for the purposes of satisfying the measure domains required under the IMPACT Act, measures that closely align with the national priorities identified in the National Quality Strategy (*http://www.ahrq.gov/workingforquality/*) and for which the MAP supports the measure concept. Further discussion as to the importance and high-priority status of these proposed measures in the HH setting is included under each quality measure in this final rule. To the extent that we have adopted measures under our exception authority, we intend to seek NQF-endorsement of those measures and will do so as soon as is feasible. Regardless of whether the measures are or are not NQF-endorsed at the time we adopt them, they have all been tested for reliability and/or validity and we believe that the results of that testing support our conclusion that they are sufficiently reliable and valid to warrant their adoption in the HH QRP. The results of our reliability and validity testing for these measures may be found in the Measure Specifications for Measures Proposed in CY 2017 HH QRP Final Rule, posted on the CMS HH QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*. In regard to additional measure development, testing, and measure refinement, we will continue to test, monitor and validate these measures as part of measure maintenance.

Comment: We received many comments regarding risk-adjusting measure results by socioeconomic status (SES) or sociodemographic status (SDS). A few commenters, including MedPAC, did not support risk-adjustment of measures by SES or SDS status. MedPAC stated that risk adjustment can hide disparities in care and suggested that risk-adjustment reduces pressure on providers to improve quality of care for low-income Medicare beneficiaries. MedPAC supported peer provider group comparisons with providers of similar low-income beneficiary populations. The majority of commenters supported the use of SES or SDS for risk adjustment to account for varying acuity levels of patients in different settings of care, as well as other differences in patient characteristics that could affect health outcomes. The commenters noted in particular the many factors outside the control of home health providers, including access to food and primary care, income, informal caregivers and the condition of a patient's home that should be considered. These

commenters expressed concern that lack of risk-adjustment for these factors may compromise credibility, provide disincentives to serve certain patients and make it difficult to validly compare providers across PAC settings. A few commenters suggested that CMS could take advantage of the National Quality Forum's sociodemographic adjustment trial period.

Response: We appreciate the considerations and suggestions conveyed in relation to the measures and the importance in balancing appropriate risk adjustment along with ensuring access to high quality care. We note that in the measures that are risk adjusted, we do take into account characteristics associated with medical complexity, as well as factors such as age where appropriate to do so. With regard to the incorporation of additional factors including patient characteristics, such as cognitive impairment and function, we have and will continue to take such factors into account, which would include further testing as part of our ongoing measure development monitoring activities. With regard to the suggestions pertaining to the incorporation of socioeconomic factors as risk-adjustors for the measures, NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails 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 encouraged to submit information such as analyses and interpretations, as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed or maintained by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measures. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the HHS 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. For each of the proposed measures, we applied consistent models where feasible to develop their definitions, other technical specifications and approach to risk-adjustment. We also intend to continue to monitor the reliability and validity of the HHQRP measures, including whether the measures are reliable and valid for cross-setting purposes.

Comment: Two commenters encouraged CMS to give consideration to burden when developing quality measures, and one additionally noted that even measures that rely on existing claims data can pose additional administrative burden, such as time and effort to compile and validate data.

Response: With all new measure development, we are committed to assessing the burden and utility of proposed measures, through Technical Expert Panels, public comment periods and other opportunities for stakeholder input. Of the four measures proposed in the proposed rule, one will be calculated using assessment items already in OASIS instrument and, for that reason, adds no new burden for HHAs. The other three proposed measures are claims-based, and consistent with our general policy for claims-based measures, are calculated using claim files that should have been already compiled and validated by HHAs for other purposes, including reimbursement. Therefore, we do not believe that the adoption of claims-based measures creates a new administrative burden for providers.

Comment: Two commenters expressed support and appreciation for the transparent process employed in developing measures to satisfy the requirements of the IMPACT Act. Other commenters expressed concern over the short timeframe available for stakeholder input into measure development.

Response: We appreciate the support for our transparent process and wish to confirm our commitment to ongoing stakeholder involvement. We appreciate the feedback regarding the timing issues related to IMPACT Act implementation. It is our intent to move forward with IMPACT Act implementation in a manner in which the measure development process continues to be transparent, and includes input and collaboration from experts, the PAC provider community, and the public at large. It is of the utmost importance to us to continue to engage stakeholders, including providers, patients and their families, throughout the measure development lifecycle through their participation in our measure development public comment periods, the pre-rulemaking process, TEPs convened by our measure development contractors, open door forums and other opportunities. With that, we note that with regard to the measure development process we have provided the various opportunities as previous described and we have provided multiple opportunities for stakeholder input on the proposed measures, including soliciting feedback from a TEP, and pre-rulemaking public comment periods. Specifically and in addition to the various opportunities for the stakeholder input previously described, we have also worked to be responsive to stakeholder concerns pertaining to the length of various comment periods, and in response to those concerns, we have extended our public comment periods for measures under development on several occasions. We also encourage feedback through our IMPACT Act PAC Quality Initiative resource and feedback mailbox at *PACQualityInitiative@cms.hhs.gov* or at the SNF QRP resource and feedback mailbox at *SNFQualityQuestions@cms.hhs.gov*. We thank all stakeholders for their thoughtful feedback on and engagement with the measure development and rulemaking process.

Comment: One commenter thanked CMS for clarifying that OASIS assessments are used for Home Health beneficiaries that are in Medicaid, MA, and FFS, and commended CMS for providing education on the changes coming for the HH QRP.

Response: We thank the commenter for their support.

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 proposed that when we initially adopt a measure for the HH QRP for a payment determination, this measure would be automatically retained for all subsequent payment determinations

unless we proposed to remove or replace the measure, or unless the exception discussed below applied.

We proposed 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 would no longer be collected for purposes of the HH QRP, and the performance data for the measure would no longer be displayed on HH Compare. We also proposed 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 would still appear on OASIS for previously established purposes that are non-related to our HH QRP. HHAs would be able to access these reports using the Certification and Survey Provider Enhanced Reports (CASPER) system and could use the information for their own monitoring and quality improvement efforts.

Further, we proposed 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 proposed that any such ''removal'' or ''replacement'' would take place through notice and comment rulemaking, unless we determined that a measure was causing concern for patient safety. Specifically, in the case of a HH QRP measure for which there was a reason to believe that the continued collection raised possible safety concerns or would cause other unintended consequences, we proposed to promptly remove the measure and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle. In addition, we would immediately notify HHAs and the public through the usual communication channels, including listening 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 invited public comment on our proposed policy for retaining, removing and replacing previously adopted quality measures, including the criteria we proposed to use when considering whether to remove a quality measure from the HH QRP

Comment: One commenter expressed support for the proposed criteria to remove or replace measures from the HH QRP and no longer display them on HH Compare. Another commenter expressed concern that the criterion ''performance or improvement on a measure does not result in better patient outcomes'' could be interpreted as equating to functional improvement and exclude patients who need skilled care to maintain function. This commenter also requested clarification of the word ''topic'' in the criterion ''a measure that is more proximal in time to desired patient outcomes for the particular topic is available.''

Response: We appreciate the support for our policy for determining when HH QRP measures should be removed or replaced. We wish to clarify that ''improvement'' on a measure means an improved agency performance score and that better patient outcomes can encompass both functional stabilization and improvement. In addition, we wish to clarify that the word ''topic'' in the referenced criterion refers to the measure focus area, such as pain management.

Final Decision: After consideration of the comments received, we are finalizing our proposed policy on the process for retaining, removing, and replacing previously adopted HH QRP measures.

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 that 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 *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 proposed 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 included within the HHQI. 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 proposed 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 supported 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 invited public comment on the above proposal to remove 6 process measures from the HH QRP.

Comment: We received many comments in favor of the removal of 28 measures from the HHQI and the proposed removal of 6 measures from the HH QRP. MedPAC and other commenters supported removal of measures that were ''topped out'' and limited in their ability to distinguish between providers. One commenter suggested CMS review the National Academy of Medicine's recent report to help identify high priority measures for a smaller measure set, while another suggested a dashboard of measures aligned across home health quality initiatives, including star ratings, Home Health Compare and the home health value-based purchasing demonstration. Some commenters recommended that removed measures be replaced by claims-based measures that can be independently verified, outcome measures or measures of patient stabilization. One commenter opposed removal of the Improvement in Grooming, Improvement in Toileting Hygiene, Improvement in Light Meal Preparation, and Improvement in Phone Use measures from the HHQI, citing these as important indicators of safety at home; the commenter also stressed the importance of fall prevention. Another commenter requested that CMS seek additional stakeholder input before removing measures. A few commenters requested that information for removed measures continue to be collected and made available to agencies for quality improvement purposes. One commenter recommended that CMS monitor removed topped out measures to assure that quality does not decrease. One commenter recommended that the measures be removed from the CASPER reporting system as well, while another requested removal from OASIS.

Response: We appreciate the support from MedPAC and other commenters for a more focused measure set. We wish to clarify that the data for the measures no longer included in the HHQI or removed from the HH QRP may still appear on OASIS for previously established purposes that are not related to our HH QRP, and if still collected will be available to home health agencies, via the CASPER on-demand reports, for the purpose of monitoring and improving quality efforts.

Final Decision: After consideration of the comments we received, we are finalizing our proposal to remove 6 process measures from the HH QRP.

E. Process for Adoption of Updates to HH QRP Measures

We believe that it is important to have in place a subregulatory 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 and might not be appropriate for adoption using a subregulatory process.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 and 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 proposed to implement the same process for adopting updates to measures in the HH QRP, and to 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 invited public comment on this proposal. We received no comments on this proposal.

Final Decision: We are finalizing our proposed process for adopting updates to HH QRP measures as proposed.

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

We proposed modifications to our coding guidance 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 will use this modified guidance for the reporting of current 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,[20] effective January 1, 2017, full-thickness (Stage 3 or 4) pressure ulcers should not be reported on OASIS as unhealed pressure ulcers once complete re-epithelialization 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 post-acute 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. To align with reporting guidance in other post-acute care settings, effective January 1, 2017, once a graft is applied to a pressure

[20] *http://www.npuap.org/wp-content/uploads/2012/01/Reverse-Staging-Position-Statement.pdf.*

ulcer, the wound will be reported on OASIS as a surgical wound, and no longer be reported as a pressure ulcer.

The following is a summary of the comments we received regarding our proposal for new pressure ulcer guidelines.

Comment: We received two comments addressing the proposal for new pressure ulcer coding guidelines, effective January 1, 2017. One commenter concurred that full thickness (Stage 3 or 4) pressure ulcers should not be reported as unhealed once re-epithelialized, but did not agree that once a graft is applied to a pressure ulcer, the wound should be reported as a surgical wound instead of a pressure ulcer. This commenter suggested that CMS clearly specify which grafts change the classification of a pressure ulcer to a surgical wound. The commenter also suggested that ''urinary diversions'' and ''arterial ulcers exempt from the stasis ulcer category'' be added to the OASIS item set for the purpose of adding case mix points. Another commenter noted the pressure ulcer related guidance and item changes would cause confusion and require extensive re-education and review of every comprehensive assessment, thus resulting in an administrative and clinician burden with risk for error. They added that caring for these ulcers without adequate reimbursement could result in poor patient outcomes and quality measure scores.

Response: We appreciate the comments and suggestions. These proposals were made to allow OASIS data collection to conform to professional clinical guidelines, and align with pressure ulcer reporting practices in other post-acute care settings to support cross-setting quality measurement related to pressure ulcers. Additional guidance and ongoing provider support will be available through the OASIS Q&A Help Desk and the OASIS Q&As, both available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/HHAQA.html.* After considering the comments received, we are making the changes to this measure as proposed.

G. 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 stated that we would retain if our proposed policy on retaining measures is finalized, we proposed to adopt four new measures. These four measures were developed to meet the requirements of the IMPACT Act. These 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 2-year 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 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.

1. Measure That Addresses the IMPACT Act Domain of Resource Use and Other Measures: MSPB–PAC HH QRP

We proposed an MSPB–PAC HH QRP measure for inclusion in the HH QRP for the CY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated Medicare spending per beneficiary, on which PAC providers consisting of SNFs, IRFs, LTCHs, and HHAs are required to submit necessary data specified by the Secretary. 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.[21] 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.[22]

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. Therefore, we proposed 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 of the Act 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 NQF-endorsed measure, and we have given due consideration to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Given the current lack of resource use measures for PAC settings, our MSPB–PAC HH QRP measure would provide valuable information to HHAs on their relative Medicare spending in delivering services to approximately 3.5 million Medicare beneficiaries.[23]

The 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 QRP 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

[21] MedPAC, ''A Data Book: Health Care Spending and the Medicare Program,'' (2015). 114.

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

[23] Figures for 2013. MedPAC, ''Medicare Payment Policy,'' Report to the Congress (2015). xvii–xviii.

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, risk-adjusted 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 post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the MSPB–PAC measures and believe that measuring Medicare spending was critical for improving efficiency, others believed that resource use measures did 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). Furthermore, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report HHAs that are involved in the provision of high quality care at lower cost.

We developed an MSPB–PAC measure for each of the four PAC settings. In addition to this measure, we finalized a LTCH-specific MSPB–PAC measure in the FY 2017 IPPS/LTCH final rule (81 FR 57199 through 57207), an IRF-specific MSPB–PAC measure in the FY 2017 IRF PPS final rule (81 FR 52087 through 52095), and a SNF-specific MSPB–PAC measure in the FY 2017 SNF PPS final rule (81 FR 52014 through 52021). These four setting-specific MSPB–PAC measures are aligned to the greatest extent possible, in terms of episode construction and measure calculation given the differences in the payment systems for each setting, and types of patients served in each setting, to ensure the accuracy of the measures in each PAC setting. The setting-specific measures account for differences between settings and between episode types within the home health setting, in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. Each of the MSPB–PAC measures assess Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined as similarly as possible across the MSPB–PAC measures. In recognition of the differences between home health episode types, 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. A PEP is a pro-rated adjustment for shortened episodes as a result of patient discharge and readmission to the same provider within the same 60-day home health claim, or patient transfer to another HHA with no common ownership within the same 60-day claim. If a patient is discharged to a hospital, SNF, or IRF, and readmitted to the same HHA within the 60-day claim, a PEP adjustment does not apply. A LUPA adjustment applies where there are four or fewer visits in a home health claim.

The MSPB–PAC measures mirror the general construction of the 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).[24] The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode which starts 3 days prior to admission and ends 30-days after discharge. 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.[25] [26] Similarly, the MSPB–PAC 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). There are differences between the MSPB–PAC measures and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. The MSPB–PAC measures exclude a limited set of services determined to be clinically unrelated that are provided to a beneficiary during the episode window while the hospital MSPB measure includes all Part A and Part B services and does not exclude services based on clinical relatedness.[27]

As noted above, the hospital-level MSPB measure includes a period spanning from three days prior to a hospitalization through 30 days post-discharge. 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 would 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 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

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

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

[26] FY 2012 IPPS/LTCH PPS final rule (76 FR 51619).

[27] FY 2012 IPPS/LTCH PPS final rule (76 FR 51620).

options for members: Encourage continued development, do not encourage further consideration, and insufficient information.[28] The MAP PAC/LTC Workgroup voted to ''encourage continued development'' for each of the MSPB–PAC measures.[29] The MAP PAC/LTC Workgroup's vote of ''encourage continued development'' was affirmed by the MAP Coordinating Committee on January 26, 2016.[30] 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.[31] [32]

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 MSPB–PAC measures. The 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 extended to 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.[33] The MSPB–PAC Public Comment Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report.pdf* and the MSPB–PAC Public Comment Supplementary Materials are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report_supplementary_materials.pdf*. These documents contain the public comments (summarized and verbatim), along with our responses including statistical analyses. The MSPB–PAC HH QRP measure, along with the other MSPB–PAC measures, as applicable, will be submitted for NQF endorsement when feasible.

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 MSPB–PAC measures, including the MSPB–PAC HH QRP measure in this rule, are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*.

a. Episode Construction

We proposed that an MSPB–PAC HH QRP episode would begin at the episode trigger, which is defined as the first day of a patient's home health claim with 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 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 HH PPS payment policy. MSPB–PAC HH Standard, PEP, and LUPA episodes would be compared only with MSPB–PAC HH Standard, PEP, and LUPA episodes, respectively. Differences in episode construction between these three episode types are noted below; they otherwise share the same definition.

We proposed that the episode window would be comprised of a treatment period and an associated services period.

The definition of the treatment period depends on the type of MSPB–PAC HH QRP episode. For MSPB–PAC HH Standard and LUPA QRP episodes, the treatment period begins at the episode trigger (that is, on the first day of the home health claim) and ends after 60 days after the episode trigger. For MSPB–PAC HH PEP QRP episodes, the treatment period begins at the episode 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 by the HHA.

The associated services period is the time during which Medicare Part A and Part B services that are not treatment services are counted towards the episode, subject to certain exclusions, such as planned admissions and organ transplants that are clinically unrelated services as discussed in detail below. The definition of the associated services period is the same for each of the MSPB–PAC HH QRP episode types: The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The length of the episode window varies between episode types: since the treatment period for the MSPB–PAC HH Standard and LUPA QRP episodes is defined as being 60 days from the episode trigger, the length of the episode window—that is, treatment period plus associated services period—will be a total of 90 days. In contrast, as the treatment period for MSPB–PAC HH PEP QRP episodes is defined as being from the episode trigger to discharge, the length of the episode window will vary depending on the length of time that the patient is under the care of the HHA.

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

[28] 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*.

[29] 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.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470*.

[30] National Quality Forum, Measure Applications Partnership, ''Meeting Transcript—Day 1 of 2'' (January 26, 2016) 231–232 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637*.

[31] 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*.

[32] 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*.

[33] 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*.

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 access to care for beneficiaries with certain conditions and complex care needs. 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 appear more expensive due to these services and do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the post-treatment associated services period of an MSPB–PAC HH QRP episode, that is, during the 30 days after the end of the treatment period as defined above for the different MSPB–PAC HH QRP episode types. One possible scenario occurs where a beneficiary leaves the care of the HHA and is then admitted to a SNF within 30 days (that is, during the post-treatment phase of the associated services period

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 QRP 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 post-treatment associated services period of another MSPB–PAC HH QRP episode, that is, during the 30 days after the end of the treatment period. 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. If a patient transfers from one HHA to another during the standard 60-day home health claim (for example, after 30 days), this first home health claim would be subject to a PEP adjustment in accordance with the HH PPS. This PEP claim would trigger an MSPB–PAC HH PEP QRP episode, and since the treatment period for an MSPB–PAC HH PEP QRP episode ends at discharge, the second MSPB–PAC HH QRP episode (of any type) would begin during the associated services period of the MSPB–PAC HH PEP QRP episode.

The MSPB–PAC HH QRP measure was 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 Standard, PEP, and LUPA QRP episodes to ensure that they are compared only to other MSPB–PAC HH Standard, PEP, and LUPA episodes, respectively. The final MSPB–PAC HH QRP measure is the episode-weighted average of the average scores for each type of episode, 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 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 be 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 risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We proposed 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).[34]

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

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. As part of the risk adjustment methodology for MSPB–PAC HH QRP episodes, we adjust for demographics (through age brackets) at the time of the episode trigger and using diagnostic information in the recent past, up to the start of the episode. 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 HH patient population, and allow us to more accurately estimate Medicare spending. Our 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 proposed 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 will monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year 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 and proposed to adjust by age brackets as a demographic factor, we did not propose to adjust the MSPB–PAC HH measure for socioeconomic factors. 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 invited public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC HH QRP measure.

The comments we received on this topic, with their responses, appear below.

Comment: Several commenters recommended that the risk adjustment model for the MSPB–PAC HH QRP measure include variables for SES/SDS factors. A commenter recommended that a ''fairer'' approach than using SES/SDS factors as risk adjustment variables would be to compare resource use levels that have not been adjusted for SES/SDS factors across peer providers (that is, providers with similar shares of beneficiaries with similar SES characteristics).

Response: We refer readers to section V.G. where we also discuss these topics.

Comment: Several commenters recommended that additional variables be included in risk adjustment to better capture clinical complexity. A few commenters suggested the inclusion of functional status and other patient assessment data. Commenters recommended that additional variables should include obesity, amputations, CVAs (hemiplegia/paresis), and ventilator status. Some commenters recommended that caregiver support be included in the risk adjustment model. One commenter recommended accounting for medical and post-surgical patients. One commenter recommended excluding high-cost and outlier patients, and a few commenters requested data be made available to stakeholders to allow them to evaluate predictors of spending.

Response: We thank the commenters for their suggestions. The risk adjustment model includes HCC indicators to account for amputations, hemiplegia, and paresis. We believe that the other risk adjustment variables adequately adjust for ventilator dependency and obesity through variables for HCCs, clinical case mix categories, and prior inpatient and ICU length of stay. We account for medical and post-surgical patients through clinical case mix categories which distinguish between beneficiaries coming to the HHA from a prior medical or surgical stay. The clinical case mix category for prior inpatient medical stays is further broken down into ICU and non-ICU stays, and the clinical case mix category for prior inpatient surgical stays is further broken down into orthopedic and non-orthopedic stays. We believe that our risk adjustment model and measure calculation accounts for high-cost and outlier patients; further details can be found in the MSPB–PAC Measure Specifications, a link for which has been provided above. Details on the coefficients of the MSPB–PAC risk adjustment models are provided in the MSPB–PAC Public Comment Supplementary Materials, a link for which has been provided above.

We understand the commenter's view of the importance of caregiver support for ensuring a successful outcome. We note that the MSPB–PAC HH QRP measure is based upon claims data, which does not include data on the availability of family or caregiver support. We considered the potential use of information about caregiver support in the risk adjustment model for the MSPB–PAC HH QRP measure.

However, as noted in the MSPB–PAC Public Comment Summary Report, a link for which has been provided above, even where non-claims data on caregiver support are available; there may be inherent subjectivity in determining the availability of such support. More details of the MSPB–PAC HH QRP risk adjustment model are provided in the MSPB–PAC Measure Specifications, and the coefficients for the MSPB–PAC risk adjustment models are included in the MSPB–PAC Public Comment Supplementary Materials; the links for these documents have been provided above.

We recognize the importance of accounting for beneficiaries' functional and cognitive status in the calculation of predicted episode spending. We considered the potential use of functional status information in the risk adjustment models for the MSPB–PAC measures. As with the caregiver support information discussed above, we decided to not include information derived from current setting-specific assessment instruments given that we are migrating towards standardized data as mandated by the IMPACT Act. We will revisit the inclusion of functional status in these measures' risk adjustment models in the future when the standardized functional status data mandated by the IMPACT Act-mandated become available. Once they are available, we will take a gradual and systematic approach in evaluating how they might be incorporated. We intend to implement any changes if appropriate based on testing.

(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, calculate the average of the ratio of the standardized spending for HH Standard episodes over the expected spending (as predicted in risk adjustment) for HH Standard episodes, the average of the ratio of the standardized spending for HH PEP episodes over the expected spending (as predicted in risk adjustment) for HH PEP episodes, and the average of the ratio of the standardized spending for HH LUPA episodes over the expected spending (as predicted in risk adjustment) for HH 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):

$$(A)\ \ MSPB\text{-}PAC\ HH\ Measure_j = \frac{MSPB\text{-}PAC\ Amount_j}{National\ Median\ MSPB\text{-}PAC\ Amount}$$

$$= \frac{\left(\frac{1}{n_j}\sum_{i\in\{I_j\}}\frac{Y_{ij}}{\widehat{Y_{ij}}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{I_j\}}Y_{ij}\right)}{Episode\text{-}Weighted\ Median\ of\ HHA\ Providers'\ MSPB\text{-}PAC\ Amount}$$

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 claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files. The claims are payment standardized to adjust for geographic and other differences, as discussed above.

b. Cohort

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

c. Reporting and Reliability

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 proposed to use 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 0.4).

The comments we received on this topic, with their responses, appear below.

Comment: Several commenters believed that the MSPB–PAC HH QRP treatment period should end at discharge, rather than 60 days after the episode trigger. A few commenters expressed concern about double-counting services through overlapping MSPB–PAC HH QRP episodes. A commenter recommended collapsing consecutive MSPB–PAC HH QRP episodes into one episode to better account for the treatment of chronically ill patients.

Response: We appreciate the commenters' feedback. The length of the MSPB–PAC HH QRP treatment period is 60 days for standard episodes to reflect that HHAs are paid under the HH PPS at a rate based on a 60-day period as determined by the Home Health Resource Groups (HHRGs), regardless of when the last visit actually takes place. Defining the MSPB–PAC HH QRP treatment period based on the relevant Medicare payment policy aligns with

the definition of the treatment periods for the other MSPB–PAC measures. Allowing an MSPB–PAC HH QRP episode to begin during the post-treatment associated services period of another MSPB–PAC HH QRP episode ensures that HHAs have continuous accountability and aligned incentives throughout a beneficiary's care trajectory. We note that the MSPB–PAC HH QRP measure is not a simple sum of spending across an HHA's episodes, mitigating concerns about double-counting. Instead, the construction of the numerator and denominator is such that the ratio of observed and predicted episode spending are averaged across all of a given providers' episodes. That is, the MSPB–PAC HH QRP measure compares the observed and expected episode spending levels for each of the MSPB–PAC HH QRP episode types (that is, Standard, PEP, and LUPA episodes) to generate the provider score. As noted in the MSPB–PAC Measure Specifications, a link for which has been provided above, patient characteristics and treatment regimens can change significantly during long sequences of consecutive home health claims. Allowing each home health claim to trigger a new episode promotes the accuracy of predicted MSPB–PAC HH QRP episode spending by using the most recent patient information for each claim in the risk adjustment model.

Comment: Several commenters recommended that a geographic-specific (for example, state or regional) median should be used instead of the national median, citing differences in cost, and patient population.

Response: We appreciate the commenters' input. We proposed to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure to account for variation in Medicare spending. 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). Given the use of payment standardization, as well as risk adjustment, calculating PAC provider resource use relative to the national median provider of the same type may also be useful in identifying variation in utilization and encouraging providers to reduce this variation, in accordance with the measures' goals of providing actionable, transparent information to providers. We believe that this approach accounts for the differences that the commenters raise while also maintaining consistency with the NQF-endorsed hospital MSPB measure's methodology for addressing regional variation through payment standardization.

Comment: A few commenters, including MedPAC, recommended the use of uniform single MSPB–PAC measure that could be used to compare providers' resource use across settings, but recognized that we do not have a uniform PPS for all the PAC settings currently. In the absence of a single PAC PPS, they recommended a single MSPB–PAC measure for each setting that could be used to compare providers within a setting. In addition, they recommended that under a single measure, the episode definitions, service inclusions/exclusions, and risk adjustment methods should be the same across all PAC settings.

Response: The four separate MSPB–PAC measures reflect the unique characteristics of each PAC setting and the population they serve. The four setting-specific MSPB–PAC measures are defined as consistently as possible across settings given the differences in the payment systems for each setting, and types of patients served in each setting. We have taken into consideration these differences and aligned the specifications, such as episode definition, service inclusions/exclusions and risk adjustment methods for each setting, to the extent possible while ensuring the accuracy of the measures in each PAC setting.

Each of the measures assess Medicare Part A and Part B spending during the episode window which begins upon admission to the provider's care and ends 30 days after the end of the treatment period. The service-level exclusions are harmonized across settings. The definition of the numerator and denominator is the same across settings. However, specifications differ between settings when necessary to ensure that the measures accurately reflect patient care and align with each setting's payment system. For example, LTCHs and IRFs are paid a stay-level payment based on the assigned MS–LTC–DRG and CMG, respectively, while SNFs are paid a daily rate based on the RUG level and HHA providers are reimbursed based on a fixed 60-day period for standard home health claims. While the definition of the episode window as consisting of a treatment period and associated services period is consistent across settings, including a post-discharge period, the duration of the treatment period varies to reflect how providers are paid under the payment policy in each setting, as discussed above. The duration of the associated services period that ends 30 days after the end of the treatment period is consistent between settings. The MSPB–PAC HH QRP measure distinguishes between episodes triggered by standard home health claims (that is, those to which neither a PEP nor LUPA adjustment applies), and claims subject to a PEP or LUPA adjustment to reflect the provisions of the HH PPS.

There are also differences in services included in consolidated billing for each setting: For example, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) claims are covered by the LTCH, IRF, and SNF PPSs but are not paid through the HH PPS. This affects the way certain first-day service exclusions related to prior institutional care are defined for each measure. Readmissions of the same patient to the same provider within 7 or fewer days are collapsed into one treatment period for the MSPB–PAC SNF, IRF, and LTCH QRP measures but are not in the MSPB–PAC HH QRP measure. This is due to the existence of many long sequences of consecutive home health claims, during which time patient characteristics and care regimens can change significantly, as discussed above.

We recognize that there is considerable overlap in where beneficiaries are treated for similar PAC needs but believe there are some important differences between the care profiles of certain types of beneficiaries that are difficult to capture in a single measure that performs comparisons across settings.

In addition, the risk adjustment models for the MSPB–PAC measures share the same covariates to the greatest extent possible to account for patient case mix; however, certain settings' measures also incorporate additional setting-specific information where available to increase the predictive power of the risk adjustment models. For example, the MSPB–PAC LTCH QRP risk adjustment model uses MS–LTC–DRGs and Major Diagnostic Categories (MDCs) and the MSPB–PAC IRF QRP model includes Rehabilitation Impairment Categories (RICs). The HH and SNF settings do not have analogous variables that directly reflect a patient's clinical profile.

We will continue to work towards a more uniform measure across settings as we gain experience with these measures, including further research and analysis about comparability of resource use measures across settings for clinically similar patients, different

treatment periods and windows, risk adjustment, service exclusions, and other factors.

Comment: A few commenters expressed concern that the MSPB–PAC HH QRP measure will give incentive to HHAs to avoid medically complex beneficiaries, such as those with chronic conditions like end-stage renal disease (ESRD), which would result in unintended consequences.

Response: To mitigate the risk of creating incentives for HHAs to avoid medically complex beneficiaries, who may be at higher risk for poor outcomes and higher costs, we have included factors related to medical complexity in the risk adjustment methodology for the MSPB–PAC HH QRP measure, including an indicator for ESRD. We also exclude certain services from the MSPB–PAC HH QRP measure that are clinically unrelated to HHA care and/or because HHAs may have limited influence over those services delivered by other providers during the episode window, such as dialysis for ESRD.

Comment: Two commenters expressed support for the MSPB–PAC HH QRP measure; one commenter noted that the MSPB–PAC measures are resource use measures that are not a standalone indicator of quality.

Response: As part of the HH QRP, the MSPB–PAC HH QRP measure will be reported with quality measures; we direct readers to section V.H. for a discussion of quality measures. We believe it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which HHAs are involved in the provision of high quality care at lower cost.

Comment: One commenter noted that the MSPB–PAC HH QRP measure is complicated and may be difficult for providers to understand.

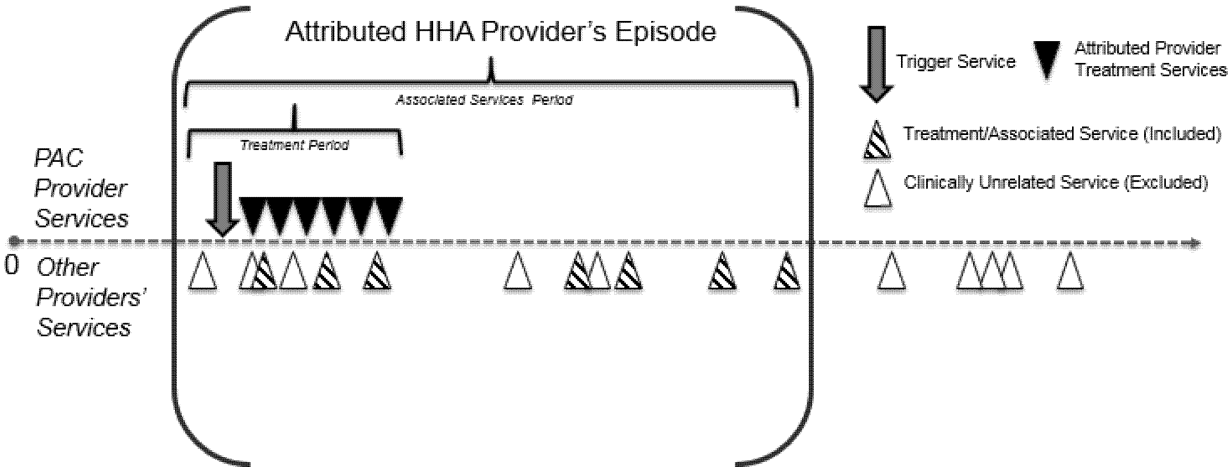
Response: With regard to the concerns regarding the complexity of the measures, we direct readers to the documentation on the MSPB–PAC measures, links for which have been provided above. In particular, the MSPB–PAC Measure Specifications include a high-level summary of the measures and simplified example of the calculation. To further clarify, please see Table 26 and Diagram 1, which further illustrate the MSP–PAC HH QRP measure's construction:

TABLE 26—MSPB–PAC HH QRP EPISODE WINDOWS

Episode type	Treatment period	Associated services period
MSPB–PAC HH Standard ...	• Begins at episode trigger	• Begins at episode trigger.
MSPB–PAC HH LUPA	• Ends 60 days after episode trigger	• Ends 30 days after the end of the treatment period.
MSPB–PAC HH PEP	• Begins at episode trigger	• Begins at episode trigger.
	• Ends at discharge	• Ends 30 days after the end of the treatment period.

This concept of an episode window consisting of a treatment period and associated services period is illustrated below in Figure 1.

FIGURE 1: MSPB-PAC HH QRP Episode Window



Regarding the commenter's concern about how the MSPB–PAC HH QRP measure will be communicated to providers, we refer readers to section V.G. where we also discuss these topics.

Comment: One commenter suggested that descriptive statistics on the measure scores by provider-level characteristics (for example, rural/urban status and bed size) would be useful to evaluate measure design decisions.

Response: Table 27 shows the MSPB–PAC HH provider scores by provider characteristics, calculated using FY 2014 data.

TABLE 27—MSPB–PAC HH SCORES BY PROVIDER CHARACTERISTIC

Provider characteristic	Number of providers	Mean score	Score percentile						
			1st	10th	25th	50th	75th	90th	99th
All Providers	11,829	0.97	0.47	0.75	0.87	0.97	1.06	1.16	1.48
Urban/Rural:									
Urban	9,798	0.96	0.46	0.74	0.86	0.97	1.06	1.16	1.48
Rural	2,025	0.98	0.52	0.80	0.89	0.98	1.06	1.15	1.48
Unknown	6	0.94	0.76	0.76	0.79	0.97	1.06	1.07	1.07
Ownership Type:									
For profit	9,360	0.97	0.46	0.74	0.86	0.97	1.07	1.17	1.48
Non-profit	1,856	0.96	0.54	0.80	0.89	0.96	1.02	1.10	1.47
Government	613	0.97	0.42	0.76	0.87	0.96	1.06	1.19	1.64
Census Division:									
New England	354	0.98	0.37	0.79	0.92	0.99	1.06	1.13	2.08
Middle Atlantic	541	0.96	0.24	0.77	0.90	0.97	1.06	1.14	1.46
East North Central	2,432	0.95	0.43	0.72	0.84	0.95	1.06	1.15	1.54
West North Central	746	0.98	0.42	0.74	0.87	0.97	1.06	1.20	1.64
South Atlantic	2,008	1.02	0.55	0.85	0.93	1.02	1.11	1.20	1.45
East South Central	439	1.03	0.65	0.89	0.97	1.03	1.10	1.17	1.34
West South Central	3,234	0.95	0.51	0.73	0.84	0.95	1.06	1.16	1.45
Mountain	698	0.97	0.46	0.77	0.88	0.97	1.07	1.16	1.63
Pacific	1,330	0.92	0.52	0.74	0.83	0.92	1.00	1.09	1.34
Other	47	0.80	0.56	0.67	0.74	0.79	0.85	0.92	1.06
No. of Episodes:									
0–99	3,395	0.92	0.30	0.60	0.75	0.90	1.06	1.24	1.89
100–249	3,011	0.96	0.65	0.77	0.86	0.96	1.05	1.15	1.34
250–499	2,523	0.98	0.70	0.82	0.89	0.97	1.06	1.14	1.28
500–1000	1,665	1.00	0.75	0.87	0.93	1.00	1.07	1.14	1.29
1000 +	1,235	1.02	0.81	0.91	0.96	1.01	1.08	1.15	1.28

Final Decision

After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Medicare Spending Per Beneficiary—Post Acute Care for the Home Health Quality Reporting Program, beginning with the CY 2018 HH QRP, as proposed. A link for the MSPB–PAC Measure Specifications has been provided above.

To summarize, we are finalizing the definition of an MSPB–PAC HH QRP episode, beginning from episode trigger. An episode window is comprised of a treatment period beginning at the episode trigger. The treatment periods ends 60 days after the episode trigger for MSPB–PAC HH Standard and LUPA QRP episodes, while the treatment period ends upon discharge for MSPB–PAC HH PEP QRP episodes. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period for each of the MSPB–PAC HH QRP episodes.

We exclude certain services that 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. We also exclude certain episodes in their entirety from the MSPB–PAC HH QRP measure, such as where a beneficiary is not enrolled in Medicare FFS for the entirety of the lookback period plus episode window.

We are finalizing the inclusion of Medicare payments for Part A and Part B claims for services included in the MSPB–PAC HH QRP episodes to calculate the MSPB–PAC HH QRP measure.

We are finalizing our proposal to risk adjust using covariates including age brackets, HCC indicators, prior inpatient stay length, ICU stay length, clinical case mix categories, indicators for originally disabled, ESRD enrollment, and long-term care status, and hospice claim in episode window. The measure also adjusts for geographic payment differences such as wage index and GPCI, and adjust for Medicare payment differences resulting from IME and DSH.

We calculate the individual providers' MSPB–PAC Amount, which is inclusive of MSPB–PAC HH QRP observed episode spending over the expected episode spending as predicted through risk adjustment. MSPB–PAC HH Standard, PEP, and LUPA QRP episode spending is compared only with MSPB–PAC HH Standard, PEP, and LUPA QRP episode spending, respectively. The final MSPB–PAC HH QRP measure is the episode-weighted average of the average scores for each type of episode.

2. Measure That Addresses 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 proposed 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-for-service (FFS) claims-based measure to meet this requirement.

This 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 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.[35] [36] 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 multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.[37] [38]

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.[39] [40] 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.[41] In addition, 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.[42] For patients who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for patients' out-of-pocket expenditures.[43]

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.[44] 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 non-community 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.[45]

Measuring and comparing agency-level 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.[46] [47] [48] [49] [50] [51] In 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 ventilator-dependent on admission were discharged to home.[52] A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.[53] 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[54] and a second study noted that between 58 percent and 63 percent of beneficiates were discharged to home with rates varying by admission site.[55] However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent),

[35] Further description of patient discharge status codes can be found, for example, at *https://med.noridianmedicare.com/web/jea/topics/claim-submission/patient-status-codes.*

[36] 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.

[37] 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.

[38] 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.

[39] 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.

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

[41] 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.

[42] Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: bundles in the real world. The Journal of arthroplasty. 2015;30(3):353–355.

[43] 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.

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

[45] Ibid.

[46] 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.

[47] 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.

[48] March 2015 Report to the Congress: Medicare Payment Policy. Medicare Payment Advisory Commission;2015.

[49] 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.

[50] Chang 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.

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

[52] 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.

[53] 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.

[54] 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.

[55] 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.

IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).[56]

Discharge to community is a desirable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.[57] [58] [59] [60] [61] Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status. [62] [63] [64] [65] [66] 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*.

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's review and recommendation of continued development, we have continued to refine the risk adjustment model and conduct measure testing for this measure, as recommended by the MAP. This measure is consistent with the information submitted to the MAP and is scientifically acceptable for current specification in the HH QRP. As discussed with the MAP, we intend to perform additional analyses as the measure steward.

We reviewed the NQF's consensus-endorsed 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 proposed 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 proposed to use data from the Medicare FFS claims and Medicare eligibility files to calculate this measure. We proposed 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 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 follow-up 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, we proposed 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 measure is calculated utilizing 2 years of data as defined below. We proposed a minimum of 20 eligible episodes in a given HHA for public reporting of the measure for that

[56] Ibid.

[57] 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.

[58] 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.

[59] 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.

[60] 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.

[61] 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.

[62] 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.

[63] 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.

[64] 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.

[65] 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.

[66] 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.

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 measure denominator is the risk-adjusted expected number of discharges to community. The 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*

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 measure to the NQF for consideration for endorsement.

We invited public comment on our proposal to adopt the measure, Discharge to Community–PAC HH QRP for the HH QRP. The following is summary of the comments we received.

Comment: Commenters noted the importance of home and community supports such as caregiver availability, willingness, and ability to support the person in the community; availability of an established home, and community supports in determining a beneficiary's ability to be discharged to community and remain in their home or community setting. Several commenters expressed concern that the risk adjustment methodology does not include adjustment for sociodemographic or socioeconomic status. Commenters believed that sociodemographic and socioeconomic factors were strong predictors of return to the community, and since they were outside a provider's control, they should be accounted for in risk adjustment. One commenter noted that the measure does not adjust for regional differences in community-based needs and supports that result from factors such as geographic variance in availability of affordable housing. Another commenter expressed concern that more than half of home health patients do not have an acute care stay within 30 days prior to admission to the HHA, and therefore, may not have the principle diagnosis and comorbidity included in the risk adjustment model.

Response: We understand the importance of home and community supports for ensuring a successful discharge to community outcome. The discharge to community measure is a claims-based measure and currently, there are no standardized data on variables such as living status or family and caregiver supports across the four PAC settings. We appreciate and will consider the commenter's suggestion to account for potential challenges of discharging patients to the community in different geographic areas. With regard to the suggestions pertaining to risk adjustment methodologies pertaining to sociodemographic factors, we refer the readers to section III.D.2.f where we also discuss these topics. For patients for whom index inpatient claims are not available, earlier inpatient claims, as well as physician and other claims, will be used to capture comorbidities and other covariates. These include principal diagnoses, surgical procedures, ESRD or disability as reason for entitlement, dialysis, prior hospitalizations and length of any previous acute hospital stays.

Comment: MedPAC and other commenters expressed concern about relying on discharge coding to determine discharge to community settings. MedPAC and other commenters recommended that we confirm discharge to a community setting with the absence of a subsequent claim to a hospital, IRF, SNF, or LTCH, to ensure that discharge to community rates reflect actual facility performance. Two commenters suggested additional measure testing and development to assess the reliability of patient discharge codes.

Response: We are committed to developing measures based on reliable and valid data. This measure does confirm the absence of hospital or LTCH claims following discharge to a community setting. Unplanned hospital and PAC readmissions following the discharge to community, including those on the day of HHA discharge, are considered an unfavorable outcome. We will consider verifying the absence of IRF and SNF claims following discharge to a community setting, as we continue to refine this measure. Nonetheless, we would like to note that an ASPE report on post-acute care relationships found that, following discharge to community settings from IRFs, LTCHs, or SNFs in a 5 percent Medicare sample, IRFs or SNFs were very infrequently reported as the next site of post-acute care. Because the discharge to community measure is a measure of discharge destination from the PAC setting, we have chosen to use the PAC-reported discharge destination (from the Medicare FFS claims) to determine whether a patient/resident was discharged to the community (based on Discharge Status Codes 01 and 81). We examined accuracy of determining discharge to a community setting using the ''Patient Discharge Status Code'' on the PAC claim by examining agreement with discharge to community as determined using assessment data; we found strong agreement between the two data sources. We found excellent agreement between the two data sources in all PAC settings for the status of ''discharge to the community,'' 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 accuracy of ''Patient Discharge Status Code'' on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up 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 claims ''Patient Discharge Status Code'' for determining discharge to a community setting for this measure. The use of the claims discharge status code to identify discharges to the community was discussed at length with the TEP convened by our measure development contractor. TEP members did not express significant concerns regarding the accuracy of the claims discharge status code in coding community discharges, nor about our use of the discharge status code for defining this quality measure. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos 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.

Comment: One commenter raised concern that the measure does not adjust for factors that are unique to certain specific provider types, such as providers offering dedicated services to patients with certain medical conditions. The commenter noted that providers caring for these populations might encounter greater challenges in discharging patients to the community due to special needs such as affordable and safe housing, mental health and substance abuse counseling, and medication management and supports. Another commenter noted that the measure could incentivize agencies to not treat patients who pose a financial risk, such as those with chronic conditions like end stage renal disease.

Response: We appreciate the commenters' suggestion that the discharge to community measure should adjust for providers primarily caring for specialty populations that may encounter greater challenges with discharge to community settings. Our risk adjustment model accounts for a comprehensive list of diagnoses and comorbidities. We will use the feedback gathered from the comment period to better assess how we can inform further testing of the association between providers primarily caring for specialty populations and discharge to community outcomes as we refine this measure.

Comment: Some commenters expressed concern regarding the use of the Patient Discharge Status Code variable to define community discharges, noting that home health agencies typically do not use code ''81'' and noted that including it in the measure specifications could increase burden and require administrative changes. Commenters additionally urged CMS to review the use discharge codes 01 and 02. Two commenters also noted that the measure specifications use ICD–9, and not ICD–10, codes and recommended a crosswalk between the two.

Response: We would like to clarify that this proposed measure only captures discharges to home- and community-based settings based on the presence of Patient Discharge Status Codes ''01'' and ''81'' on the Medicare FFS claim. Code ''01'' on the Medicare FFS claim is used to determine discharge to home/self-care (routine discharge). Code ''81'' on the Medicare FFS claim is used to determine discharge to home or self-care with a planned acute care hospital readmission. This proposed measure does not include any claims where the HHA used Patient Discharge code ''02'' because that code assesses discharges to hospital inpatient care, a discharge setting that is not included in the outcome of this discharge to community measure. Codes ''01'' and ''81'' were chosen for the calculation of this measure because they are commonly used for all home health Medicare FFS claims. We disagree that the inclusion of code ''81'' in the measure will create a new burden for HHAs because HHAs should already be using that code if it accurately describes the beneficiary's discharge status.

We agree with commenters that it is important to assess the impact of the ICD–9 to ICD–10 transition on the discharge to community measure. We are committed to maximizing accuracy and validity of our measures. We are developing an ICD–9 to ICD–10 crosswalk for the discharge to community measure, as well as other measures that use ICD codes.

Comment: Several commenters expressed concern that there was overlap between the current OASIS-derived measure Discharge to Community HH QI measure and the proposed claims-based cross-setting Discharge to Community measure. The commenters noted that using two separate measures might be confusing to consumers and providers, making it challenging for HHAs to track and improve performance on these metrics. The commenters recommended that only one measure be publicly-reported or that we do not use one of the two measures. One commenter noted that the Discharge to Community measure was essentially a hospitalization measure and supported the use of a single acute care hospitalization measure in the HH QRP.

Response: We acknowledge that we currently have two measures addressing the topic of ''discharge to community'' but note that the overlap between the two measures is limited. We do not believe that the two measures will be confusing to providers and consumers. The proposed discharge to community measure, Discharge to Community PAC HH QRP, is unique in that it incorporates both within-stay and post-discharge hospitalization and mortality in the measure. The claims based discharge to community measure assesses broader outcomes; it first examines whether or not a patient was discharged to the community from the PAC setting and for patients discharged to the community, this measure examines whether they remained alive in the community without an unplanned readmission in the 31-day window following discharge to the community. The overall goal of CMS is to develop measures that are meaningful to patients and consumers, and assist them in making informed choices when selecting post-acute providers. Since the goal of PAC for most patients and family members is to be discharged to the community and remain in the community, from a patient/consumer perspective, it is important to assess whether a patient remained in the community after discharge and to separately report discharge to community rates. For these reasons, we believe that the measure, Discharge to Community-PAC HH QRP, is sufficiently different from OASIS derived measure so as not to be duplicative. Nonetheless, we intend to engage in public communication efforts for providers and other stakeholders to clarify the intent of the cross-setting measure and to distinguish it from the current OASIS-based measure so that HHAs are able to appropriately track and improve performance on these measure metrics.

Comment: One commenter suggested that the discharge to community measure examine emergency room visits in the post-discharge observation window, in addition to unplanned readmissions. The commenter noted that this addition would impose no additional data collection burden on HHAs or hospitals, since these data are already collected by CMS.

Response: The discharge to community measure captures patients that are discharged to the community and remain in the community post-discharge. An emergency department visit that does not result in hospitalization would not be considered a failure to remain in the community. Nevertheless, we will assess emergency department visit rates in the post-discharge observation window to monitor for increasing rates, and potential indication of poor quality of care or inappropriate community discharges.

Comment: One commenter supported including functional status in the risk adjustment for the discharge to community measure. They noted that functional status is associated with increased risk of 30-day all-cause hospital readmissions, and since readmissions and discharge to community are closely related, functional status risk adjustment is also important for this measure.

Response: We appreciate the commenter's support. As mandated by

the IMPACT Act, we are moving toward the goal of collecting standardized patient assessment data for functional status across PAC settings. Once standardized functional status data become available across settings, it is our intent to use these data to assess patients' functional gains during their PAC stay, and to examine the relationship between functional status, discharge destination, and patients' ability to discharge to community. As we examine these relationships between functional outcomes and discharge to community outcomes in the future, we will assess the feasibility of leveraging these standardized patient assessment data to incorporate functional outcomes into the discharge to community measure in all PAC settings. Standardized cross-setting patient assessment data will also allow us to examine interrelationships between the quality and resource use measures in each PAC setting, to understand how these measures are correlated.

Comment: One commenter encouraged us to provide PAC settings with access to measure performance data as early as possible so providers have time to adequately review these data, and implement strategies to decrease readmissions where necessary.

Response: We intend to provide initial confidential feedback to PAC providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016.

Comment: Some commenters expressed concern that the Discharge to Community HH QRP measure differs from the version for other PAC settings, and recommended that the denominator be limited to those patients admitted to home health within 30 days of discharge from an acute care hospital to allow for valid comparisons between PAC settings. Another commenter noted that home health patients are already ''in the community'' and that agencies have limited control over patient outcomes after discharge.

Response: The Discharge to Community measure is aligned across PAC settings in terms of risk-adjustment, exclusions, numerator and measure intent. For the target population and denominator, which is the risk-adjusted expected number of discharges to community, our analyses revealed that the majority of HHA patients (56 percent) did not have an acute care stay within the 30 days preceding their HHA episode. Further, there was significant heterogeneity in HHA size, with many small agencies. As a result, requiring a prior acute stay for this measure would result in approximately 31.9 percent of HHAs not having the minimum number of episodes necessary to report a measure result with two years of data. In general, our policy is to develop measures that can capture the quality of care furnished to the maximum number of Medicare beneficiaries.

We adjusted this proposed measure for a recent prior acute care stay in the risk adjustment model to accommodate the inclusion of both patients with and without a prior proximal hospitalization. For patients for whom index inpatient claims are not available, earlier inpatient claims, as well as physician and other claims, will be used to capture comorbidities and other covariates. Finalized measures such as the Acute Care Hospitalization (NQF #0171) and Emergency Department Use without Hospitalization (NQF #0173) have also found prior hospitalizations to be a significant predictor in the risk adjustment model but do not require that all patients have a prior acute care stay. Due to this measurement approach, we did not leverage the prior proximal hospitalization in this proposed measure. Similar to this proposed discharge to community measure, these finalized measures, NQF #0173 and NQF #0171, do not require episodes to have a prior acute care stay.

We recognize that home health patients are by definition not in institutional settings, and we note that the proposed measure assesses continued successful community tenure post-discharge. To ensure we are able to adequately assess continued successful community tenure post-discharge, this proposed measure is risk-adjusted to address initial patient characteristics that are predictors of failed community discharge.

Comment: A few commenters requested clarification on whether patients who are discharged to home under hospice care qualify as a discharge to community for the purposes of the measure. One commenter suggested that patients who die on hospice within the post-discharge observation window be excluded from the discharge to community measures. Two commenters recommended that the measure exclude any patients who have been discharged to the community and expire within the post-discharge observation window.

Response: The discharge to community measure excludes patients discharged to home- or facility-based hospice care. Thus, discharges to hospice are not considered discharges to community, but rather are excluded from the measure calculation. With respect to the suggestion that any patients who expire within the post-discharge window be excluded, we wish to note that including 31-day post-discharge mortality outcomes is intended to identify successful discharges to community, and to avoid the potential unintended consequence of inappropriate community discharges. We do not expect facilities to achieve a 0 percent death rate in the measure's post-discharge observation window; the focus is to identify unexpectedly high rates of death for quality monitoring purposes.

Comment: One commenter noted the importance of patient education, engagement, coaching, accountability and commitment to their goals of care is critical to a successful discharge to the community.

Response: We appreciate the comments and acknowledge the importance of patient engagement in successful community discharge. We intend to provide provider education for appropriate coding of discharge status to aid in their understanding of how discharge codes are used in the measure.

Comment: One commenter recommended that patients discharged to long term care facilities paid by sources other than Medicare be excluded from the home health version of this measure.

Response: The discharge to community measure only captures discharges to home and community based settings as discharges to community, based on Patient Discharge Status Codes 01 and 81on the Medicare FFS PAC claim.[1] Code ''01'' on the Medicare FFS claim is used to determine discharge to home/self-care (routine discharge). Code ''81'' on the Medicare FFS claim is used to determine discharge to home or self-care with a planned acute care hospital readmission. Codes ''01'' and ''81'' do not include discharges to long-term care nursing facilities or any other institutional setting.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to adopt the measure, Discharge to Community-Post Acute Care for the Home Health Quality Reporting Program, beginning with the CY 2018 HH QRP.

3. Measure That Addresses 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 all-condition risk-adjusted potentially preventable hospital readmission rates. We proposed the measure Potentially Preventable 30-Day Post-Discharge Readmission (PPR) 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 providers, are common, costly, and often preventable.[67] [68] 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.'' [69] 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.[70] 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.[71] 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.[72] 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 post-acute services after discharge from home health care. Within 30 days of discharge from home health, 29 percent of patients were admitted to a hospital.[73] 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).[74] 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 settings. 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 NQF #2512 for LTCHs).[75] 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 HHS Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.[76] [77] [78] 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.[79] [80] 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.[81] [82] [83]

[67] 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.

[68] 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.

[69] 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*.

[70] Ibid.

[71] Ibid.

[72] 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.

[73] 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.

[74] 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.

[75] 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*.

[76] 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/*.

[77] National Quality Forum: Prevention Quality Indicators Overview. 2008.

[78] 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*.

[79] 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*.

[80] 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*.

[81] 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.

[82] Gao, J., Moran, E., Li, Y.-F., et al. Predicting potentially avoidable hospitalizations. Med. Care 52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

Continued

Potentially Preventable Readmission (PPR) 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 (PPR) 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 conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events.

Additional 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 post-acute 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/HomeHealthQualityInits/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 risk-adjusted, 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 risk-standardized 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 risk-adjustment 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, to ensure the statistical reliability of this measure for smaller agencies. In addition, we proposed 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-Assessment-Instruments/HomeHealthQualityInits/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 were either 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*.

[83] 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.

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 risk-adjustment 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 proposed 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.

Due to timeline limitations we have not yet submitted the proposed measure to the NQF for consideration of endorsement, but we intend to do so in the future. We also stated in the proposed rule that 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 also stated that we intend to publicly report this measure using claims data from CYs 2015, 2016 and 2017.

We invited public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP. The following is summary of the comments we received.

Comment: MedPAC and other commenters expressed general support for the proposed Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP. One commenter specifically stated their support for the infectious conditions defined as potentially preventable, stating that many of these conditions are preventable using appropriate infection prevention interventions.

Response: We agree that the measure will provide strong incentives for care coordination and will appropriately capture preventable readmissions, including infection-related readmissions.

Comment: Several commenters expressed concern over the overlap between the proposed PPR measure and other HH QRP measures, including the existing all-cause readmission measure. Commenters noted that public reporting of more than one hospital readmission measure for HHAs may result in confusion among the public; the commenters also noted that HHAs could face confusion over two distinct but similar measures, which could potentially pose challenges for quality improvement efforts. One commenter noted that the proposed PPR measures and the existing all-cause measure are distinct yet overlapping, adding that the PPR measure is a subset of the all-cause readmission measure. Given this overlap, one commenter expressed concern that providers who perform poorly on the all-cause readmission measure are also likely to perform poorly on the proposed PPR measure, and suggested CMS not adopt the measure until it could evaluate the necessity of each measure. Some commenters requested that CMS clarify the overlap and intent of these measures, and provide more education to providers and the public on the multiple HH QRP readmission measures.

Response: With regard to overlap with the existing HH QRP readmission measure, we wish to clarify that there are distinct differences between the all-cause readmission measure and the PPR measure. The all-cause measure assesses readmissions occurring within the first 30 days following the start of a home health stay, during which time a patient is in the HHA's care, and the potentially preventable measure assesses readmissions during the first 30 days post-discharge from the HHA. While a small overlap between the two measures is expected, the all-cause performance rates are more heavily driven by within-stay re-hospitalizations while PPR performance rates are driven purely by post-discharge re-hospitalizations. We are committed to ensuring that measures in the HH QRP are useful in assessing quality and will continue to evaluate all readmission measures over time.

Comment: Several commenters provided feedback on the PPR definitions or lists of conditions for which readmissions would be considered potentially preventable. Some commenters believed that the definitions were too broad or were concerned about the applicability of the PPR conditions to the HH setting. MedPAC commented that the measure definitions and risk adjustment should be identical across PAC settings so that potentially preventable readmission rates can be compared across settings. In addition to general comments about the PPR definitions, we also received feedback on specific conditions and received suggestions to add or remove conditions. One commenter specifically supported the inclusion of infectious conditions in the ''inadequate management of infections'' and ''inadequate management of other unplanned events'' categories in the measure's definition of potentially preventable hospital readmissions. Other commenters specifically requested conditions—specifically patient falls and behavioral health diagnoses—be excluded from this measure until further study is conducted. Additionally, two commenters suggested that it was inappropriate for the measure to include conditions unrelated to the reason for HH admission. A few commenters recommended that CMS continue evaluating and testing the measure to ensure that the codes used for the PPR definition are clinically relevant.

Response: The PPR list of conditions for which readmissions would be considered potentially preventable is aligned for measures with the same readmission window, regardless of PAC setting. Specifically, the post-PAC discharge PPR measures that were developed for each of the PAC settings contain the same list of PPR conditions (available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Proposed-Measure-Specifications-for-Measures-Proposed-in-CY-2017-HH-QRP-NPRM.pdf*). Although there are some minor differences in the specifications across the measures (for example, years of data used to calculate the measures to ensure reliability and some of the measure exclusions necessary to attribute responsibility to the individual settings), the IMPACT Act PPR measures are standardized. The statistical approach for risk adjustment is also aligned across the measures;

however, there is variation in the exact risk adjusters. The risk adjustment models are empirically driven and differ between measures as a consequence of case mix differences, which is necessary to ensure that the estimates are valid. The approach for defining PPRs for these measures was based on comprehensive reviews of the scientific literature, input from clinical experts, and recommendations from our TEP, including TEP members' in-person feedback and their written ratings of the conditions.

Though readmissions may be considered potentially preventable even if they may not appear to be clinically related to the patient's original reason for HH admission, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Furthermore, this measure is based on Medicare FFS claims data and it may not always be feasible to determine whether a subsequent readmission is or is not clinically related to the reason why the patient was receiving inpatient rehabilitation. We intend to conduct ongoing evaluation and monitoring of this measure to ensure that the PPR definition codes remain clinically relevant.

Comment: Commenters sought clarification on whether emergency department (ED) visits were included in the measure. One commenter suggested that the PPR measure incorporate both inpatient and emergency department (ED) visits to enhance consumer understanding.

Response: The PPR measure was developed to fulfill the IMPACT Act's statutory requirement for a measure to address the domain of potentially preventable hospital readmissions. We agree that ED visits are also an important outcome, but they do not fall under the same domain as hospital readmissions and are not included in the measure.

Comment: We received several comments encouraging additional testing and evaluation of the measure prior to implementation. Specifically, several comments suggested that CMS should not finalize this measure because the measure was still under development and the MAP did not vote to support it, but instead encouraged continued development. Commenters also recommended that the measure be submitted for NQF endorsement and that CMS only propose NQF-endorsed measures for use in the HHQRP.

Response: We intend to submit this measure to NQF for consideration of endorsement.

Although the measure is not currently endorsed, we did conduct additional testing subsequent to the MAP meeting. Based on that testing, we were able to complete the risk adjustment model and evaluate facilities' PPR rates, and we made the results of our analyses available at the time of the proposed rule. We found that testing results were similar to the current home health all-cause readmission measures (NQF #2380) and allowed us to conclude that the measure is sufficiently developed, valid and reliable for adoption in the HH QRP. We would also like to clarify that the finalized risk-adjustment models and coefficients are included in the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Proposed-Measure-Specifications-for-Measures-Proposed-in-CY-2017-HH-QRP-NPRM.pdf*. We will make additional testing results available in the future.

Comment: Two commenters requested that CMS cross-walk the ICD–9 to ICD–10 codes for the lists of conditions for which readmissions may be considered potentially preventable, and one further requested this information be made publicly available.

Response: Our measure development contractors have developed preliminary ICD–10 cross-walks for the lists of conditions. The current ICD–10 cross-walks can be found in the link for the technical specifications posted below, and any adjustments made to the cross-walks will be implemented in future rulemaking. With regard to the planned readmission approach, we also direct readers to the technical specifications for the measure, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Proposed-Measure-Specifications-for-Measures-Proposed-in-CY-2017-HH-QRP-NPRM.pdf*.

Comment: While we received comments in support of risk adjustment, several commenters raised concern over the specific risk adjustment approach for the PPR measures. Specifically, commenters were concerned that the approach is insufficient or does not adequately take into account patient frailty, prior PAC stays, multiple comorbidities, or sociodemographic factors to address income, and caregiver support. Several commenters expressed concern that this measure would capture outcomes that are outside of HH providers' control, specifically for chronically ill patients, instances of poor patient compliance, unhealthy choices, and various SDS factors, such as lack of resources or limited access to follow up or primary care. Several commenters suggested that CMS risk adjust for cognitive impairments/behavioral health, whether or not the patient had a follow-up visit with a physician, and for functional status and activities of daily living (ADL) scores, in all settings.

Response: The risk adjustment approach developed for these measures is comprehensive and captures a variety of patient case mix characteristics, including sociodemographic characteristics (age, sex, original reason for entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, comorbidities, and prior service utilization. The measure's comprehensive risk-adjustment approach and exclusion criteria are intended to capture many of these factors. As described above, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. We would like to clarify that the focus of the PPR measure is to identify excess PPR rates for the purposes of quality improvement. With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons, we refer the readers to section V. B of this final rule where we discuss these topics. This risk adjustment approach was designed to harmonize with approaches developed and refined over several years and used for other claims-based NQF-endorsed hospital readmission measures by CMS in inpatient, as well as PAC quality reporting programs. As described for all IMPACT Act measures in section V.G., the statistical approach for risk adjustment is also aligned across the measures; however, there is variation in the exact risk adjusters. The risk-adjustment models are empirically driven and differ between measures as a consequence of case mix differences, which is necessary to ensure that the estimates are valid. The risk-adjustment model takes into account medical complexity, as patients with multiple risk factors will rate as having higher risk of readmission. For those cross-setting post-acute measures such as those intended to satisfy the IMPACT

Act domains that use the patient assessment-based data elements for risk adjustment, we have either made such items standardized, or intend to do so as feasible.

Comment: Two commenters expressed concern over using claims data for hospital readmissions, noting that these data may not be accurate. A commenter additionally suggested that CMS add a system to support providers to understand how data were calculated, to report errors, and to promote quality improvement purposes.

Response: The claims data used to calculate this measure are validated and are used for several NQF endorsed measures adopted for CMS programs, including the HH QRP, for example, the home health Acute Care Hospitalization and Emergency Department Use without Hospitalization measures (NQF 0171 and 0173, respectively). Multiple studies have been conducted to examine the validity of using Medicare hospital claims for several NQF endorsed quality measures used in public reporting such as 30-day mortality rates for pneumonia patients, 30-day all-cause readmission rates among patients with heart failure and 30-day mortality rates among patients with heart failure.[84] [85] [86] These studies supported the use of claims data as a valid means for risk adjustment and assessing hospital readmissions. Additionally, although assessment and other data sources may be valuable for risk adjustment, we are not aware of another data source aside from Medicare claims data that could be used to reliably assess the outcome of potentially preventable hospital readmissions post-HHA discharge.

Comment: Two commenters cautioned against potential unintended consequences of the measure, in particular, noting that the measure could incentivize HHAs to delay necessary readmission to the hospital. One commenter noted that the measure could cause HHAs to be selective about the patients they admit.

Response: We intend to conduct ongoing monitoring to assess for potential unintended consequences associated with the implementation of this measure. A major goal of risk adjustment is to ensure that patient case mix is taken into account in order to allow for fair comparisons of facilities. Given that this is a post-HHA discharge measure; HHAs would have no ability to delay hospital readmissions as the patient is no longer in the care of the HHA.

Final Decision: After consideration of the public comments received, we are finalizing our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP beginning with the CY 2018 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 proposed to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for the HH QRP as a patient-assessment based, cross-setting quality measure to meet this requirement with data collection beginning January 1, 2017, beginning with the CY 2018 payment determination.

This measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the 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 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 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 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.[87] 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.[88] 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.[89] 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.[90] There is universal agreement that medication reconciliation directly addresses patient safety issues that can result from medication miscommunication and unavailable or incorrect information.[91] [92] [93] [94]

[84] Bratzler DW, Normand SL, Wang Y, et al. An administrative claims model for profiling hospital 30-day mortality rates for pneumonia patients. PLoS One 2011;6(4):e17401.

[85] Keenan PS, Normand SL, Lin Z, et al. An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. Circulation 2008;1(1):29–37.

[86] Krumholz HM, Wang Y, Mattera JA, et al. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with heart failure. Circulation 2006;113:1693–1701.

[87] Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

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

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

[90] 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.

[91] 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*.

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

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

[93] Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered,

Continued

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,[95] [96] 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.[97]

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.[98] [99] [100] [101] [102] [103] 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.[104] [105]

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.[106] Potential medication problems upon admission to HHAs have been reported as occurring at a rate of 39 percent of reviewed charts [107] and mean medication discrepancies between 2.0 ± 2.3 and 2.1 ± 2.4.[108] Similarly, medication discrepancies were noted as patients transitioned from the hospital to home health settings.[109] An estimated fifty percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.[110]

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.[111] [112] Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy.[113] [114] [115] [116] [117] [118] Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.[119] [120] For older patients who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,[121] and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.[122] The 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 cross-

clinically relevant and implementable: a consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

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

[95] Jha AK, Kuperman GJ, 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.

[96] Hohl CM, Nosyk B, Kuramoto L, et al. Outcomes of emergency department patients presenting with adverse drug events. Ann Emerg Med. 2011;58:270–279.

[97] Kohn LT, Corrigan JM, Donaldson MS, ''To Err Is Human: Building a Safer Health System,'' National Academies Press, Washington, DC, 1999.

[98] Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academies Press; 2000.

[99] Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. JAMA. 1997:277(4): 312–317.

[100] Bond CA, Raehl CL, & Franke T. Clinical pharmacy services, hospital pharmacy staffing, and medication errors in United States hospitals. Pharmacotherapy. 2002:22(2): 134–147.

[101] Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995:274(1): 29–34.

[102] Barker KN, Flynn EA, Pepper GA, Bates DW, & Mikeal RL. Medication errors observed in 36 health care facilities. JAMA. 2002: 162(16):1897–1903.

[103] Bates DW, Boyle DL, Vander Vliet MB, Schneider J, & Leape L. Relationship between medication errors and adverse drug events. J Gen Intern Med. 1995:10(4): 199–205.

[104] Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academies Press; 2000.

[105] 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.

[106] Wong, JD., et al. ''Medication reconciliation at hospital discharge: evaluating discrepancies.'' Annals of Pharmacotherapy 42.10 (2008): 1373–1379.

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

[108] Setter SM, Corbett CF, Neumiller JJ, Gates BJ, 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.

[109] Zillich AJ, Snyder ME, Frail CK, Lewis JL, 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.

[110] 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.

[111] 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.

[112] Gandara, 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.

[113] Coleman EA, Smith JD, Raha D, Min SJ. Post hospital medication discrepancies: prevalence and contributing factors. Arch Intern Med. 2005 165(16):1842–1847.

[114] Wong JD, Bajcar JM, Wong GG, et al. Medication reconciliation at hospital discharge: evaluating discrepancies. Ann Pharmacother. 2008 42(10):1373–1379.

[115] Hawes EM, Maxwell WD, White SF, Mangun J, Lin FC. 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.

[116] Foust JB, Naylor MD, Bixby MB, Ratcliffe SJ. Medication problems occurring at hospital discharge among older adults with heart failure. Research in Gerontological Nursing. 2012, 5(1): 25–33.

[117] Pherson EC, Shermock KM, Efird LE, et al. Development and implementation of a post discharge home-based medication management service. Am J Health Syst Pharm. 2014; 71(18): 1576–1583.

[118] 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.

[119] Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995:274(1): 29–34.

[120] 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.

[121] 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.

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

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

We reviewed the NQF's endorsed measures and identified one NQF-endorsed 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 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 proposed 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 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 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 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 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 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, we proposed 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 quality measure will be based on the data collection of three standardized items that will be added to the OASIS. The collection of data by means of the standardized items will be obtained at start or resumption of care and end of care. For more information about the data submission required for this 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 quality measure would replace existing items currently used for data collection within the OASIS. The measure denominator is the number of patient episodes with an end of care assessment during the reporting period. The 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 followed-up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this 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 invited 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. The following is summary of the comments we received regarding our proposal.

Comment: Several commenters expressed support for the proposed quality measure, expressing appreciation to CMS for proposing a quality measure to address the IMPACT Act domain, Medication Reconciliation that acknowledges the importance of medication reconciliation to address patient safety issues. Two commenters additionally emphasized the importance of preventing and responding to ADEs to reduce health services utilization and associated healthcare costs, and emphasized that medication reconciliation is fundamental to patient safety during care transitions.

Response: We agree that medication reconciliation is an important patient safety process for addressing medication accuracy during transitions in patient care and identifying preventable ADEs, which may lead to reduced health services utilization and associated costs.

Comment: We received several comments expressing concern about the timely follow-up component of this measure. Several commenters addressed the issue of timely physician response to communication about potential clinically significant medication issues and physician accountability in this process measure. Many commenters noted the challenge of obtaining a physician response within one calendar day, which may be impeded by events such as physician vacations or contact after hours or during holidays. One commenter specifically recommended a more flexible timeframe to accommodate holidays and weekends. Another commenter noted that HHAs have limited access to pharmacists, as well as multiple physicians who may be involved in a patient's care, and that this lack of access presents a barrier to timely follow-up. Several commenters recommended that HHAs only be held accountable for contacting a physician or physician-designee, but not for completing follow-up actions, within the measure timeframe. One commenter requested guidance from CMS as to whether HHAs will be held accountable for the physician's own timely response. One commenter recommended revising the OASIS–C2 guidance manual to align with the previous guidance for OASIS–C1 items M2002 and M2004 that require physician notification only.

Response: The intervention timeline of midnight of the next calendar day is consistent with clinical practice when a clinically significant medication issue arises requiring intervention. We believe that high quality care should be provided wherever healthcare services are provided, and that this measure helps to ensure that high quality care services are furnished and that patient harm is avoided. The OASIS C2 guidance manual will be updated to reflect information on how to collect and code for these revised items that will be used to calculate the proposed measure.

Comment: Four commenters expressed concern that this measure will create additional burden for HH clinicians. Three commenters specifically noted the lookback period for the measure, the entire episode of care, is a source of additional burden.

Response: This measure is calculated using items that are already collected in the OASIS and that capture good clinical care. The intent of the measure is to capture timely follow up for all ''potential clinically significant issues.'' Although we acknowledge that the measure may create a new burden for some HHAs, we believe the timely review and follow up of potential clinically significant medication issues at every assessment time period and across the patient's episode of care is essential for providing the best quality care for patients. Documenting that this review has occurred is an important component of safe and high-quality care.

Comment: We received several comments requesting CMS further clarify the definition of key terms used in the measure, most often ''potentially clinically significant'' medication issues, but also ''significant drug interactions,'' ''significant side effects,'' ''any potential adverse effects'' and ''physician-designee.'' Several commenters were concerned that these terms could be interpreted differently by clinicians, and that this could result in a challenge to collect reliable and accurate data for this quality measure. One commenter recommended that the definition of ''potentially clinically significant medication issues'' not change for drug regimen review from the published OASIS–C2 item intent and instructions, and the recently released FY17 SNF PPS final rule.

Response: For this measure, potential clinically significant medication issues are defined as those issues that, in the clinician's professional judgment, warrant interventions, such as alerting the physician and/or others, and the timely completion of any recommended actions (by midnight of the next calendar day) so as to avoid and mitigate any untoward or adverse outcomes. The process to identify ''clinically significant'' medication issues depends on the clinical situation at any given time where providers apply appropriate clinical judgment to ensure an adequate response. We recognize that there may be instances in which a provider identifies clinically significant medication issues that require immediate attention, and therefore, timely interventions would include immediate actions by the HHA. The definition of ''potentially clinically significant medication issues'' has not changed from the published OASIS–C2 item intent and instructions or the recently published FY 2017 SNF PPS Final Rule.

The OASIS–C2 manual defines ''medication interactions'' as the impact of another substance (such as another medication, nutritional supplement including herbal products, food, or substances used in diagnostic studies) upon a medication, and adverse drug reactions as ''a form of adverse consequences.'' It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment''. Further the physician designee is defined by the physician's office within the legal scope of practice in the area where the agency operates. Of note, the OASIS–C2 manual is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html*.

We note that the guidance as delineated in the guidance manual should be utilized to guide definitional interpretation and coding for these items that are used to calculate this proposed quality measure. However, guidance should not supersede the immediate actions needed by the HHA for appropriate clinical care.

Comment: Two commenters requested that we test this measure prior to implementing it as part of the quality reporting system and expressed concern that the measure was not NQF endorsed.

Response: This measure is calculated using existing OASIS items that have been slightly modified for cross-setting purposes. Therefore, since these items have been collected by HHAs in past versions of the OASIS, we believe these items will be feasible to collect. In order to test measure performance, we applied the measure specifications to the current OASIS–C1 items and found a median rate of 84.3 percent, with an interquartile range of 22.7 percent across HHAs nationwide based on 2013 data. We plan to submit the measure to NQF for consideration of endorsement.

Comment: Some commenters indicated that the quality measure focuses on drug regimen review rather than medication reconciliation. Commenters recommended that the measure explicitly include medication reconciliation to meet the medication reconciliation domain of the IMPACT Act.

Response: We believe that the proposed measure not only squarely addresses medication reconciliation, as mandated by the IMPACT Act, but does so in a manner that also allows for the assessment of drug regimen review, which is a process we believe goes hand in hand with medication reconciliation. Specifically, we believe that medication reconciliation is the initial step of the drug regimen review process and that the latter is actually dependent on the identification of an accurate medication list.

Comment: Several commenters addressed the challenge and importance of medication reconciliation across the continuum of care. They cited the importance of a discharge summary from the prior care setting that includes a current medication list, by indication, in avoiding medication discrepancies. One commenter suggested that we consider the need for increased collaboration with hospitals to address this issue. Other commenters suggested that we develop a measure that evaluates whether agencies are sending medication lists to the next level of care. Another commenter recommended that we add a medication management measure to fully address patients' medication management routine needs in order to prepare patients for discharge to PAC settings or the community.

Response: We believe that all providers should strive to ensure accurate, sufficient, and efficient patient-centered care during their care transitions across the continuum, including medication oversight. Thus while we may implement quality measures that address gaps in quality, such as information exchange during care transitions, ultimately providers must act to ensure that such coordination is taking place. We appreciate the interest in future quality measure development, including measures related to sending a medication list at discharge and adding a medication management measure. As a requirement of this measure and as with common clinical practice, HHAs are expected to document information pertaining to the process of drug regimen review, which includes medication reconciliation. However, we will take the commenters recommendations into consideration as we continue to develop additional quality measures under the domain of Medication Reconciliation

Comment: One commenter expressed concern about the appropriateness of a cross-setting measure on medication reconciliation in home-based settings, noting that relative to other PAC settings, home health agencies have limited control over medications.

Response: This measure is consistent with standard clinical practice requirements of ongoing review, documentation, and timely reconciliation of all patient medications, with appropriate follow up to address all clinically significant medication concerns. Thus, the documentation of drug regimen review, along with timely follow-up, aligns with professional practice standards expected of all PAC providers to ensure adherence to providing quality care. Further, we wish to note that this measure is based on items that have been modified from existing OASIS items, which have been collected for several years.

Comment: One commenter stated that the proposed measure would not capture process gaps to improve performance related to medication reconciliation and recommended that individual steps in the process be measured separately.

Response: This proposed measure assesses whether medication reconciliation and the other components of drug regimen review, including timely follow-up, were completed. The clinician is required to assess at the start of care, resumption of care, or at discharge assessment whether any concerns related to medication reconciliation has occurred. Completion of this measure is required at any assessment performed during a patient's time in the care of an agency. Any process gaps will be reflected in the measure outcome, as all processes of the drug regimen review and the medication reconciliation must be performed to meet the numerator criteria. Through the collection of the data, providers will be able to determine what areas of improvement are required and whether any systematic gaps in appropriate care are present for their agency.

Comment: One commenter requested that an ED visit as directed by the HHA, when a physician does not respond to a clinically-significant medication issue, should not always be included in the ''unplanned emergency department (ED) use'' statistical measurement outcome.

Response: This measure is not a measure of emergency department use nor is this measure related to the measures ''Emergency Department Use without Hospitalization'' (NQF #0173) or Emergency ''Department Use without Hospital Readmission During the First 30 Days of Home Health'' (NQF #2505) that are currently used in the Home Health Quality Reporting Program. While we understand the commenter's concern, the methodologies behind these measures are not being proposed for change, and therefore the comment is outside the scope of this rulemaking.

Comment: One commenter expressed concern that the process of documenting medication follow-up in the OASIS via a check box does not provide sufficient information on the processes completed or opportunities to assess and improve the quality of medication reconciliation. This commenter recommended that CMS delay this measure to develop an improved approach to data collection on the medication reconciliation process.

Response: The items used to assess the documentation of medication follow-up have been used in versions of the OASIS for some time. These items, as with many others in the OASIS instrument, have been carefully considered to provide the amount of information that address the important issue of drug regimen review without adding undue burden to clinicians. In order to appropriately respond to the correct response categories via checkbox, clinicians must review the medical record in order to attest that the follow up was done each time, which should provide information to the HHA about the processes and quality of review. That is, this proposed measure will inform HHA's quality improvement efforts by indicating how often these processes are completed correctly. Agencies can use these results to conduct additional review of these processes and improve the quality of medication reconciliation.

Final Decision: After consideration of the public comments, we are finalizing

our proposal to adopt the measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues for the HH QRP beginning with the CY 2018 HH QRP.

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

We invited public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 28 for use in future years in the HH QRP.

TABLE 28—HH QRP QUALITY 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 #0680—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, we are considering development of measures that assess if functional abilities were maintained during a care episode and composite measures that combine multiple evidence-based processes. We invited feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

We invited public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 28 for use in future years in the HH QRP. The following is summary of the comments we received regarding our measure concepts under consideration for future years.

Comment: Some commenters remarked on the limited number of standardized items under consideration for measure development related to communication, cognition, and swallowing and noted that these three domains stand as major obstacles to validly determine the status, needs, and outcomes of individuals with neurological disorders. They recommended adding functional cognitive assessment items to the OASIS. One commenter further encouraged us to adopt a specific screening tool, the Montreal Cognitive Assessment (MoCA), or similar screening tools and assessment tools (that is, CARE–C) to best meet the needs of Medicare beneficiaries and the intent of the IMPACT Act.

Response: We agree that future measure development should include other areas of function, such as communication, cognition, and swallowing. We will continue to engage stakeholders in future measure development and will take these suggested quality measure concepts and recommendations regarding measure specifications into consideration in our ongoing measure development and testing efforts.

Comment: Several comments addressed future measure development related to patient functioning. One commenter expressed support for a core set of functional measures to assess patients consistently across the continuum of care. Three commenters encouraged CMS to develop measures that assess stabilization in patient functioning, and another commenter opposed development of measures that assess change in function as compared to the expected function of a patient. This commenter noted that these measure constructs imply an expectation of improvement and do not reflect the role of the home health benefit in maintaining function and reducing deterioration. Another commenter suggested that CMS should clarify if home health versions of the function measures listed in Table 29 would be developed, noting that the

NQF-endorsed measures reference ''Medical Rehabilitation Patients''. One commenter encouraged no more development of process measures, while two other supported aligning measures across Home Health Compare, CASPER, star ratings and value-based purchasing, and one further supported a single acute care hospitalization measure. Finally, one commenter recommended that future measure development be limited to measures required by the IMPACT Act.

Response: We believe that maintenance of function and avoidance or reduction in functional decline are appropriate goals for some home health patients. As we continue to develop and refine standardized function measures, we will continue to assess and account for the unique characteristics of home health patients and the home health setting. In addition, we note our support for outcome measures and the six measures proposed for removal from the HH QRP are all process measures.

Comment: Two commenters expressed support for developing measures related to the IMPACT Act domain, accurately communicating the existence of and providing for the transfer of health information and care preferences when the individual transitions. These commenters cited the importance of patient and family engagement in care decisions. One commenter further encouraged CMS to add quality measures that include consumer-reported experience of care, as well as one or more measure(s) regarding HHA interaction with and support of family caregivers. They cited the important role that family caregivers play in discharge planning and suggested measurement constructs including documenting the presence of an informal caregiver, caregivers' ability to provide supports and referrals to caregivers for available supports.

Response: We appreciate the support for future development of measures to assess accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual. We concur with the importance of experience-of-care measures. We additionally acknowledge the important role of family caregivers in home health and appreciate the suggestion for future measure development.

Comment: We received two comments regarding future development of a standardized measure of falls with major injury for home health patients. One commenter noted that home health agencies would have unique challenges with measures related to falls in people over 65 in home-based settings, given limited control over the home setting and other risk factors. This commenter expressed support for the goal of minimizing patient falls, but encouraged CMS not to compare outcomes to facility-based providers, given the challenges of the home setting. Another commenter noted that if a home health appropriate version of the standardized Falls with Major Injury measure were implemented, agencies would need information from the removed HH QI measures Emergent Care for Injury Caused by Fall, and Improvement in Urinary Incontinence to assess their status in this area and potentially make improvements.

Response: We note this measure is restricted to falls with major injuries, which should be never events for home health patients. We additionally wish to clarify that data for the two removed measures, Emergent Care for Injury Caused by Fall and Improvement in Urinary Incontinence, will continue to be available to agencies through the CASPER reporting system.

Comment: One commenter recommended developing quality measures assessing outcomes beyond the immediate post-discharge timeframe, such as 60 days after the end of an episode. They noted that such a measure could reflect occupational therapists' contributions to long-term success for post-discharge.

Response: We will take these measure recommendations into consideration.

Comment: One commenter expressed support for future application of the standardized measure ''Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).'' This commenter noted the importance of adult immunization measures in reducing rates of morbidity and mortality from preventable conditions.

Response: We appreciate the commenter's support for a future standardized measure of seasonal influenza vaccination.

We thank commenters for these suggestions. We will consider these comments when we develop future measure proposals.

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-for-reporting 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.

We did not propose any additional policies related to the pay-for-reporting performance requirement. However, we received several comments regarding pay for reporting, while they are out of scope of the current rule we summarize them below.

Comment: One commenter thanked CMS for clarifying how the state-based OASIS submission system had converted to a new national OASIS submission system known as the Assessment Submission and Processing (ASAP). Other commenters addressed the submission of quality data to meet pay-for-reporting requirements under the HH QRP. Two commenters expressed support for the increased threshold, and two commenters requested CMS monitor the implementation of the new thresholds, as well as release the revised Conditions of Participation as soon as possible. One commenter requested that CMS to extend the timeframe for agencies request a reconsideration.

Response: While we did not propose any additional policies related to the pay-for-reporting performance requirement, we appreciate the considerations and suggestions conveyed. On January 1, 2015, we transitioned the state based OASIS transmission to the ASAP system. We finalized the collection of OASIS data through the ASAP system in the CY 2015 HH PPS rule published in the November 6, 2014 **Federal Register** (79 FR 66031). Please see the comments received and our responses on pages 66078 and 66079. Additionally, we finalized the pay-for-reporting threshold requirements in the CY 2016 HH PPS rule, published in the November 5, 2015 **Federal Register** (80, FR 68624). Please see the comments received and our responses on page 68705).

4. Timeline and Data Submission Mechanisms for Measures 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 proposed in the proposed rule, are Medicare FFS claims-based 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 section V.G., for the Discharge to Community-PAC HH QRP measure, we proposed 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 proposed 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 proposed 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 the 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 proposed 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 proposed 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 invited public comments on the proposed HH QRP data collection requirements for the proposed measures affecting CY 2018 payment determination and subsequent years. We received no comments on this proposal.

Final Decision: We are finalizing the timeline and data submission mechanisms for measures for the CY 2018 Payment Determination and Subsequent Years.

5. 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 proposed 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 invited 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. The following is summary of the comments we received regarding our proposal.

Comment: One commenter recommended that CMS not use data collected in the first 6 months of any new measure in public reporting and specifically cited the application of NQF#0678 and on Drug Regimen Review Conducted with Follow-Up for Identified Issues.

Response: We wish to clarify that this proposal specifically pertained to the use of the first 6 months of data collection for these two measures for the purpose of determining compliance with our CY 2018 HHA QRP reporting requirements. Timeframes for which data are used for public reporting purposes is outside the scope of this proposal. For additional information regarding proposals related to public reporting we refer readers to section V.J. of this rule.

Final Decision: Based on the comments, we are finalizing as proposed a calendar year data collection time frame, using an initial 6-month reporting period from January 1, 2017, to June 30, 2017 for determining compliance with our CY 2018 reporting requirements, 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 proposed for both the finalized measure, NQF #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 proposed to continue to use the same 12-month timeframe of July 1–June 30 for these measures for subsequent years for APU determinations.

We invited comment on the proposals for the data collection timelines and requirements. We did not receive any comments relevant to those proposals.

Final Decision: We are finalizing our use of a July 1–June 30 time frame for HH QRP payment determinations. This is in alignment with the previously established data collection timeline for a given calendar year HH QRP payment determination time period, beginning with the CY 2019 for measures finalized for adoption in the HH QRP.

7. 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 proposed to implement calendar year provider review and correction periods for the OASIS assessment-based quality measures implemented into the HH QRP 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 proposed that HHAs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data (that appear on the CASPER generated Review and Correct 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 occurred, the data are ''frozen'' and calculated for public reporting and providers can no longer submit any corrections. As detailed in Table 29, 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 noted that the proposal to review and correct data does not replace other requirements associated with timely data submission. We also stated that 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 29—PROPOSED CY DATA COLLECTION/SUBMISSION QUARTERLY REPORTING PERIODS AND DATA SUBMISSION DEADLINES* AFFECTING FINALIZED AND ASSESSMENT-BASED MEASURES

Quality measures	Data collection source	Data collection/submission quarterly reporting period*	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 2017 Q1 Deadline: August 15, 2017
		CY 17 Q2 4/1/2017–6/30/17	CY 2017 Q2 Deadline: November 15, 2017
Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP.		CY 17 Q3 7/1/2017–9/30/2017	CY 2017 Q3 Deadline: February 15, 2018
		CY 17 Q4 10/1/2017–12/31/2017	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 invited 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.

We did not receive any comments relevant to this proposal.

Final Decision: We are finalizing, as proposed, our proposal to establish a 4.5 month period of time for review and correction beginning with CY 2017 as outlined in Table 29 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 proposed 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 30 for all reporting years unless otherwise specified. We stated that this policy would apply to all proposed and finalized assessment-based measures in the HH QRP.

TABLE 30—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

CY Data collection quarter	Data collection/submission quarterly reporting period	Quarterly review and correction periods and data submission quarterly deadlines*	Correction deadlines*
Quarter 1	January 1–March 31	April 1–August 15	August 15.
Quarter 2	April 1–June 30	July 1–November 15	November 15.
Quarter 3	July 1–September 30	October 1–February 15	February 15.
Quarter 4	October 1–December 31	January 1–May 15	May 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 invited 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. We did not receive any comments on this proposal.

Final Decision: In alignment with the previously established timeframe data collection for a given calendar year APU determination time period, we are finalizing our proposal to use 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 as outlined in Table 30.

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) of the Act, 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 the proposed rule, we proposed 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. 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 28, for assessment-based measures, we proposed 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 also proposed that these confidential feedback reports that 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, 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 CASPER-generated Review and Correct, QM reports pertaining to their assessment-based 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 proposed that, in addition to the data submission/correction and review period, HHAs would 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 further proposed 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 proposed 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 proposed 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 site.

We invited public comment on these proposals; the following is a summary of the comments received.

Comment: MedPAC supported public reporting of the cross-setting quality measures. We received one comment recommending that prior to public reporting of any data collected under these requirements that CMS conduct analysis to determine whether it is possible to compare the data across settings as intended.

Response: 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. QRPs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. CMS is committed to ensuring valid, reliable, and relevant quality measures and are fundamental to the effectiveness of our QRPs. This includes ongoing analysis of collected data prior to public reporting, including comparability of data.

Final Decision: After considering the comments received, we are finalizing our proposal to allow individual HHAs to review and correct their assessment-based measure data including and information on IMPACT Act measures that are to be made public before those measure data are made public.

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

In addition to assessment-based measures, we 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 proposed 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 proposed 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 proposed 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 proposed 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 episode-based 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 the 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 proposed 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. We stated that if this proposal was finalized, we intended 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 re-calculated 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 invited public comment on these proposals for the public display of

quality measure data. The following is summary of the comments we received.

Comment: One commenter expressed concern about the 90 day post-discharge time frame proposed for calculating claims-based measures and the subsequent prohibition on correcting or filing new claims. They recommended that we continue to use our current claim filing and correction practices.

Response: We seek to have as complete a data set as possible. We recognize that the 90-day ''run-off'' period, when we will run the data extract to calculate the claims-based measures, is shorter than the one year period that providers have under Medicare's timely claims filing policy to submit and correct claims. We considered a number of factors in determining that a 90-day run-off 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 or episode-based 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 will not be able to deliver the calculations to HHAs sooner than 18 to 24 months after the last discharge. We believe this will create an unacceptably long delay both for HHAs and for us to deliver timely calculations to HHAs for internal quality improvement.

Final Decision: After careful consideration of the public comments, we are finalizing as proposed, our policies and procedures for the review and correction of claims-based measures prior to public display.

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 proposed 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 proposed 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 proposed 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 invited public comment on this proposal to satisfy the requirement to provide confidential feedback reports to HHAs specific to the requirements of the Act. The following is summary of the comments we received.

Comment: Two commenters requested that CMS provide patient-level data for the three proposed claims-based measures more frequently than once a year, and suggested quarterly updates. They noted that more frequent reporting would support using the measures for quality improvement.

Response: The decision to update claims-based measures on an annual basis was to ensure that the amount of data received during the reporting period was sufficient to generate reliable measure rates. However, we will look into the feasibility of providing HHA's with information more frequently.

Final Decision: As a result of the comments received, we are finalizing our proposal to provide confidential feedback reports to HHAs through the CASPER system as proposed above.

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 continue 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 AHRQ's Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program and endorsed by the NQF in March 2009 (NQF Number 0517) and NQF re-endorsed 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://homehealthcahps.org*.

2. HHCAHPS Oversight Activities

We stated in prior final rules that all approved HHCAHPS survey vendors are required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. For CY 2017 and forward, we continue to state that HHCAHPS survey vendors are to participate in HHCAHPS oversight activities. The purpose of the oversight activities is to ensure that approved HHCAHPS survey vendors follow the *HHCAHPS Protocols and Guidelines Manual.* When all HHCAHPS survey vendors follow the HHCAHPS Protocols and Guidelines Manual, it is most likely that the national survey implementation will occur the same way for all HHA providers participating in the HHCAHPS Survey.

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., eastern daylight time (e.d.t.) 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 Medicare-certification 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., e.d.t. 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., e.s.t. on April 20, 2017; and for the first quarter 2017 by 11:59 p.m., e.d.t. 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 HHCAHPS-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., e.d.t. 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 Medicare-certification 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., e.d.t. on October 19, 2017; for the third quarter 2017 by 11:59 p.m., e.s.t. on January 18, 2018; for the fourth quarter 2017 by 11:59 p.m., e.d.t. on April 19, 2018; and for the first quarter 2018 by 11:59 p.m., e.d.t. on July 19, 2018. These deadlines are firm; no exceptions will be permitted.

For 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., e.d.t. 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 Medicare-certification 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., e.d.t. on October 18, 2018; for the third quarter 2018 by 11:59 p.m., e.s.t. on January 17, 2019; for the fourth quarter 2018 by 11:59 p.m., e.d.t. on April 18, 2019; and for the first quarter 2019 by 11:59 p.m., e.d.t. on July 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., e.d.t. 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 Medicare-certification 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 receive comments for HHCAHPS in the 60-day comment period. We are finalizing the HHCAHPS Survey section as proposed. There are no changes to the HHCAHPS participation requirements, or to the requirements pertaining to the implementation of the Home Health CAHPS® Survey. In this rule, we only updated the information to reflect the dates for future APU years. We again strongly encourage HHAs to keep up-to-date about the HHCAHPS by regularly viewing the official Web site for 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 final 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. To facilitate the reporting of OASIS data as it relates to the implementation of ICD–10, we submitted a new request for approval to OMB for the OASIS–C1/ICD–10 version under the Paperwork Reduction Act (PRA) process. The extension of OASIS–C1/ICD–9 will be discontinued as the 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. 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. We are requesting a new OMB control number for the OASIS–C2 version under the PRA process (81 FR 18855). The new information collection request is currently pending OMB approval.

VII. 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 applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that was the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase.

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 4-year 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 −$130 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 consider this rulemaking as ''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 604 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule is applicable exclusively to HHAs. Therefore, the Secretary has determined this rule would not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This final 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 $130 million in decreased payments to HHAs in CY 2017. We applied a wage index budget neutrality factor and a case-mix weight budget neutrality factor to the rates as discussed in section III.C.3 of this final rule. Therefore, the estimated impact of the 2017 wage index and the recalibration of the case-mix weights for 2017 is zero. We estimate the impact due to the final payment procedures for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device, as outlined in section III.E.3 of this final rule, is less than a one-tenth of one percent increase in payments for CY 2017. Therefore, the −$130 million impact reflects the distributional effects of the 2.5 percent HH payment update percentage ($450 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 −2.3 percent ($420 million decrease), and 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). The $130 million in decreased payments is reflected in the last column of the first row in Table 31 as a 0.7 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 Medicare-paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies in this 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 final rule would have a significant economic impact on a substantial number of small entities. Further detail is presented in Table 31, 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, non-routine 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 final rule. Since the rebasing adjustments are mandated by section 3131(a) of the Affordable Care 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 final 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 60-day 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 nominal case-mix reductions 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.

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 5 performance years of the Model and only 2 payment adjustment years. We now estimate that this will be approximately a decrease of $378 million. This estimate represents the 5 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 provides 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 the final rule presents the estimated expenditure effects of policy changes in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 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. Finally, due to current data limitations we are unable to, with great confidence, estimate the distributional effects of the payment procedures for furnishing NPWT using a disposable device as finalized in section III.E of this rule. However, we note that the overall impact of this final policy was less than one-tenth of one percent and if distributional effects were able to be determined, they would in all likelihood round to zero.

Table 31 represents how HHA revenues are likely to be affected by the policy changes 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 June 30, 2016). The first column of Table 31 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 2017 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 determine whether an episode of care receives an outlier payment from 0.45 to 0.55. 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 in this rule. Overall, it is projected that aggregate payments in CY 2017 would decrease by 0.7 percent. As illustrated in Table 31, 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 31—ESTIMATED HOME HEALTH AGENCY IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2017

	Number of agencies [1]	CY 2017 wage index [2] (%)	CY 2017 case-mix weights [3] (%)	60-Day episode rate nominal case-mix reduction [4]	Rebasing [5] (%)	Revised outlier FDL (%)	Revised outlier method-ology (%)	HH payment update percent-age [6]	Total (%)
All Agencies	11,327	0.0	0.0	−0.9	−2.3	0.0	0.0	2.5	−0.7
Facility Type and Control:									
Free-Standing/Other Vol/NP	1,108	−0.2	−0.1	−0.9	−2.2	0.0	0.8	2.5	−0.1
Free-Standing/Other Proprietary	8,876	0.1	0.0	−0.9	−2.3	0.0	−0.4	2.5	−1.0
Free-Standing/Other Government	357	0.2	0.1	−0.9	−2.2	0.0	0.1	2.5	−0.2
Facility-Based Vol/NP	682	−0.1	0.0	−0.9	−2.2	0.0	0.8	2.5	0.1
Facility-Based Proprietary	102	0.1	0.0	−0.9	−2.3	0.0	0.3	2.5	−0.3
Facility-Based Government	202	0.1	0.0	−0.9	−2.3	0.0	0.6	2.5	0.0
Subtotal: Freestanding	10,341	0.0	0.0	−0.9	−2.3	0.0	−0.1	2.5	−0.8
Subtotal: Facility-based	986	−0.1	0.0	−0.9	−2.2	0.0	0.7	2.5	0.0
Subtotal: Vol/NP	1,790	−0.2	0.0	−0.9	−2.2	0.0	0.8	2.5	0.0
Subtotal: Proprietary	8,978	0.1	0.0	−0.9	−2.3	0.0	−0.4	2.5	−1.0
Subtotal: Government	559	0.1	0.1	−0.9	−2.3	0.0	0.4	2.5	−0.1
Facility Type and Control: Rural:									
Free-Standing/Other Vol/NP	278	0.2	0.0	−0.9	−2.3	0.0	0.5	2.5	0.0
Free-Standing/Other Proprietary	808	0.3	0.0	−0.9	−2.4	0.0	−0.2	2.5	−0.7
Free-Standing/Other Government	250	0.3	0.1	−0.9	−2.2	0.0	0.1	2.5	−0.1
Facility-Based Vol/NP	312	0.4	0.1	−0.9	−2.3	0.0	0.4	2.5	0.2
Facility-Based Proprietary	50	−0.3	0.1	−0.9	−2.3	0.0	0.5	2.5	−0.4

TABLE 31—ESTIMATED HOME HEALTH AGENCY IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2017—Continued

	Number of agencies [1]	CY 2017 wage index [2] (%)	CY 2017 case-mix weights [3] (%)	60-Day episode rate nominal case-mix reduction [4]	Rebasing [5] (%)	Revised outlier FDL (%)	Revised outlier methodology (%)	HH payment update percentage [6]	Total (%)
Facility-Based Government	144	0.1	0.1	−0.9	−2.3	0.0	0.3	2.5	−0.2
Facility Type and Control: Urban:									
Free-Standing/Other Vol/NP	829	−0.2	−0.1	−0.9	−2.2	0.0	0.8	2.5	−0.1
Free-Standing/Other Proprietary	8,063	0.0	0.0	−0.9	−2.3	0.0	−0.4	2.5	−1.1
Free-Standing/Other Government	107	0.0	0.0	−0.9	−2.2	0.0	0.0	2.5	−0.6
Facility-Based Vol/NP	370	−0.2	0.0	−0.9	−2.2	0.0	0.9	2.5	0.1
Facility-Based Proprietary	52	0.3	0.0	−0.9	−2.2	0.0	0.1	2.5	−0.2
Facility-Based Government	58	0.1	0.0	−0.9	−2.3	0.0	0.9	2.5	0.3
Facility Location: Urban or Rural:									
Rural	1,842	0.3	0.0	−0.9	−2.3	0.0	0.0	2.5	−0.4
Urban	9,479	0.0	0.0	−0.9	−2.3	0.0	0.0	2.5	−0.7
Facility Location: Region of the Country:									
Northeast	863	−0.3	−0.1	−0.9	−2.1	0.0	0.7	2.5	−0.2
Midwest	3,038	−0.1	0.1	−0.9	−2.4	0.0	0.4	2.5	−0.4
South	5,363	−0.1	−0.1	−0.9	−2.3	0.0	−0.6	2.5	−1.5
West	2,013	0.6	0.1	−0.9	−2.3	0.0	0.3	2.5	0.3
Other	50	−0.3	−0.4	−0.9	−2.3	0.0	0.8	2.5	−0.6
Facility Location: Region of the Country (Census Region):									
New England	355	−0.8	−0.1	−0.9	−2.1	−0.1	0.1	2.5	−1.4
Mid Atlantic	508	0.0	−0.1	−0.9	−2.1	0.0	1.1	2.5	0.5
East North Central	2,306	−0.1	0.1	−0.9	−2.4	0.0	0.4	2.5	−0.4
West North Central	732	−0.1	0.0	−0.9	−2.3	0.0	0.5	2.5	−0.3
South Atlantic	1,818	−0.4	−0.2	−0.9	−2.3	0.0	−0.6	2.5	−1.9
East South Central	426	0.0	−0.1	−0.9	−2.5	0.0	0.0	2.5	−1.0
West South Central	3,119	0.3	0.0	−0.9	−2.3	0.0	−0.8	2.5	−1.2
Mountain	682	0.1	−0.1	−0.9	−2.3	0.0	−0.3	2.5	−1.0
Pacific	1,331	0.7	0.2	−0.9	−2.3	0.0	0.5	2.5	0.7
Facility Size (Number of 1st Episodes):									
<100 episodes	2,926	−0.1	0.2	−0.9	−2.3	0.0	0.5	2.5	−0.1
100 to 249	2,599	0.0	0.1	−0.9	−2.4	0.0	0.1	2.5	−0.6
250 to 499	2,423	0.0	0.1	−0.9	−2.3	0.0	−0.1	2.5	−0.7
500 to 999	1,831	0.0	0.0	−0.9	−2.3	0.0	−0.1	2.5	−0.8
1,000 or More	1,548	0.0	−0.1	−0.9	−2.3	0.0	0.0	2.5	−0.8

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of June 30, 2016) for which we had a linked OASIS assessment.

[1] The number of rural HHAs (1,842) plus the number of urban HHAs (9,479) does not add up to the total number of HHAs (11,327) due to six HHAs that have a missing value for the urban/rural indicator in the impact analysis file.

[2] 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 final rule.

[3] 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 final rule offset by the case-mix weights budget neutrality factor described in section III.C.3 of this final rule.

[4] 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.

[5] 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 estimated payments to HHAs

[6] The CY 2017 home health payment update percentage reflects the home health market basket update of 2.8 percent, reduced by a 0.3 percentage point multifactor 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 final 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 32 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 finalized proposals to change the smaller-volume cohort size determination, calculate achievement thresholds and benchmarks 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 QIES Roll Up File data in the same manner as they will be in the Model. The five (5) HHCAHPS measures were based on archived data. The size of the cohorts was 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) states.

Table 33 displays our analysis of the distribution of possible payment adjustments based on the same 2013–2014 data used to calculate Table 32, providing information on the estimated impact of this final rule. We note that this impact analysis is based on the aggregate value of all nine (9) 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 will compete in the HHVBP Model are stratified by size as described in section IV.B. of this final rule. As finalized in section IV.B. of this final rule, there must be a minimum of eight (8) HHAs in any cohort.

Those HHAs that are in states who do not have at least eight small HHAs will not have a smaller-volume cohort and thus there will only be one cohort that will include all the HHAs in that state. As indicated in Table 33, Massachusetts, Maryland, North Carolina, Tennessee and Washington will only have one cohort and Florida, Arizona, Iowa, and Nebraska will 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 33 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 final rule is lower than that included in CY 2016 HH PPS 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 34 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 will 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 32—ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES

[Percentage]

Payment Adjustment Distribution	Range	10%	20%	30%	40%	Median	60%	70%	80%	90%
3% Payment Adjustment For Performance year 1 of the Model	3.08	−1.23	−0.87	−0.56	−0.30	−0.02	0.27	0.61	1.11	1.85
5% Payment Adjustment For Performance year 2 of the Model	5.12	−2.04	−1.45	−0.94	−0.50	−0.03	0.46	1.01	1.85	3.08
6% Payment Adjustment For Performance year 3 of the Model	6.15	−2.45	−1.74	−1.13	−0.61	−0.04	0.55	1.21	2.22	3.70
7% Payment Adjustment For Performance year 4 of the Model	7.18	−2.86	−2.03	−1.32	−0.71	−0.04	0.64	1.42	2.59	4.32
8% Payment Adjustment For Performance year 5 of the Model	8.25	−3.27	−2.32	−1.50	−0.81	−0.05	0.73	1.62	2.96	4.93

TABLE 33—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	0.00	−2.20	−1.50	−1.10	−0.70	−0.30	0.00	0.80	1.40	2.70
MD	53	0.56	−1.50	−1.10	−0.80	−0.10	0.20	0.50	1.40	2.00	3.60
NC	172	0.16	−1.90	−1.50	−1.00	−0.50	0.10	0.50	0.90	1.70	2.40
TN	135	0.36	−2.00	−1.30	−0.80	−0.40	−0.10	0.30	0.90	2.00	3.10
WA	59	0.71	−1.70	−0.70	−0.30	0.20	0.50	0.80	1.70	2.30	2.90
Smaller-volume HHA Cohort in states with small cohort (percent)											
AZ small	9	0.53	−1.20	−0.70	−0.70	−0.50	−0.30	−0.10	0.60	0.90	5.00
FL small	130	−0.14	−2.20	−1.70	−1.20	−0.60	−0.20	0.10	0.40	1.20	1.80
IA small	29	0.62	−2.30	−1.10	−0.80	0.00	0.30	0.90	1.70	2.30	3.80
NE small	16	0.48	−1.70	−1.60	−1.20	−0.60	−0.40	1.30	2.20	2.40	4.00
Larger-volume HHA Cohort in states with small cohorts (percent)											
AZ large	112	−0.06	−2.20	−1.50	−1.10	−0.70	−0.30	0.10	0.50	1.30	2.30
FL large	889	0.37	−2.10	−1.50	−0.90	−0.40	0.00	0.60	1.30	2.20	3.30
IA large	107	−0.21	−2.30	−1.60	−1.30	−0.70	−0.20	0.10	0.50	1.00	1.80
NE large	49	0.31	−1.80	−1.20	−0.90	−0.60	−0.10	0.30	0.70	1.80	3.70

TABLE 34—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. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 35, we have prepared an accounting statement showing the classification of the transfers and costs associated with the HH PPS provisions of this final rule. Table 35 provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this final rule for the HH PPS provisions.

TABLE 35—ACCOUNTING STATEMENT—HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM THE CYS 2016 TO 2017*

Category	Transfers
Annualized Monetized Transfers.	−$130 million.
From Whom to Whom?	Federal Government to HHAs.

Table 36 provides our best estimate of the decrease in Medicare payments under the HHVBP Model.

TABLE 36—ACCOUNTING STATEMENT—HHVBP MODEL CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS FOR CY 2018–2022

Category	Transfers
5-Year Gross Transfers.	−$378 million.
From Whom to Whom?	Federal Government to Hospitals and SNFs.

E. Conclusion

1. HH PPS

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is a decrease of 0.7 percent, or $130 million, in Medicare payments to HHAs for CY 2017. The −$130 million impact reflects the effects of the 2.5 percent CY 2017 HH payment update percentage ($450 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 2017 to account for nominal case-mix growth from 2012 through 2014 ($160 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 a final 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 final 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.[123] 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. The Innovation Center 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 6 performance year gross savings of $378 million. Based on the JAGS study, which observed hospitalization reductions of over 20-percent, the 6-percent ultimate annual hospitalization reduction assumptions are considered reasonable.

VIII. 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 final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have

[123] 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.*

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 Social Security 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 the following home health services is:

(a) DME—20 percent of the customary (insofar as reasonable) charge.

(b) An applicable disposable device (as defined in section 1834(s)(2) of the Act)—20 percent of the payment amount for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device (as that term is defined in § 484.202 of this chapter).

PART 484—HOME HEALTH SERVICES

■ 3. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 4. Section 484.202 is amended by adding the definition of ''Furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device'' in alphabetical order to read as follows:

§ 484.202 Definitions.

* * * * *

Furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device means the application of a new applicable disposable device, as that term is defined in section 1834(s)(2) of the Act, which includes the professional services (specified by the assigned CPT® code) that are provided.

* * * * *

■ 5. Section 484.205 is amended by revising paragraph (b) introductory text to read as follows;

§ 484.205 Basis of payment.

* * * * *

(b) *Episode payment* The national, standardized prospective 60-day episode payment represents payment in full for all costs associated with furnishing home health services previously paid on a reasonable cost basis (except the osteoporosis drug listed in section 1861(m) of the Act as defined in section 1861(kk) of the Act) as of August 5, 1997 unless the national 60-day episode payment is subject to a low-utilization payment adjustment set forth in § 484.230, a partial episode payment adjustment set forth at § 484.235, or an additional outlier payment set forth in § 484.240. All payments under this system may be subject to a medical review adjustment reflecting beneficiary eligibility, medical necessity determinations, and HHRG assignment. DME provided as a home health service as defined in section 1861(m) of the Act continues to be paid the fee schedule amount. Separate payment is made for ''furnishing NPWT using a disposable device,'' as that term is defined in § 484.202, which is not included in the episode payment.

* * * * *

■ 6. 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.

* * * * *

■ 7. Section 484.305 is amended by revising the definition of ''Benchmark'' and by removing the definition of ''Starter set'' 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.

* * * * *

■ 8. 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]

■ 9. Section 484.320 is amended by—:

■ a. Amending paragraphs (a), (b), and (c) by removing the phrase, ''in the starter set,'' and

■ b. Amending paragraph (d) by removing the phrase, ''in the starter set''.

■ 10. 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).

(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 recalculation 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 its annual total performance score and payment adjustment percentage following a decision on the home health agency's recalculation request submitted under paragraph (a) of this section, or the decision to deny the 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: October 24, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: October 25, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–26290 Filed 10–31–16; 4:15 pm]

BILLING CODE 4120–01–P